

A DOCTOR'S ORDER
THE DUTCH CASE OF EVIDENCE-BASED MEDICINE (1970-2015)

Op doktersrecept
De Nederlandse casus van evidence-based medicine (1970-2015)
(met een samenvatting in het Nederlands)

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General Introduction

The 'Paradox of Modern Medicine'

The recent history of medicine and healthcare is characterised by a fascinating paradox. This paradox forms the central theme in the bestseller, *The Rise and Fall of Modern Medicine*, by the British physician and publicist James Le Fanu, in which, on the one hand, Le Fanu zealously demonstrates how important and spectacular the developments in medicine were in the latter half of the twentieth century:

'The history of medicine in the fifty years since the end of the Second World War rank as one of the most impressive epochs of human achievement. So dramatically successful has been the assault on disease that it is now almost impossible to imagine what life must have been like back in 1945, when death in childhood from polio, diphtheria and whooping cough were commonplace; when there were no drugs for tuberculosis, or schizophrenia, or rheumatoid arthritis, or indeed for virtually any disease the doctor encountered; a time before open-heart surgery, transplantation and test-tube babies.¹

On the other hand, Le Fanu argues that there is another side to this shiny coin. In his view, the unprecedented success of modern medicine has had 'perverse consequences', 'leaving doctors less professionally fulfilled, the public more neurotic about its health, alternative medicine in the ascendancy and an unaccounted-for explosion in Health Service costs'²

With his notion of the 'paradox of modern medicine', Le Fanu is far from being alone. The recent history of medicine is cast in this frame, not only in his 'popular' book, but also in the academic, scholarly literature. Where Le Fanu speaks, for example, of the 'present discontents' with regard to medicine and healthcare, the well-known American medical historian, Charles Rosenberg, published a compilation of essays in 2007 under the umbrella title *Our Present Complaint*. This 'present complaint' refers to several paradoxes in modern medicine and healthcare, including the tension between (technology-driven) progress and spiralling healthcare costs; between the increase in diagnostic and

1. J. Le Fanu, *The Rise and Fall of Modern Medicine*, 2nd edn (New York: Basic Books, 2012), p. 1.
2. *Ibid.*, pp. 6-7.

therapeutic abilities and the decrease in respect for the profession of medicine; and between the promise of a longer and healthier life versus the possibility of a ‘dystopia of life artificially extended in pain and incapacity’.³ The British medical historians, Anne Hardy and E.M. Tansey are on the same wavelength. They wrote the chapter on the period 1945-2000 in the standard work on the history of Western medicine, *The Western Medical Tradition*. One of the two central themes in this chapter was ‘the paradoxical phenomenon of “doing better and feeling worse” that developed in the West’.⁴

Besides with regard to the relevance of the ‘paradox of modern medicine’, there is also a great deal of agreement in the literature on its *chronology*. The first decades after the Second World War are considered to be the ‘golden era’ of Western medicine, after which a turnaround followed around 1970.⁵ This turnaround is very sharply depicted by Le Fanu as a period in which the ‘rise’ of modern medicine turned into its ‘fall’. To a certain extent, the ‘fall’ could also be considered to be the *result* of the ‘rise’, as it was only with the passage of time that the unintended negative consequences of all medical successes became noticeable, while the law of diminishing returns increasingly exerted its influence as well.

To put matters into perspective, it should be emphasized that it did not suddenly become all doom and gloom in Western medicine. Le Fanu himself writes about this in his introduction: ‘It is important to keep a sense of proportion to all this. In general, doctors do find fulfilment in their work, and in general people appreciate the benefits of modern medicine [...]’.⁶ Nevertheless, it appears that a significant change did occur, which was described by Hardy and Tansey in the following, nuanced way:

‘In the second half of the twentieth century, Western medicine moved from being powerful, purposeful, and progressive towards a more uncertain identity: conscious of shortcomings, uneasy at the future, yet continuing, if less spectacularly, on an innovative therapeutic path.’⁷

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3. C. E. Rosenberg, *Our Present Complaint. American Medicine, Then and Now* (Baltimore: Johns Hopkins University Press, 2007) p. 2.
 4. W. F. Bynum et al., *The Western Medical Tradition: 1800 to 2000* (Cambridge: Cambridge University Press, 2006), p. 408. See also on the ‘paradox of modern medicine’, for example, an article by a (former) professor of social medicine and a book by a Dutch historian: D. Post, ‘Grenzen aan de Groei: de Paradox van de Geneeskunde’, *Medisch Contact* 55: 25 (2000), pp. 947-9; A. Mooij, *De Polsslag van de Stad: 350 Jaar Academische Geneeskunde in Amsterdam* (Amsterdam: De Arbeiderspers, 1999), pp. 454-61 and in particular p. 461.
 5. *Ibid.*, p. 406. See also Le Fanu & Rosenberg (n. 1 and 3); Mooij, *Polsslag*, p. 454; and, for example the volume: V. Berridge (ed.), *Making Health Policy: Networks in Research and Policy after 1945* (Amsterdam/ New York: Rodopi, 2005), see in particular the introduction by Berridge, pp. 5-36.
 6. Le Fanu, *Rise and Fall*, p. 7.
 7. Bynum et al., *Western Medical Tradition*, p. 408.

One of the things that make human history so fascinating is that humans – and human institutions – not only passively undergo such changes but respond to them as well. They seek solutions to problems that have arisen, or attempt to adapt to changing circumstances. This is also apparent in recent medical history. Various stakeholders in medicine and healthcare have endeavoured to cope with the ‘paradox’ outlined above in all manner of ways. To start with, a great many initiatives were developed by the medical profession itself, which were focused on, for example, the reinforcement of medical research, the modernisation of medical training, or the enhancement of the rationality, effectiveness and efficiency of medical practice. A trend that has moreover been generally identified is that since around 1970, an increasing number of other, *non-medical* parties began to interfere with medical practice. With a view to cost control in particular, governments, insurers and hospital directors have increasingly started to look ‘over the shoulder of the physician’ in the consultation room. Furthermore, patients and patients’ organisations have begun to place higher demands on the provision of care. Over the course of time, medical practice has also been increasingly and ever more explicitly bound, in a formal sense at least, by ethical and legal frameworks, as reflected, among others, in the realisation of legislation with regard to patients’ rights, access to the medical profession and protection of subjects in medical research. As an extension of this, health law and medical ethics have acquired a more or less institutionalised and recognised position (as non-medical disciplines) in many countries. The latter is the subject of the influential book by David Rothman, which bears the telling title: *Strangers at the Bedside*.⁸

The common factor of these diverse developments and initiatives is, so it seems, the desire to gain some sort of *grip* on a domain that is in continuous flux – or: to steer all the rapid developments in medicine and healthcare in the right direction so that, on the one hand, there may be benefits from ongoing progress while, on the other hand, its (potential) undesired side-effects are contained as much as possible. It seems, however, that the various stakeholders continue to find it extraordinarily difficult to actually get a grip on this complex domain either internally or externally. This is illustrated by a statement made by Wouter Bos, the former Dutch Minister of Finance, looking back in 2011 on his term in office (between 2007 and 2010):

‘When I was Minister of Finance, healthcare was a headache that lasted three years. Nowhere in the public sector are we so incapable of keeping costs under control and giving shape to what we desire.’⁹

8. D. J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: Basic Books, 1991). See also notes 1-7 above.

9. “Burger ziet staat als bedreiging, niet als redder”, *de Volkskrant*, 6 November 2010, pp. 2-3.

The ‘paradox of modern medicine’ – which mainly became manifest after the ‘turnaround’ about 1970 – and (above all) the manner in which various stakeholders dealt with it (or contributed to it!) form the main theme of the Utrecht/Maastricht medical-historical research programme, *Medicine in Transition*, which is supervised by Frank Huisman, professor of medical history at University Medical Centre Utrecht (UMC Utrecht).¹⁰ The present PhD dissertation is a product of this research programme and, following Rosenberg’s example, may be described as: ‘a historian’s attempt to put these contradictions [e.g. the ‘paradox of modern medicine’ – TB] into a longer-term perspective, to link past and present, and suggest some ways of thinking about prospects for our new healing order [...], and about the medical profession’s peculiar role and responsibilities’.¹¹

Yet all this is easier said than done. Besides the many methodological challenges that accompany any form of contemporary history, the field of contemporary *medical* history involves a number of specific problems. Firstly, this is an area of largely untapped potential, as concluded by Hardy and Tansey in 2006 in their contribution to the standard work, *The Western Medical Tradition*: ‘The post 1945 world has as yet attracted little sustained attention from medical historians’.¹² This admittedly underlines the relevance of the Utrecht/Maastricht research programme, but the lack of a substantial body of relevant historical literature also leads to restrictions. This dissertation will necessarily largely be of an exploratory character which, above all, aims to encourage historical debate on the highlighted issues. Secondly, it is also very difficult for historians to get a grip on the highly complex, vast and dynamic domain of (the) contemporary (history of) medi-

10. Other components of the research programme, ‘Medicine in Transition’, include PhD research projects by: Floor Haalboom on the history of dealings with zoonoses in the twentieth century; Noortje Jacobs on the development of medical research ethics since the Second World War; and Roland Bertens on the development of health law (and in particular patients’ rights) since approximately 1970. In all these projects, the ‘Netherlands case’ is central, although it is explicitly placed in an international perspective, with the work of Theodore Porter and the idea that, since 1970, all manner of ‘mechanisms of control’ for medicine/healthcare have emerged or been tested (with varying degrees of success), serving as a theoretical framework (see the remainder of this general introduction). The research programme ‘*Medicine in Transition*’ is substantively, as well as through the person of programme leader, professor Frank Huisman, related and linked to the initiative ‘Science in Transition’, which originated in the Netherlands several years ago from the conviction that the current ‘system’ of science needs reforming. *Science in Transition* has generated much publicity and also set a great deal in motion in the Netherlands, both in politics and society and in the scientific ‘world’ itself. A good example of the latter is the project, ‘Systeemfalen’ (‘System failure’), which was commenced in 2013 by The Netherlands Organisation for Health Research and Development (Dutch abbreviation: ZonMW) – one of the main subsidisers of health research in the Netherlands – in order to obtain more insight into the ‘system failure’ in/of health research, create awareness about it and offer possible paths towards solutions. See the ‘Launch Document System Failure’ which may be downloaded from: <http://www.zonmw.nl/nl/themas/thema-detail/implementatie/bruikbaar-onderzoek>. And see for *Science in Transition*: <http://www.scienceintransition.nl/English>.

11. Rosenberg, *Our Present Complaint*, p. 2.

12. Bynum et al., *Western Medical Tradition*, p. 408.

cine and healthcare. Hardy and Tansey, for example, point to ‘the problems of retrieving factual information and of drawing historical synthesis from an abundance of primary materials’.¹³

In order to be able to cope with these problems to some extent, this dissertation hinges on three ‘points of reference’, namely a ‘*window*’, a (theoretical) ‘*coat rack*’ and an (empirical) ‘*floor*’.

The main subject of this dissertation – *evidence-based medicine* (EBM) – serves as a *window*: Not only can this subject, as will be explained below, offer a specific view of the ‘paradox of modern medicine’, and the manner in which stakeholders have handled it, but evidence-based medicine is, in itself a fascinating and significant phenomenon in contemporary medicine and healthcare, which calls for historical analysis and interpretation. A good example of this is that, in 2007, EBM was proclaimed by a panel of experts assembled by the *British Medical Journal* to be one of the ‘15 most important medical milestones [...] since 1840’ – together with, among others, antibiotics (including penicillin), the contraceptive pill and the discovery of the structure of DNA.¹⁴ Evidence-based medicine is, among other things, one of the most striking manifestations of the growing influence of quantification and statistical-epidemiological reasoning in present-day medicine and healthcare.¹⁵ To a certain extent, this dissertation may therefore be interpreted as a historical reflection on the rise and impact of quantification and statistical reasoning in medicine.

In order to be able to observe the view offered by the ‘EBM window’ in a structured and focused way and to give meaning to it as well, a theoretical framework is helpful. This theoretical framework is used in a heuristic sense here, as a *coat rack* on which empirical findings and analytical interpretations may be ‘hung’. In brief, this coat rack mainly (but not exclusively) consists of the notion – which is partly inspired by the work of the historian Theodore Porter – that evidence-based medicine emerged, arose and was embraced as a *mechanism of control*. This requires further explanation, but it may be clear that such a coat rack assists in the formulation of hypotheses and research questions.

In order to be able to assess or answer these hypotheses or research questions, empirical data are required on the ‘landscape’ that is viewed through the EBM window (with a vision focused by the theoretical coat rack). In historical research, this usually comes down to the collection of data on persons, events and developments specific to time, place and context. These data forms the empirical *floor* on which the historical interpretations and explanations are founded. The ‘floor’ of this study is the *Dutch case of evidence-based*

13. Ibid.

14. ‘Medical Milestones: Celebrating Key Advances Since 1840’, *British Medical Journal* 334: supplement (2007), pp. s1-s22.

15. See the next section of this general introduction, entitled: ‘Window: Evidence-Based Medicine’.

medicine. Partly because of the – in an international perspective – relatively significant impact of EBM in this country, ‘the Netherlands’ constitutes an interesting case that may offer insight into the origin, emergence and significance of EBM as a mechanism of control in general – and which eventually also offers a specific perspective on the topic of the ‘paradox of modern medicine’.

In this general introduction, the ‘window’, the ‘coat rack’ and the ‘floor’ will be successively elaborated upon. Moreover, the main research questions that virtually automatically result from this will be formulated. Some digressions will subsequently follow on the structure and design of this dissertation, on the sources and methods used, on how notions, concepts and definitions are dealt with, and finally on the parameters and limitations of this study.

‘Window’: Evidence-Based Medicine

In the early 1990s, a new term was introduced: ‘evidence-based medicine’ (EBM).¹⁶ After a remarkably short time, medicine could no longer be imagined without EBM. Moreover, all manner of non-medical disciplines in (mental) healthcare, ranging from physiotherapy to pastoral care, also professed their faith in ‘evidence-based practice’.¹⁷ Even outside the world of healthcare, the new concept became fashionable, for example in the shape of (pleas for) ‘evidence-based management’¹⁸ and ‘evidence-based policy’.¹⁹ With some degree of exaggeration, it may be argued that ‘evidence-based’ soon developed into one of the mantras of the current era. This raises all sorts of questions, for example: Why did the ‘evidence-based’ concept become so popular, within as well as outside medicine? What was it an answer to? Yet the question preceding this is: What *is* evidence-based medicine actually?

16. Evidence-Based Medicine Working Group, ‘Evidence-Based Medicine: a New Approach to Teaching the Practice of Medicine’, *JAMA* 268 (1992), pp. 2420-5.

17. See on this, for example: R. Abma et al., *Evidentie en Existentie: Evidence-Based Behandelen en Verder...* (Tilburg: KSGV, 2010). I. S. Kristiansen & G. Mooney, ‘Evidence-Based Medicine: Method, Collaboration, Movement, or Crusade’, in I. S. Kristiansen & G. Mooney (eds.), *Evidence-Based Medicine: in its Place* (London/New York: Routledge, 2004), pp. 1-19.

18. See for example: *Ibid.*, and: D. M. Rousseau (ed.), *The Oxford Handbook of Evidence-Based Management* (Oxford: Oxford University Press, 2012); K. Walshe & T. G. Rundall, ‘Evidence-Based Management: from Theory to Practice in Health Care’, *Milbank Quarterly* 79 (2001), pp. 429-57.

19. See for example: M. Gray, *Evidence-Based Healthcare: How to Make Health Policy and Management Decisions* (New York: Churchill Livingstone, 1997). See also on this, for example: V. Berridge, ‘Changing Policy: Reflections on the Role of Public Health Evidence’, in A. Killoran & M. P. Kelly (eds.), *Evidence-Based Public Health: Effectiveness and Efficiency* (Oxford: Oxford University Press, 2009), pp. 448-58; S. R. Hanney & M. A. González-Block, ‘Evidence-Informed Health Policies: Are we Beginning to Get there at Last?’, *Health Research Policy and Systems* 7: 30 (2009).

Formulated in 1996, the most widely used and influential definition of EBM is: ‘the conscientious, explicit, and judicious use of the best current evidence in making decisions about the care of individual patients.’²⁰ This definition, which has been criticised for being ‘overly broad,’²¹ is not immediately very clarifying. It seems obvious that physicians have to make their decisions in a careful manner, and thereby make full use of the available scientific knowledge. Many a layman will wonder: did evidence-based medicine have to be invented for this? Or, as the philosopher Jeremy Howick once phrased it: ‘What on earth was medicine based on before evidence-based medicine?’²²

This last question is actually a historical question. With the necessary good will, this could be perceived as an indication that a historical approach can help to understand and interpret EBM. Not a (vague) definition, but a description of the historical development of this phenomenon could provide an answer to the question of what EBM actually is.

This question is all the more relevant because, on reflection, evidence-based medicine proves to be an elusive, multifaceted phenomenon. EBM primarily originated as an *educational approach* developed within the department of clinical epidemiology and biostatistics of the medical school of McMaster University in Hamilton, Canada. In 1992, a group of people from this department launched the new notion of ‘evidence-based medicine’ in an article in the *Journal of the American Medical Association* (JAMA), in which it was presented as ‘a new approach to *teaching* the practice of medicine.’²³

At the same time, it was immediately clear that the clinical epidemiologists of McMaster considered evidence-based medicine to be much *more* than an educational approach. The first sentence of the above-mentioned JAMA article said: ‘A *new paradigm* for medical practice is emerging.’²⁴ With this claim that EBM represented no less than a new paradigm, the tone was immediately set for a passionate plea in which, as various involved parties subsequently explicitly phrased it, the *gospel* of EBM was preached. While this somewhat pompous approach did evoke irritation here and there, the enthusiasm with which the new ‘paradigm’ was ‘sold’ was infectious as well. Thus, evidence-based medicine developed distinct traits of a powerful *ideological*, almost religious *movement*. Within several years, this movement developed into a worldwide phenomenon that ex-

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20. D. L. Sackett et al., ‘Evidence-Based Medicine: What It Is and What It Isn’t’, *BMJ* 312: 7023 (1996) pp. 71-2. See also, for example: M. Offringa, W. J. J. Assendelft & R. J. P. M. Scholten (eds.), *Inleiding in Evidence-Based Medicine: Klinisch Handelen Gebaseerd op Bewijsmateriaal*. 4th edn. (Houten: Bohn Stafleu van Loghum, 2014), p. 3.
 21. S. R. Sehon & D. E. Stanley, ‘A Philosophical Analysis of the Evidence-Based Medicine Debate’, *BMC Health Services Research* 3:14 (2003), p. 2
 22. This was the title of Howick’s lecture at the ‘Night of Descartes 2009’ (Dutch: ‘Nacht van Descartes 2009’), a symposium on EBM in Utrecht, see: <http://www.sg.uu.nl/opnames/bewezen-beter-nacht-van-descartes/prof-dr-frank-huisman-en-dr-jeremy-howick>. See also, for similar remarks: Kristiansen and Mooney, ‘Evidence-Based Medicine’, p. 3.
 23. EBM Working Group, ‘Evidence-Based Medicine’. TB’s italics.
 24. *Ibid.*, p. 2420. TB’s italics.

erted its influence in all sorts of areas in healthcare. In many countries, new institutes, networks, handbooks, journals and databases emerged which were dominated by EBM.²⁵

According to some critical commentators, however, EBM was not *more* than ‘just’ a new educational approach, but rather a great deal *less*. The term ‘evidence-based’, it was argued, was no more than an attractive yet rather *empty slogan*. It was argued that ‘evidence-based medicine’ represented nothing new. The term mainly *sounded* good and could therefore be used or exploited in a rhetorical way.²⁶

The picture becomes even more diffuse as evidence-based medicine, as far as its most specific manifestations are concerned, changed character over time. Initially, the emphasis was mainly on *critical appraisal* of the medical literature. The principle of the education at McMaster University was that students sought answers to clinical questions themselves, rather than accepting what they learned from their teachers at face value. In this respect, EBM may be regarded as a rejection of the teacher apprenticeship model in medical education – or, in other words: a rejection of ‘eminence-based’ or ‘authority-based’ medicine. Students learned to personally search for relevant evidence in the medical literature, enabling them to solve clinical issues themselves. They moreover learned that they were not to put blind faith in everything that was printed, but instead judge the scientific quality and clinical relevance of the articles retrieved from the medical literature. To this end, specific ‘critical appraisal tools’ were developed at McMaster, and students were supposed to acquire ‘critical appraisal skills’ as well. To many early exponents of the EBM movement, critical appraisal, and in particular the underlying critical, anti-authoritarian *attitude, mentality, or mind-set* represented the core of evidence-based medicine.²⁷

Within several years, however, there was a significant shift in focus towards *systematic reviews* and *clinical practice guidelines*. Systematic reviews are (critical) summaries of the relevant scientific literature on a specific subject. The critical appraisal of the literature is ‘outsourced’ to a team of experts which creates the systematic review. Thus, the ‘aver-

25. See for example: A. Hijdra et al., *Vernieuwingen in de Neurologie: de Rol van Hans van Crevel* (Amsterdam: Boom, 2003), p. 16; Kristiansen & Mooney, ‘Evidence-Based Medicine’. See for more on this: chapter 3.

26. See on this, for example: M. Edwards, *Control and the Therapeutic Trial. Rhetoric and Experimentation in Britain 1914-1948* (Amsterdam/New York: Rodopi, 2007), see in particular chapter 7; Sehon & Stanley, ‘A Philosophical Analysis’, pp. 2-3; G. Weisz, ‘From Clinical Counting to Evidence-Based Medicine’, in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen’s University Press, 2005), pp. 377-93, on pp. 388-9. EBM proponents too, see the danger of EBM being reduced to an empty slogan. In the Dutch textbook on EBM, for example, it is explicitly stressed that this should be prevented. See: Offringa, Assendelft & Scholten, *Inleiding*. 4th edn., p. 183. See for more on this (and for a discussion of the criticisms of EBM): chapter 3.

27. See a.o.: Interviews with Büller en Dekker; R. E. G., Upshur, ‘Looking for Rules in a World of Exceptions’, *Perspectives in Biology and Medicine* 48 (2005), pp. 477-89. See also chapters 6 and 9.

age' practising physician no longer needs to search for, review and critically evaluate the enormous amount of relevant published literature themselves, but can find the information sought – which has been filtered for quality – in a systematic review. The strong rise of the systematic review had everything to do with the increasing influence of the British 'systematic review movement', which began to manifest itself as early as the 1970s, and in the 1990s resulted in the Cochrane Collaboration, an international partnership dedicated to the production of systematic reviews. This systematic review movement forms the second 'root' of the EBM movement, in addition to the 'Canadian root' represented by the clinical epidemiologists of McMaster.²⁸

Simultaneously with the rise of the systematic review, the (evidence-based) guidelines underwent a rapid development. In these guidelines, the evidence, which mainly originated from systematic reviews, was translated into specific instructions, roadmaps and criteria, which could assist physicians in taking decisions on, usually, the diagnostics or treatment of a particular condition. Guidelines have developed into the most important specific manifestation of evidence-based medicine. Indeed, it seems that some stakeholders in healthcare have come to regard EBM and guidelines as more or less synonymous with each other. It is precisely these guidelines that have been the subject of intense debate from the outset. Critics of EBM consider the application of evidence-based guidelines to be 'cookbook medicine', yet proponents of EBM and the use of guidelines are also apprehensive about the misuse of guidelines by, for example, disciplinary boards, managers, insurers and governments.²⁹

The latter refers to another shift within EBM. Over the course of time, the *political and macroeconomic dimension* of evidence-based medicine, which has existed ever since the beginning, for that matter, seems to have gained significance. This was reflected, for example, in the introduction and the increasing use of such terms as 'evidence-based policy' and 'evidence-based healthcare'.³⁰ This trend was noticed, for example, in a report from 2007 by the Dutch Healthcare Insurance Board (Dutch abbreviation: CVZ), which stated:

'EBM was primarily developed as a guideline for practising physicians in making clinical decisions on individual patients. However, the method has since been applied more broadly, for example in the development of guidelines by professional associations of healthcare providers and in the development of policies in the field of public health'.³¹

28. See chapter 3.

29. See, in particular, chapters 3 and 9.

30. See, in particular: M. Gray, *Evidence-Based Healthcare*.

31. P. C. Staal & G. Ligtenberg, *Beoordeling Stand van de Wetenschap en Praktijk*. Publicatienummer 254 (Diemen: College voor Zorgverzekeringen, 2007), p. 10. See also, for example: Kristiansen & Mooney, 'Evidence-Based Medicine'.

The fact that EBM, besides a *micro dimension*, also has a *macro dimension* implies that EBM is not only relevant to medicine and the medical profession. It proves to be a phenomenon that has *societal significance* as well. EBM touches on the political issue of the fair distribution of scarce resources as well as on the question of how society wants to organise medicine and healthcare. In this respect, evidence-based medicine has everything to do with the theme of the ‘paradox of modern medicine’ and the attempts of medical *as well as* non-medical parties to deal with it.

Indeed, all manner of stakeholders in healthcare – medical professional associations, professional organisations of associated non-medical disciplines, boards of healthcare institutions, governments, insurers, pharmaceutical companies, legal experts, patients’ and consumers’ organisations as well as numerous individual patients and (both medical and non-medical) professionals in healthcare – have embraced EBM (to a greater or lesser extent). It is important to note here, however, that this large variety of parties by no means always did so for the same reasons and for the same purposes, as a result of which they sometimes lend widely differing meanings to evidence-based medicine and, for example, think very differently about the way in which the instrument of the clinical guideline is to be handled.³²

All in all, EBM proves to be a phenomenon with many faces and identities. EBM has been described as an educational approach, an ideological movement, a rather empty slogan and as a critical attitude or mentality. As far as the specific forms and tools of EBM are concerned, the focus shifted from critical appraisal to systematic reviews and clinical guidelines. Furthermore, apart from a micro dimension, EBM also appears to have a macro dimension; apart from being important to medicine, it also proves to be significant in social terms, as a result of which many different parties are involved in it, who each give their own meaning to the concept. In other words, EBM proves to be an instrument that is by no means neutral and quickly becomes politicised. Partly for this reason, it forms a suitable window on the developments in healthcare of the last few decades, including the attempts by a variety of stakeholders to get some grip on this domain.

At the same time, the question presents itself as to whether the ‘EBM window’ – due to the many different faces, identities and influences of various parties – is perhaps too ‘cloudy’ in order to be able to offer a clear ‘view’. Yet this problem may be overcome to a significant extent because there is one aspect that is widely considered to be the ultimate

32. See, in particular, chapter 9. The many different (and often conflicting) objectives attributed to clinical practice guidelines by various parties are summed up and discussed in: M. Berg, N. M. Bezemer & M. van den Burg, ‘Normatieve Aspecten van Richtlijnen en Kosten-effectiviteitsanalyses’, in M. van den Burg et al., *Normatieve Aspecten van Richtlijnontwikkeling en Kosteneffectiviteitsstudies in de Cardiologie en Psychiatrie*. KNMG-Project Passende Medische Zorg, Deelrapport C (Utrecht: KNMG, 2000), appendix 4, on pp. 16-22.

distinguishing feature of evidence-based medicine: central in the EBM ideology are very definite ideas about what may serve as good, better and the best evidence for making clinical decisions.³³ This very soon came to the fore in the aforementioned article from 1992 in *JAMA*, in which it was stated:

‘Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research.’³⁴

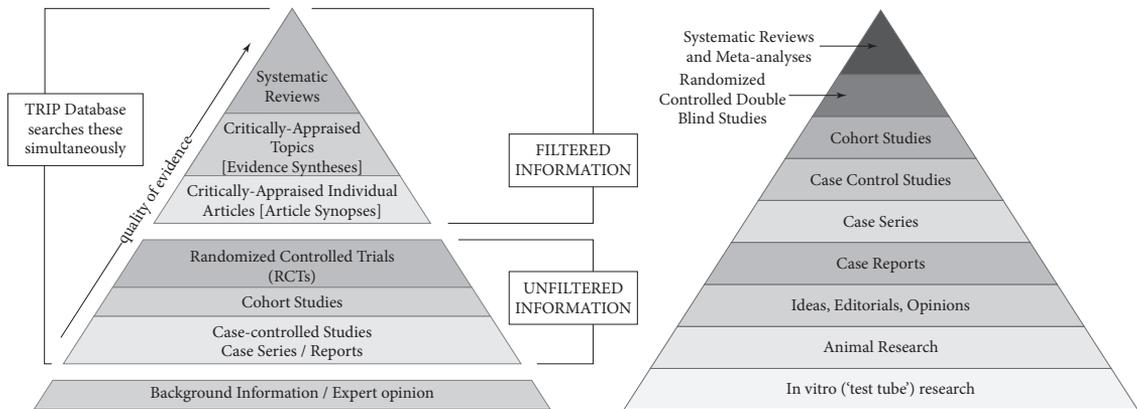
Thus, some forms of evidence were assessed more favourably than others. This quotation particularly expresses the preference of (statistical-epidemiological) evidence from clinical research to clinical experience and pathophysiological reasoning as a basis for medical decision-making. Within the EBM movement, the notion of various levels of evidence is further developed in pyramid-shaped ‘hierarchies of evidence’, with the ‘lowest’ forms of evidence at the bottom, at the base, and the ‘highest’ forms of evidence at the top. Two examples are shown on p. 20.³⁵

What was called ‘intuition’, ‘experience’ and ‘pathophysiological rationale’ in the previously quoted article is indeed ranked low in these pyramids, under ‘background information/expert opinion’ (to the left) and ‘ideas, editorials, opinions’, ‘animal research’ and ‘in vitro (test tube) research’ (to the right). Higher up in the hierarchy are various forms of clinical research. A high position is assigned to the so-called Randomised Controlled Trial (RCT). The RCT is so highly regarded because the use of control groups, randomisation and (double) blinding minimises the impact of various forms of bias of the researchers and subjects involved on the results obtained. The same criterion is also decisive for the position of other forms of research. The issue is invariably to what extent subjectivity and bias may be eliminated: the more this is the case, the more highly the evidence is valued.

33. See for example: Kristiansen & Mooney, ‘Evidence-Based Medicine’, pp. 8-14.

34. EBM Working Group, ‘Evidence-Based Medicine’, p. 2420.

35. The figure on the left is obtained from a weblog on EBM of the Dartmouth Biomedical Libraries: see: <http://www.dartmouth.edu/~library/biomed/about/pulse/pulse-apr-10.html#ebm>. The figure on the right is obtained from the website of *The Hospitalist*: http://www.the-hospitalist.org/wp-content/uploads/springboard/image/2005_07_pp33_t01_LG.jpg. The original source of this figure is the SUNY Downstate Medical Center: Medical Research Library of Brooklyn. The figure has been used at an EBM course/tutorial there.



Right at the top of the hierarchies of evidence are usually systematic reviews and meta-analyses, but this only enhances the privileged position of the RCT. Due to the highly standardised manner in which these clinical trials are set up, they are mutually highly comparable and are thus well-suited to systematic reviews and meta-analyses. This applies to a much lesser extent to the various forms of observational (so: non-experimental) clinical research, such as the cohort studies and case control studies, which are ranked lower in the hierarchy of evidence. This is why, in practice, systematic reviews mainly, and meta-analyses virtually exclusively, pertain to RCTs.

Given the fact that some forms of evidence enjoy a higher status than others in the EBM ideology, it seems possible after all to pinpoint a rather specific and concrete aspect of the phenomenon of EBM that is so ungraspable. It moreover concerns a very essential aspect. In the Netherlands, for example, the 'levels of evidence' are used as a guiding principle for both the 'evidence-based guideline development'³⁶ and for the assessment as to whether medical facilities are 'proven to be effective' and thus eligible for inclusion in the basic package for insured healthcare. In 2007, the Healthcare Insurance Board, which was mainly involved in the latter, wrote on the central role of the evidentiary hierarchy in the EBM ideology:

*'Core of the EBM method is that a level of evidentiary force is assigned to the selected medical-scientific information [...] which results in a hierarchy in evidence [...]. A vital starting point with EBM is furthermore that, in principle, strong evidence displaces weaker evidence.'*³⁷

36. See for example, J. J. E. van Everdingen et al. (eds.), *Evidence-Based Richtlijnontwikkeling: een Leidraad voor de Praktijk* (Houten: Bohn Stafleu Van Loghum, 2004), in particular pp. 21, 33-4, 158-9, 169.

37. Staal & Ligtenberg, *Beoordeling Stand van de Wetenschap*, p. 12.

Besides being concrete and significant, the EBM notion of a hierarchy of evidence is an expression of an intriguing *historical change*. Western medicine in the nineteenth century and the greater part of the twentieth century was dominated by a ‘hierarchy of evidence’ that is completely different from the present ‘EBM era’. The consensus among both historians and medical professionals is that at least up to and including the 1950s and probably for several more decades, the priority lay with expert opinion and pathophysiological reasoning – i.e. with matters that are regarded within EBM as the lowest forms of evidence. In this context, the historian J. Rosser Matthews points to the evidentiary hierarchy below, which was drawn up in 1912 by the British physician Wright and which virtually totally constitutes the opposite of the various ‘EBM pyramids’.³⁸

‘Evidentiary hierarchy’ (Wright 1912)

- 1) Crucial experiment (laboratory/biomechanical)
- 2) Cumulative experiment (laboratory/biomechanical)
- 3) Experiential method (clinical observation/experience)
- 4) Statistical method

It thus appears that the top and the base of the ‘pyramids of evidence’, which used to be predominant in medicine, were completely reversed in the latter half of the twentieth century. The question is raised here as to how and why such an about-turn occurred within medicine roughly between 1950 and 1990. Or, as the historian Theodore Porter formulates it: ‘How then, did controlled clinical trials and statistical analysis become standard, even obligatory?’³⁹

With this (historical!) question by Porter, one of the principal points of this dissertation has been indicated. EBM will be historicised here as a striking manifestation of the increasing impact of quantification and statistical-epidemiological reasoning in Western medicine and healthcare, which took shape in the latter half of the twentieth century in particular. In doing so, an attempt will be made to interpret and give meaning to this trend with the help of a theoretical ‘coat rack’.

38. See Matthews’ contribution to the ‘Night of Descartes 2009’ (including his powerpoint presentation), on: <http://www.sg.uu.nl/opnames/bewezen-beter-nacht-van-descartes/prof-dr-ted-porter-en-prof-dr-j-rosser-matthews>. See also: J. R. Matthews, ‘Almroth Wright, Vaccine Therapy and British Biometrics: Disciplinary Expertise versus Statistical Objectivity’, in: E. Magnello & A. Hardy (eds.), *The Road to Medical Statistics* (Amsterdam/New York: Rodopi, 2002), pp. 125-47, in particular pp. 143-4.

39. Th. M. Porter, *Trust in Numbers. The Pursuit of Objectivity in Science and Public Life* (Princeton, New Jersey: Princeton University Press, 1995), pp. 203-4.

'Coat Rack': Professional Response and Mechanism of Control

One of the most influential works on quantification and the rise of statistical thinking is the book *Trust in Numbers*, which was published in 1995 by the aforementioned historian, Theodore Porter. In this book, he outlines a number of theoretical ideas that seem ideally suited to serve as 'coat rack' for a historical study and interpretation of the rise of evidence-based medicine towards the close of the twentieth century.

Following the example of the Canadian historian Allen Megill, Porter first of all makes a distinction between various forms of objectivity, concentrating on the relationship between disciplinary and mechanical objectivity. *Disciplinary objectivity* refers to 'consensus [...] within a specialist disciplinary community'.⁴⁰ It concerns, in other words, a form of intersubjectivity that is based on the shared (and tacit) knowledge, training and experience of experts – and often also the unwritten rules – within a specific discipline. In Porter's view, the power or impact of disciplinary objectivity is greatest when there is a good deal of trust with the 'public' in the professional expertise of the relevant 'disciplinary community'.⁴¹

Mechanical objectivity is mainly characterised by what it is *not*. In the case of mechanical objectivity, subjectivity and the personal are eliminated as much as possible and replaced by *impersonal*, formal procedures and explicit criteria. Thus, 'objective' does not mean 'true' here, but 'non-subjective'. Porter also groups *numbers* and quantification under mechanical objectivity, because numbers and quantitative data are often considered to be non-subjective. According to him, mechanical objectivity flourishes in circumstances in which there is no natural trust in authorities and there is a need, for example from society, for transparency and accountability – in other words: when there is more 'trust in numbers' than 'trust in professional experts'.⁴²

The central idea that Porter develops in his book is that these two forms of objectivity not only form analytical categories but can also be placed in a chronological context. His thesis is that, especially in the nineteenth and twentieth century, numerous domains, disciplines and professions as well as government bureaucracies in many countries, experienced a shift from disciplinary to mechanical objectivity, or a shift from 'trust in experts' to 'trust in numbers'. The crucial factor here was invariably external pressure or even distrust. If the authority or the expertise of, for example, a discipline declined, then this discipline was forced to resort to more transparent, impersonal procedures, which was often also accompanied by increased quantification.⁴³

40. Ibid., p. 3.

41. Ibid, pp. 3-4.

42. Ibid, pp. ix, 4-6, 74-8, 85-6.

43. Ibid, see in particular pp. vii-xii, 3-8, 199-202.

Porter places this trend of a shift from disciplinary to mechanical objectivity and of increasing quantification in numerous areas in the very broad context of the process of modernisation in (especially) the Western world. The small-scale communities in which personal trust and disciplinary objectivity could thrive made way during the nineteenth and twentieth centuries for democratic, highly bureaucratised mass societies in which quite different demands were imposed on officials, professional experts and figures of authority. Among other things, a democratic political culture is accompanied by 'a moral demand for impartiality and fairness'.⁴⁴ The weight of this 'moral demand' increased as the average educational level of the population rose and, partly in consequence of this, the call for transparency and accountability became stronger. Mechanical objectivity was more in line with this development than disciplinary objectivity was, for, as Porter writes:

'In a political culture that idealizes the rule of law, it seems bad policy to rely on mere judgment, however seasoned [...]. A decision made by the numbers (or by explicit rules of some other sort) has at least the appearance of being fair and impersonal'.⁴⁵

Besides the democratic culture, according to Porter, the large *scale* of modern mass society also facilitates 'trust in numbers'. In this context, he regards quantification as 'a strategy of communication' and 'a technology of distance', which he clarifies as follows:

'Perhaps most crucially, reliance on numbers and quantitative manipulation minimizes the need for intimate knowledge and personal trust. Quantification is well suited for communication that goes beyond the boundaries of locality and community'.⁴⁶

In Porter's view, numbers are not only 'more open and less personal',⁴⁷ they also allow for scrutiny and control.⁴⁸ His view in this respect ties in with a whole body of literature in which quantification is associated with notions such as order(ing), regulation, standardisation, control, transparency and accountability.⁴⁹ As trust (in experts or numbers) is moreover the central notion in Porter's work, he thus thematises an important dilemma. On the one hand, it is of great importance that matters be well-regulated and formalised to such an extent that bias, arbitrariness and unfairness are prevented and

44. Ibid, p. 8.

45. Ibid.

46. Ibid, p. ix.

47. Ibid, p. 7.

48. Ibid, see in particular pp. 21-9, 32-3, 37, 48-51, 77, 84-6, 228-9.

49. Ibid. See also on this: La Berge, *Medical Statistics at the Paris School: What was at Stake?*, in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005), pp. 89-108, on pp. 90, 98-101. See also the references in the section 'Modernisation, Numbers and Control' of chapter 1.

there is compliance with the minimum requirements of transparency and accountability. On the other hand, there is the immense hazard, which has already become a reality in too many situations, of an excessive bureaucracy of control and supervision, of an overzealous culture of (quantitative) assessment and of institutionalised mistrust.

For this and other reasons, the relevance of the Porter thesis for a good understanding of the functioning of modern Western societies is widely recognised. It is beyond dispute that, under the influence of the social and political processes he describes, quantitative methods and impersonal procedures have progressed considerably in government bureaucracies, in research, in the business world and in countless other domains. Yet to what extent can Porter's ideas be used for a historical interpretation of the rise of evidence-based medicine?

Specifically with regard to medicine, Porter argues that *trust in numbers*, in the form of inferential statistics, has become the standard 'as a response to internal disciplinary weakness and external regulatory pressures'.⁵⁰ In his view, 'traditional' medical practice based on clinical judgment and pathophysiological reasoning no longer sufficed when, in the modernising mass society, there was an increasingly loud call for transparency, accountability, 'objective' (impersonal) standards and cost control. In order to be able to cope with the demands of the times, the medical profession subsequently embraced mechanical objectivity – among others in the form of randomised controlled trials and evidence-based medicine.⁵¹ Porter concludes:

'The advances of statistics in medicine must be understood as *responses to problems of trust*, which have been most acute in the context of regulatory and disciplinary confrontations. This, and not any inherently statistical character of clinical medicine, explains why inferential statistics entered medicine through therapeutics.'⁵²

For several reasons, Porter's analysis is relevant for a historical interpretation of the rise of evidence-based medicine. Firstly, in the EBM ideology, the focus seems indeed to be on mechanical objectivity and 'trust in numbers'. How high evidence is ranked in a hierarchy of evidence depends, after all, on the extent to which various forms of bias, or subjective, personal influences are eliminated. This corresponds exactly with Porter's description of mechanical objectivity as *impersonal, non-subjective knowledge or procedures*. At the launch of EBM in 1992, it was moreover explicitly stated that quantitative, statistical- epi-

50. Porter, *Trust in Numbers*, p. xi.

51. *Ibid.*, see in particular pp. 201-9. And see also Porters lecture and powerpoint presentation at the 'Night of Descartes 2009' symposium, available at <http://www.sg.uu.nl/opnames/bewezen-beter-nacht-van-descartes/prof-dr-ted-porter-en-prof-dr-j-rosser-matthews>.

52. Porter, *Trust in Numbers*, pp. 208-9.

demiological knowledge was preferred to expert judgement as a foundation for medical decision-making.

Secondly, it seems that the rise of EBM may, to a certain extent, be interpreted as a professional response to external pressures. An important indication for this is that several EBM proponents subscribe to this point of view themselves. Gordon Guyatt for example, one of the pioneering clinical epidemiologists of McMaster University and moreover the person who coined the term ‘evidence-based medicine’ in 1990, gave the following answer to the question of why EBM ‘was taken up so easily’ in an interview from 2014:

‘Well, I guess I don’t really understand why the term hit so well, but one theory is that it came along at a time when medicine was getting challenged in a way and losing its authority to some extent, and this was a way for it to reestablish its legitimacy. I hadn’t particularly been thinking along those lines at the time, but in retrospect it makes a lot of sense.’⁵³

Even more explicit references to the Porter thesis were made by several representatives of the EBM movement in the Netherlands. Patrick Bossuyt and Martin Offringa, for example – then a professor of clinical epidemiology in Amsterdam and one of the directors of the Dutch Cochrane Centre respectively – wrote in 2001:

‘EBM was and is the perfect answer to this challenge: a *professional response to demands* for scientific underpinning and accountability in a climate of crumbling trust. [...]. A *new objectivity*, a rationality based on results and rules, numbers and graphics, is to curb the influence of subjective opinions and interests, and thus lead to better healthcare. As far as this evolution is concerned, medicine is not unique: in a time of a retreating government and responsibility, more and more institutes call on *numbers* to exert their influence.’⁵⁴

53. ‘Question of the Month: Gordon Guyatt’, *Newsletter Centre for Evidence-Based Management*, May 2014. Retrieved d.d. 29 January 2015 from: <http://www.cebma.org/newsletter/may-2014/may2014-6/>.

54. P. Bossuyt & M. Offringa, ‘De Wortels van Evidence Based Medicine: Gerede Twijfel en Gegronde Zorg’, in P. Bossuyt & J. Kortenray (eds.), *Schaatsen Op Dik Ijs: Evidence Based Medicine in de Praktijk* (Amsterdam: Boom, 2001), pp. 27-48, on pp. 44-5. TB’s italics. See also: P. M. M. Bossuyt, ‘Evidence-Based Medical Testing. Developing Evidence-Based Reimbursement Recommendations for Tests and Markers’, in *Medische Tests (Beoordeling Stand van de Wetenschap en Praktijk)*. Publicatienummer 293 (Diemen: College voor Zorgverzekeringen, 2011), pp. 10-11; P. M. M. Bossuyt, *De Idolen van Kieslowski: de Onvermijdelijkheid van Evaluatieonderzoek voor het Klinisch Handelen* (Utrecht: Bunge, 1997), p. 9 and p. 21, n. 32. Bossuyt confirmed this in the interview by TB on 6 January 2012. See also the reference to Porter’s work by the GP and philosopher Tjerk Wiersma, who is closely involved with the evidence-based ‘standards’-program of the NHG (the Dutch Society of GP’s), in: T. Wiersma, *Twee Eeuwen Zoeken naar Medische Bewijsvoering. De Gespannen Verhouding tussen Experimentele Fysiologie en Klinische Epidemiologie* (Amsterdam: Boom, 1999), p. 261. In a book on quality improvement in general practice, published by the NHG itself, the need for ‘quality systems’ was explained by referring explicitly and elaborately to the necessity of *earning* the trust of patients and society (as this trust was no longer self-evidently given to physicians) in an age of an increasing demand for transparency and accountabi-

In line with Porter's work, evidence-based medicine could be conceptualised as a shift from disciplinary to mechanical objectivity and as a professional response to external pressures, where the quantitative knowledge emphasised by the EBM movement and, for example, the clinical guidelines as well should, at least in theory, contribute to increased transparency and accountability in respect of medical practice, at a time when this was required by the government, insurers and society. This would mean that the connection that Porter (as well as many other scholars) made between 'trust in numbers' on the one hand, and matters such as scrutiny, control, formalisation, regulation and standardisation on the other hand, could also apply to evidence-based medicine.

It is against this background that the *hypothesis* may be formulated that EBM may (partly) be considered to be a *mechanism of control* for medicine in the late twentieth century and early twenty-first century. In this dissertation, it will be studied to what extent evidence-based medicine emerged and was embraced by various stakeholders as a mechanism of control. In addition, the last chapter will tentatively focus on the question of what the role and impact of EBM is or will be as mechanism of control in Dutch healthcare in the 21st century. The word 'control' should be interpreted in broad terms here. It may refer to 'containment' and 'control', but also to 'regulation', 'formalisation' and 'proper management' of medicine at the micro-, meso- and macro-level.

It is important to note that the Porter thesis, on which this hypothesis is based, does not exist in isolation. Not only is Porter's work highly valued internationally, but it is also strongly related to and, to a significant extent, supported by the work of other historians and social scientists on the subject of objectivity, quantification and the rise of statistics. In particular, the work of Peter Galison and Lorraine Daston deserves a mention here.⁵⁵

Furthermore, Porter's ideas fit in well with the developments in the social-scientific literature on professions and professionalisation. While, in the past, this literature often considered the medical profession to be an outstanding example of a successful profession that continuously managed to expand its 'jurisdiction', in recent times, the processes of *deprofessionalisation* and *reprofessionalisation* have been written about more. A great deal of attention is paid here to the increasing importance of protocols and (evidence-based) clinical guidelines in healthcare and their impact on the professional autonomy

lity – in other words: a 'Porterian schema' was adopted (without referring to Porter's work). See: J. C. C. Braspenning et al. (eds.), *Werken aan de Kwaliteit in de Huisartsenpraktijk: Indicatoren Gebaseerd op de NHG-Standaarden* (Houten: Bohn Stafleu van Loghum, 2005), pp. 1-3.

In a report for the Royal Dutch Medical Association (Dutch abbreviation: KNMG), written in the context of the KNMG-project 'Appropriate Medical Care' (in Dutch: *Passende Medische Zorg*) in 2000, Porter's thesis is explicitly referred to as a valid way of explaining or interpreting the rise of clinical practice guidelines and the accompanying process of quantification and objectification of medical practice. See: Berg, Bezemer & Van den Burg, 'Normatieve Aspecten', pp. 13-14.

55. L. Daston & P. Galison, *Objectivity* (New York: Zone Books, 2007), see in particular pp. 371-82.

of (paramedical) disciplines.⁵⁶ The way in which the ideas of the sociologist Eliot Freidson have developed is exemplary in this respect. In the 1970s, Freidson belonged to the ‘critical leftist intellectuals’ who challenged the power and paternalism of professions and the medical profession in particular. In the decades that followed, however, Freidson found that professions came under pressure from more directive governments, the increasingly powerful industry and from citizens who increasingly presented themselves as empowered consumers. He became increasingly aware of the drawbacks involved in both the ‘logic of bureaucracy’ and the ‘logic of the market’ as ordering mechanisms for the performance of sectors such as education, welfare and healthcare. This led him to the conclusion in the early 2000s that the ‘third logic’, namely the logic of professionalism, was due for reappraisal.⁵⁷

Furthermore, the contribution of the sociologist, Thomas Gieryn, on ‘boundary work’⁵⁸ may be considered to be related to that of Porter to a certain degree. Where *trust* is the key notion with Porter, with Gieryn it is *credibility*. According to Gieryn, boundary work, or the (re)defining of the boundaries of what is (proper) science mainly takes place when there is conflict or doubt about the credibility of scientists or scientific disciplines. He distinguishes three main forms of boundary work here, including ‘protection of autonomy’.⁵⁹ This ties in with the notion – derived from Porter – of EBM as a professional response to external pressure or even distrust. The shift to ‘mechanical objectivity’ in the form of quantitative evidence and clinical guidelines could then be interpreted as a form of boundary work, in which case EBM has, in other words, redefined the scientific foundation of medical practice, so as to be able to preserve the credibility of and trust in medicine in changing circumstances.⁶⁰ An interesting question here could be whether this would indeed defend the professional autonomy of physicians, or restrict it after all, because quantitative evidence and guidelines would seem to open up medical practice to scrutiny and control.

56. See respectively an example of, an overview of and two comments on this social scientific literature: J. W. Duijvendak, T. Knijn & M. Kremer (eds.), *Policy, People, and the New Professional: De-Professionalisation and Re-Professionalisation in Care and Welfare* (Amsterdam: Amsterdam University Press, 2006); J. Dwarswaard, *De Dokter en de Tijdgeest: een Halve Eeuw Veranderingen in de Beroepsethiek van Huisartsen en Chirurgen* (Den Haag: Boomlemma, 2011), pp. 5-7, 21-8; S. Timmermans & E. S. Kolker, ‘Evidence-Based Medicine and the Reconfiguration of Medical Knowledge’, *Journal of Health and Social Behavior* 45: extra issue (2004), pp. 177-93; G. Weisz et al., ‘The Emergence of Clinical Practice Guidelines’, *Milbank Quarterly* 85 (2007), pp. 691-727.

57. E. Freidson, *Professionalism: the Third Logic* (Cambridge: Polity, 2001). See also n. 56 above.

58. Thomas F. Gieryn, *Cultural Boundaries of Science: Credibility on the Line* (Chicago & London: University of Chicago Press, 1999).

59. *Ibid.*, pp. 17-18.

60. Both the issues of *trust* and *credibility* are explicitly and elaborately linked to (the creation of) evidence-based guidelines in: E. van Loon & R. Bal, ‘Uncertainty and the Development of Evidence-Based Guidelines’, *Valuation Studies* 2 (2014), pp. 43-64.

Because the issue of the boundaries of (proper) science touches upon the core of evidence-based medicine – and in particular on the notion of ‘levels of evidence’ – it is useful to dwell longer upon Gieryn’s work, in which he studied a number of specific episodes where there was a dispute about questions such as: What is science and what is not? What is reliable knowledge and what is not? Who is a ‘real scientist’ and who is not? Who is allowed to call themselves a physician and who is a quack? In Gieryn’s view, people who are involved in disputes about such questions consciously or unconsciously assume a ‘cultural map of science’. Such a ‘cultural map’ indicates the boundaries of science as it were. These boundaries become ‘visible’ because certain characteristics of science are selectively accentuated, serving as landmarks and ‘boundary markers’. It is this (sometimes implicit) construction of ‘cultural maps of science’ Gieryn refers to with the term ‘boundary work’.

The strength of Gieryn’s work is that it is very *practice-oriented*. He himself explains this by reference to the contrast between his approach and that of figures such as Popper, Merton and Kuhn. According to him, these famous philosophers primarily focused on what happens ‘*upstream*’ in science, that is to say, on issues such as: how are facts and scientific knowledge produced? And: what makes science science? Gieryn, however, as he writes himself, looks precisely in the opposite direction: his focus is ‘*downstream*’, as he believes this is where decisions are made on the credibility of scientific knowledge – and in particular on the question as to whether certain scientific knowledge is credible enough to serve as a foundation to make or legitimise *practical decisions*. Thus, the questions Gieryn asks himself while studying cultural maps of science pertain to their *pragmatic utility*: Is this ‘map’ useful? And if so, for what and for whom? How is this ‘map’ used for making and legitimising practical decisions?⁶¹

Because of this focus on pragmatic utility, Gieryn’s ‘cartographic approach’ seems a very suitable tool in the analysis of the phenomenon of evidence-based medicine, as EBM is not characterised by a profoundly philosophically elaborated ideology, but above all by its *practical* purpose. It serves to solve practical problems, both at the micro- and at the macro-level. The principles and methods of EBM are applied while making *decisions* on the care of individual patients, on the content of clinical guidelines and on the question of whether a certain diagnostic method or therapy ‘is proven to be effective’ to a sufficient extent to be eligible for reimbursement in the system for insured healthcare. Here, the various ‘levels of evidence’ used may be interpreted as various areas on a cultural map.

Complemented by Gieryn’s ‘boundary work’ and the sociological literature on professions and professionalisation, Porter’s views (and those of authors such as Galison and Daston) seem to constitute a suitable ‘coat rack’ for the study of EBM. The term ‘coat rack’

61. Gieryn, *Cultural Boundaries*, see in particular pp. 1-35

is used deliberately here, for the theoretical framework sketched here and the hypothesis of EBM as a mechanism of control are only used *heuristically*, so as to be able to structure and interpret empirical findings. The ‘empirical *floor*’ of the specific historical case of EBM in the Netherlands ultimately forms the nucleus of this dissertation. A number of considerations provide the basis for this and they will be outlined below.

‘Floor’: The Dutch Case of EBM

Porter may be considered a ‘sociologising’ historian. This is important for, as a rule, sociologists and historians study reality from essentially different angles. Sociology is often inclined towards a ‘nomothetic’ approach, which is characterised by a focus on the acquisition of general insights. History is an ‘idiographic’ discipline, that is to say, a discipline that aims to understand individual, discrete, or unique facts or events. This classic contradiction between nomothetic and idiographic approaches is not absolute. Historians, for example, often use nomothetic approaches – in particular in the form of theories and models from social sciences – but they usually serve only as a tool or framework for the historical interpretation of the specific and special subject of study.⁶² Porter seems to have shifted a step further towards a ‘nomothetic direction’. In his book *Trust in numbers*, he builds a model that offers a general explanation for the processes of objectification and quantification that occurred in all manner of domains. His central ideas on the shift from disciplinary to mechanical objectivity appear to be applicable to countless developments in the nineteenth, twentieth and twenty-first centuries. Thus, he makes a contribution of which the significance is widely recognised. The drawback, however, is that Porter’s model places specific historic phenomena, such as the emergence of evidence-based medicine, merely in a general framework, while the unique or special aspect of this (mostly) remains out of sight. For a historical interpretation of EBM, it is therefore necessary to supplement Porter’s (to a certain extent) nomothetic approach from a more idiographic angle, by mapping out events and developments that are specific in time, place, and context.

In addition, with Porter, there is a strong emphasis on ‘structure’ while, for a good understanding of the rise of EBM, it is also necessary to take a closer look at ‘content’. Porter places the emphasis on the (more or less) internal cohesion of disciplines, and on their social position, which he mainly measures by the degree of external pressure or mistrust. The precise issues that were involved within these disciplines, and the social field in which they played a role, is of secondary importance to him. Using the distinc-

62. See on this o.a.: E. Breisach, *Historiography: Ancient, Medieval, & Modern*, 2nd ed. (Chicago: Chicago University Press, 1994), pp. 282-4.

tion between disciplinary and mechanical objectivity, he focuses on the acquisition of more theoretical insights into the process of quantification that occurred in many fields in the Western world, as part of general developments such as modernisation, bureaucratisation and democratisation. Similar comments may be made on the social scientific literature on professions and processes of (de-/re-)professionalisation. Without intending to disqualify the Porter thesis and the ‘professionalisation literature’, it is important to complement their more general and structural approach with an analysis of more substantive and specific aspects.⁶³

In this respect, it should be noted that it does not suffice to interpret EBM as just a professional strategy of quantification, with which the medical profession has attempted to protect its credibility and autonomy under the pressure of changing circumstances. It is also necessary to acquire more insight into the ‘content’ of the process of quantification of which EBM is a manifestation. This means, for example, that the focus must be more specifically on the rise and impact of the *statistical-probabilistic* mode of thought in medicine. Porter’s ideas and those of the sociological professionalisation literature are too broad or general to get a handle on these and other specific substantive aspects of EBM. Two quotations by the historian Harry Marks aptly illustrate this:

‘The temptation is great for historians to assume that if statistical concepts were influential across a wide variety of domains, then this “influence” flowed from some central source, whether that be a common set of theoretical ideas, a general cultural need for “objective” techniques of analysis, or a social force common to multiple settings after World War II – e.g. bureaucratization or the professionalization of expertise. As historians long ago noted, the notion of intellectual “influence” is extremely nebulous and often substitutes for a more substantive analysis of change.’⁶⁴

[...]

‘How do we explain the extraordinary success of statistics in contemporary medicine? The answer may well differ for each medical domain [...].’⁶⁵

In line with these considerations, Marks very consciously developed his widely acclaimed book *The Progress of Experiment* as a historical case study – or actually a series of case studies – in which he tells the story of the rise of the Randomised Controlled Trial specifically in the United States. He writes about this: ‘While the controlled clinical trial may be

63. See for more or less comparable reflections the inaugural lecture of cultural anthropologist Anton Blok on (more or less) the same issue: A. Blok, *Wittgenstein en Elias: een Methodische Richtlijn voor de Antropologie* (Amsterdam: Athenaeum-Polak & Van Genneep, 1976).

64. H. M. Marks, *The Progress of Experiment. Science and Therapeutic Reform in the United States, 1900-1990* (Cambridge: Cambridge University Press, 1997), p. 131.

65. *Ibid.*, p. 138.

an international scientific accomplishment, the ways in which trials were organized and understood mark them as belonging to *a particular place as well as time*.⁶⁶ In this specifically ‘American story’ that Marks tells, ‘therapeutic reformers’, as he calls them, are the main protagonists. He describes them as ‘individuals who sought to use the science of controlled experiments to direct medical practice.’⁶⁷

This way, Marks’s work offers an interesting counterpoint to Porter’s ‘coat rack’. Where the latter deals with general structures, processes and factors at great length, Marks tries to do justice to do the specific, local and contingent quality – and moreover to the role – of individual (or groups of) people. His underlying message seems to be that eventually it is not abstract structures, such as ‘professions’, but real people of flesh and blood who ‘make’ history. This virtually literally came to the fore in a paraphrase by his almost namesake (Karl) Marx: ‘men make their own history but not in the circumstances described in the prefaces to history books.’⁶⁸

With Marks’s book as a source of inspiration, it will be attempted in this dissertation to amend Porter’s model with a description and analysis of the specific Dutch case of EBM. Yet the ‘Netherlands case’, as well as the various local histories of which it is composed, is interesting in its own right as well. It seems, for example, that nowhere in the world was clinical epidemiology – the discipline from which evidence-based medicine developed – able to establish itself as successfully in the academic world as in the Netherlands. By extension, evidence-based medicine too seems to have gained a much firmer foothold in this country than in surrounding countries. In order to be able to account for this, it is essential that, besides the general, international factors, the specifically Dutch and sometimes very local factors that contributed to the rise of clinical epidemiology and EBM in this country be explored as well. Following Marks’s example, it is possible, for example, to point to the role of ‘therapeutic reformers’ here, who include pioneering (clinical) epidemiologists and researchers, directors of medical faculties and university hospitals, leading figures within professional medical associations, and, not least, Els Borst Eilers who, as vice chairwoman of the Health Council and subsequently as Minister of Health (1994-2002), provided a major impetus to evidence-based medicine in the Netherlands.

Furthermore, a historical study of the situation in a specific country may offer insights into the actual specific meaning, effects or impact of the rise of clinical epidemiology and EBM. While it is nearly impossible to say anything sensible about this in a general sense, research into specific, concrete developments in, in this case, the Netherlands, may offer some understanding of this. A case study of the Netherlands lends itself ideally

66. Ibid., pp. 6-7.

67. Ibid., p. 2.

68. Ibid., p. 7.

to this, precisely because clinical epidemiology and evidence-based medicine have been relatively successful here. In other words, the Dutch case of EBM offers an excellent opportunity to map out a *reception history* that can shed some light on numerous issues, including: How does EBM as an ideal relate to the manner in which EBM is fleshed out in practice? What useful role and function may EBM (potentially) fulfil in healthcare in the 21st century? What impediments and threats are there with regard to this useful role and function? The last chapter in particular will, albeit somewhat tentatively, reflect on these issues.

All in all, this dissertation will feature a great many ‘back and forth motions’ between the local, national and international levels, as well as between, on the one hand, the more theoretical interpretation of the phenomenon of EBM as a mechanism of control and a professional response to external pressure and, on the other hand, the more empirical description regarding the rise and reception of clinical epidemiology and EBM in the Netherlands, with particular attention being paid to the role of specific persons (‘therapeutic reformers’). What form the foregoing will take will be specified below.

Structure

In the preceding pages, the main objectives, research questions and hypotheses of this study were addressed. First of all, it was stated that an attempt will be made to look at ‘the paradox of modern medicine’ – and the related themes of the Utrecht/Maastricht research programme, *Medicine in Transition* – from the perspective of the ‘EBM window’. One of the main objectives here is to obtain some clarity as regards what evidence-based medicine actually *is*. The focus will largely be on one specific and important aspect, namely the preference for statistical-epidemiological evidence (particularly from RCTs) to matters such as clinical expertise and pathophysiological reasoning as a foundation for medical practice. In this regard, EBM seems to be an important manifestation of the rise, in the latter half of the twentieth century, of what could be termed the ‘statistical era’ in medicine. Using the work of Porter (and others), this development could be (partly) considered to be a professional response to external pressures and a shift from disciplinary to mechanical objectivity, or from trust in experts to trust in numbers. Because quantification, mechanical objectivity and numbers are associated with scrutiny and control, the hypothesis follows from this that EBM emerged and was embraced by various stakeholders as a mechanism of control for medicine and healthcare in an era of transparency and accountability. Derived from Porter’s work, this hypothesis ties in well with the sociological literature on professions and Gieryn’s contributions on boundary work. This, among others, raises the question as to what extent evidence-based medicine – in particular in the shape of evidence-based clinical practice guidelines – impacted the professional autonomy of physicians.

The hypothesis of EBM as a mechanism of control will be assessed against the Dutch case of EBM in which, following Marks's example, the focus will be on the role of the concrete, the specific and the personal. An attempt will be made, first and foremost, to map out specifically how the introduction of clinical epidemiology and EBM in the Netherlands unfolded. On the basis of empirical findings on this, the endeavour will be to ascertain the extent to which the Porter thesis requires amendment as an explanatory and interpretation framework, and also to obtain (tentative) answers to the questions regarding the extent and the whys and wherefores of the rise of clinical epidemiology and EBM in the Netherlands, and ultimately to the question as to what type of phenomenon EBM actually is and what role and impact it has or could have.

Thus, the 'programme' of this dissertation is sketched in brief terms. This will be elaborated in three parts, each comprising three chapters. In the first part, the phenomenon of evidence-based medicine will be placed in both a long-term and international perspective. To this end, chapter 1 will contrast the existing historiography with the way in which EBM will be historicised in this dissertation. While the medical literature focuses on 'historical precursors' and a great deal of the historical and philosophical literature concentrates on the seemingly endless struggle between various philosophical positions in medicine (e.g. theory versus empiricism), a different approach is opted for here, since evidence-based medicine – as argued in the first chapter – may be placed against the historical background of a process of objectification and quantification in medicine which already began in the nineteenth century. This will be theoretically supported by the works of Porter and many others on objectification, quantification and the 'probability revolution', the writings of Rosenberg on the 'specificity revolution' and the studies of Gieryn on the boundaries of science. At the end of chapter 1, the general outlines of the way in which EBM could be interpreted historically will thus become apparent. Chapter 2 will subsequently focus on the advent of 'the statistical era' in medicine in the latter half of the twentieth century, with reference to the developments in the epidemiology chronic diseases and the rise of the RCT. Thus, an important 'link' in the (prior) history of evidence-based medicine is discussed, as EBM is a manifestation of a highly *specific* form of objectification and quantification, namely the increasing impact of probabilistic, statistical-epidemiological reasoning in medicine. Thus, chapter 2 forms the connection between chapter 1 and chapter 3, which contains a great deal of (descriptive) information on the rise and the development of clinical epidemiology initially, and EBM subsequently. At the end of chapter 3, the (international) history of EBM will be outlined in broad terms and in rough features. In addition, a first attempt will be made here to indicate what is actually new or distinctive about evidence-based medicine.

In order to obtain a truly historical view of this phenomenon – and of the validity of the interpretation derived from Porter, of EBM as a mechanism of control – the 'Netherlands case' will be elaborated in parts II and III. The second part of the book will focus

on the statistical-epidemiological 'evidence base' of EBM. Much of this 'evidence base' is provided by clinical epidemiology. The remarkable rise of this discipline in the Netherlands will be studied in the context of international and national developments in medical (and especially clinical) research since the 1970s, such as the transformation from 'little science' into 'big science', the ever increasing pressure on researchers to 'publish' in order not to 'perish', the specific Dutch science policies, and the resulting profound changes in Dutch academic medical research. In addition, the role of specific individuals (e.g. 'therapeutic reformers') and local circumstances will be addressed. Chapter 4 will discuss developments in general or 'population' epidemiology in the Netherlands, which preceded and in part paved the way for the subsequent success of clinical epidemiology in this country. Chapter 5 analyses the metamorphosis of patient-related research in the Netherlands in the 1980s, in which clinical epidemiology played a pivotal role. In chapter 6, the emergence and evolution of four specific academic departments of clinical epidemiology in the Netherlands will be described, in order to be able to identify relevant 'success factors' at the personal, local, national and international levels.

In the third part of the book, the emphasis will shift from the production of medical evidence to the application of the evidence both in medical practice and healthcare policy. In this part, in particular, the Porter thesis (mentioned above) – and also the ideas of Freidson and other social scientists on (de-/re-)professionalisation and 'professional logic' – will be confronted with the specific findings on events in the Netherlands. The hypothesis that EBM emerged as a professional response to internal and external pressures, and that it can consequently be regarded as a mechanism of control, will be tested via a detailed historical description and analysis of how and why EBM was introduced in the Netherlands. In chapter 7, the historical background of the 1970s and 1980s will be outlined first. Both the pressures on medicine and on the medical profession as well as the way in which physicians and medical associations handled this will be addressed here. In chapter 8, it will subsequently be examined how, in the course of the 1990s, evidence-based medicine made a very rapid advance in the Netherlands. This is related to a number of developments in healthcare policy in the Netherlands, and in particular to the role of the Minister of Health between 1994 and 2002, Els Borst-Eilers. Under her direction, the emphasis in healthcare policy shifted from choices at the macro-level towards the stimulation of efficiency at the micro-level (with the development and implementation of evidence-based guidelines as key instrument). The question will be raised here as to what extent this policy was an admission of weakness or, in fact, wise and visionary. In chapter 9, there will be a tentative attempt to offer insight into the significance and impact of evidence-based medicine in the Netherlands. The focus here will mainly be on (the lack of) implementation of evidence-based clinical guidelines and the effects of this for, among others, the clinical autonomy of physicians. In addition, the current debate on the main opportunities and threats for EBM in the 21st century will be mapped out.

In particular, the findings from this third part, but also those of the other two parts, will provide many new insights into the value of the notions derived from Porter about EBM as a professional response to external pressure, as an example of the shift from disciplinary to mechanical objectivity and as a mechanism of control. In the 'overall conclusion', it will be outlined to what extent these notions can be sustained and to what extent they should be adapted or complemented. This will result in an argument about the way in which Marks's concept of 'therapeutic reformers' constitutes a sensible amendment to the Porter thesis in the interpretation of evidence-based medicine. It will also be explained here why, in the title of this dissertation, EBM is typified with a pun as 'A Doctor's Order'.

Sources, Working Method and Scope

As the above description of the structure of this dissertation has already implicitly revealed, the selected working methods may be typified as those of a historian who emphatically wishes to stick to his trade. This means that EBM will mainly be *historicised* and *contextualised* here. The focus will be on the relationship between relevant continuities and changes over a longer period of time, with the emphasis being on the *societal dimension* of the developments described. For example, the rise of clinical epidemiology is placed in the context of changes in the academic research climate, and that of EBM in the context of the need for medical and non-medical parties to get some sort of grip on the rapid developments in medicine and healthcare. As a result, the focus will be on issues such as the significance of the evidence-based 'era' for the professional autonomy and (thus) the social position of physicians.

This immediately identifies a number of important constraints within this study. Philosophical, epistemological and methodological aspects will only be discussed in passing. The content of (evidence-based) medical practice as such will not be discussed in detail either, and certainly not in the way a practising medical professional would be able to do this. Nor will this study offer many insights into the attitudes, behaviours and practices of physicians, for example, with regard to the implementation of evidence-based clinical guidelines, insofar as social scientists and implementation researchers are able to do this. Nor does this dissertation contain 'hard evidence' with respect to the (lack of) effectiveness or impact of evidence-based medicine – this is best left to experts in the field of intervention and evaluation research.

Not only the substantive choices made, but also the methods used, are those of a historian. In order to be able to historicise and contextualise a broad and elusive phenomenon such as EBM, a rather extensive source and literature study was carried out to start with. Only on the basis of such a study will it be possible to make connections and switch between local, national and international levels and developments in diverse areas. The

set of tools of the ‘craft of history’ were implicitly or explicitly used here, which includes, among others, source criticism and (double) hermeneutics.⁶⁹ Another important aspect of this ‘craft’ is being receptive to assessment and criticism and entering into a historical debate. Partly for this reason, this dissertation contains a wide-ranging series of notes and an extensive bibliography.

Part I of this dissertation is almost entirely based on a study of secondary literature. It should be considered an attempted synthesis of the existing literature, which introduces the ‘case study’ of clinical epidemiology and EBM in the Netherlands in parts II and III, placing it in an international perspective. Besides secondary literature, primary sources and writings were actually studied for this Dutch ‘case study’. For part II, which focuses on the rise and development of (clinical) epidemiology as a *scientific* discipline in the Netherlands, in particular, sources and literature on developments in medical research and the scientific climate in the Netherlands were sought, including government policy memorandums, reports by advisory bodies such as the Advisory Council for Scientific Policy (Dutch abbreviation: RAWB) and the Royal Netherlands Academy for Arts and Sciences (Dutch abbreviation: KNAW), the most important general medical-scientific journal in the Netherlands, *Nederlands Tijdschrift voor Geneeskunde* (‘Dutch Journal for Medicine’), inaugural lectures, data on publications and achievements by (medical) scientists in the Netherlands and all manner of relevant publications in the field of the history and sociology of science.

It was possible to effectively map out the general developments in the field of (academic) science in the Netherlands this way, but sources specifically about the rise of epidemiology and clinical epidemiology in the Netherlands were lacking, except for several commemorative publications by involved (clinical) epidemiologists themselves. Partly for this reason, several interviews were conducted with people who, according to insiders, (to a greater or lesser extent) stood at the cradle of the striking ‘success’, from an international perspective, of clinical epidemiology in the Netherlands (see the bibliography for more data on the interviews). When the interviews were conducted, no attempt was made to be exhaustive, not least due to the very time-consuming nature of conducting, processing and using interviews in historical research. The group of people interviewed was established rather arbitrarily, mainly on the basis of (quick) availability and willingness to be interviewed. In no way do the interviews purport to provide ‘hard evidence’, let alone quantitative givens with some degree of statistical power. A great deal has been

69. ‘Hermeneutics’ (in the field of history) refers to the interpretation or ‘understanding’ of (the meaning of) textual sources – as opposed to the ‘explaining’ of phenomena by/in the natural sciences. Because textual sources are the products of interpreting minds too, hermeneutics ‘doubles upon itself’. Hence the need for (or the problem of) ‘double hermeneutics’ – ‘the interpretation of that which has always already been interpreted’. See on this: P. Gardner, *Hermeneutics, History and Memory* (London: Routledge, 2010), pp. 26-7.

written about the fallibility of memory precisely with regard to the reconstruction of events from the past.⁷⁰

Yet the interviews proved useful in several respects. First of all, they mainly had an exploratory function. They were very consciously conducted in an early stage of this research project, with the aim of finding out the relevant questions, issues and entries for further research. In many cases, this allowed for a targeted search for written sources or literature, on the basis of which substantiated statements could actually be made. Secondly, the interviews offered an insight into the personal motives and drives of prominent representatives of the Dutch 'clinical epidemiology and EBM movement'. Without thereby claiming that the personal motives and drives of the respondents were representative of the entire 'movement' in the Netherlands, this produced interesting angles with a view to a hermeneutic, *interpretative* approach (not just from 'the outside, but also from the 'inside') to the history of EBM in the Netherlands. Following on from this, in the third place, the interviews sometimes offered fascinating 'glimpses behind the scenes', which were not possible in any other way, and did offer new insights. It concerns matters here that, by definition, cannot be retrieved from written sources, yet it was regularly possible to verify them by asking other involved people about them. Only in the event of such a confirmation from several sources, were these 'glimpses behind the scenes' used. The interviews were thus able to contribute to a proper balance between attention to general, structural factors on the one hand, and local, contingent and personal factors on the other hand.

For part III too, the interviews were used in a similar way, albeit to a lesser extent than in part II. In addition, a detailed study was carried out into sources and literature in the area of healthcare policy and in the field of the production and implementation of evidence-based clinical practice guidelines. As it was impossible to identify the developments in the field of EBM with regard to all medical disciplines, sources and literature on the standards of the Dutch College of General Practitioners (Dutch abbreviation: NHG) were studied above all, because the so-called 'NHG-standards' have gained international renown and are considered to be the ultimate in the field of evidence-based medicine in the Netherlands. In addition, in a more impressionistic manner, possible significant developments in the field of guidelines for medical specialists were considered, with particular attention being paid to cardiology and psychiatry (in part because quite a good deal of information was available on this) and to the role of the quality institute best known under the acronym 'CBO'.

70. See for example the introduction in: N. Adler & S. Leydesdorff (eds.), *Tapestry of Memory: Evidence and Testimony in Life-Story Narratives* (New Brunswick, NJ: Transaction, 2013). See for more extensive reflections on the value, methodology and problems of oral history: S. Leydesdorff, *De Mensen en de Woorden: Geschiedenis op Basis van Verhalen* (Amsterdam: Meulenhoff, 2004).

However, the main source for part III is the journal *Medisch Contact* ('Medical Contact'). As the official publication of the the Royal Dutch Medical Association (Dutch abbreviation: KNMG), this weekly journal may be regarded as the 'barometer of the medical profession in the Netherlands'. Several studies have shown that *Medisch Contact* is well read by the vast majority of Dutch physicians.⁷¹ As such, the journal offers an ideal gateway for further analysis of the themes of the third part, which focuses on the societal position of the medical profession rather than on, for example, scientific developments. All of the approximately 2,300 editions of *Medisch Contact* between 1970 and 2014 have been integrally and chronologically studied in order to obtain a clearer view of relevant continuities and changes. In addition, in order to be able to verify and supplement the findings from *Medisch Contact*, all manner of source material was used, including other journals, reports from (government) agencies, interviews, inaugural lectures, and secondary literature.

In studying *Medisch Contact*, a conscious choice was made *not* to use encoding and quantitative analysis, as the added value of such a highly time-consuming analysis was assessed as being very limited, partly because the underlying research questions were mainly qualitative and exploratory in nature. Moreover, the main objective of the 'traditional', 'analogue', integral and chronological study of successive volumes of *Medisch Contact* was to gain a 'feel' for both the relevant debates conducted over the course of time by the medical profession and the *context* in which these debates took place. In other words, the approach was above all interpretative and hermeneutic, not quantitatively analytical.

In this respect, this part of the research was a conscious counterbalance to the era of 'digital history'. First of all, it should be underlined how propitious it is that, thanks to digitalisation and digital tools, an enormous amount of data has become available and accessible to historians, which would otherwise not have been within reach – and certainly not as easy to search and analyse. Without digitalisation and digital tools, it would be impossible to even remotely cope with the 'information avalanche' with which everyone who pursues contemporary (medical) history is confronted. This is why also in this study – except during the evaluation of *Medisch Contact* – the possibilities of online information gathering and processing were used frequently. At the same time, it is important that historians remain aware of the potential pitfalls of this.

In a recent special edition of *BMGN – Low Countries Historical Review* on 'digital history', the necessity of more reflection on both the fantastic opportunities and the possible

71. This was confirmed several times over the years by surveys that were carried out among the readership. See for example: B. V. M. Crul, 'Lezersonderzoek 2005', *Medisch Contact* 60: 34 (2005), p. 1335; J. Visser, 'Huisartsen Prefereren Medisch Contact', *Medisch Contact* 58: 34 (2003), p. 1249; M. van der Velde, 'Een Steun in de Rug: Lezersonderzoek 2000', *Medisch Contact* 55: 17 (2000), pp. 623-44; M. C. A. van Wandelen, 'Lezers over Medisch Contact', *Medisch Contact* 42: 36 (1987), pp. 1131-2. See also a special issue from 1982 which was devoted on (the history of) the journal itself: *Medisch Contact* 37: 35 (1982).

dangers of the digital era was addressed.⁷² An important subject in this special edition is source *selection*, for example. When historians limit themselves to source material that is digitally available and easily searchable and analysable, the historical research is ‘steered’ by (the interests of) those who decide what is worth being digitalised and in what manner this occurs. Another important observation is that when, for example, journal articles or archival documents are only studied digitally in PDF format, historians lose the *materiality* of these sources. As a result of this, valuable knowledge may be lost and the imagination of historians, which is so important to historical interpretations, is also stirred a great deal less than when they hold and see the actual source material. Moreover, a great deal of *context* is lost, for example, when studying journal articles in PDF format which are retrieved digitally with the help of search terms. For the historical interpretation of articles sought and retrieved in a targeted manner, it may, for example, be of great importance to see what other articles were listed ‘around’ them. In the case of the study of successive editions of *Medisch Contact*, for example, an impression or feeling developed for what was going on within the medical profession – besides the specific debates that were relevant to the (prior) history of EBM. This made it possible to assess the relative weight or importance of these specific debates, and to place them in a broader context alongside other or more general trends within the medical profession. In this respect, in addition to the many articles from *Medisch Contact* referred to in the notes and bibliography in this book, countless other articles and also letters to the editor *not* referred to, have nevertheless contributed to the present research.

The typically historical working method of this dissertation is also reflected in the highly heuristic and pragmatic handling of notions, terms and concepts. For a number of reasons, a choice was made not to define very precisely terms such as ‘discipline’, ‘statistics’, ‘numerical methods’, ‘guidelines’ and ‘EBM movement’ and also, for example, not to indicate very specifically the boundaries between statistics and epidemiology or between guidelines, standards and protocols. In the first place, said terms are often simply used in their ‘common sense’ meaning in everyday (non-scientific) usage. When, for example, there is mention of the academic establishment of clinical epidemiology as a ‘discipline’, there is not an underlying highly fundamental vision on or theory of disciplines and ‘discipline formation.’⁷³ It is no more and no less about the ‘common sense’ fact that clinical

72. The reflections below are above all derived from the introductory article of this special edition: G. Zaagsma, ‘On Digital History’, *BMGN – Low Countries Historical Review* 128: 4 (2013), pp. 3-29.

73. In recent years, various scholars of the Descartes Centre for the History and Philosophy of the Sciences and Humanities, to which TB is also affiliated, have focused explicitly on the subject of scientific disciplines and discipline formation. This has produced all manner of insights into the historicity, the variability and the non-essentialist character of disciplines and into the limited value of definitions and theories of discipline formation. This has contributed to the decision in this dissertation to describe the academic establishment in the Netherlands in an empirical, pragmatic and ‘common sense’ manner, without ex-

epidemiology began to show characteristics of an academic discipline, because chairs, departments, textbooks, journals, courses and conferences on ‘clinical epidemiology’ emerged and because (to a certain extent) a community of professionals was formed who consider themselves, and are considered by others, to be clinical epidemiologists.

Secondly, the rather ‘loose’ usage of definitions and notions in this dissertation is prompted in part by the manner in which they are used by most historical actors themselves. In general, the principal protagonists in this book are not overly concerned either with the careful and precise description of what they mean by, for example, evidence-based medicine or evidence-based clinical guidelines. Added to this, involved parties sometimes stress very diverse aspects or even hold widely different views. This is why the decision was sometimes deliberately made to leave open to some extent, for example, the question of the difference between a guideline and a protocol, of when exactly a guideline is ‘evidence-based’ and when it is not, and whether, for example, EBM and the Cochrane Collaboration should be regarded as one broad movement, or as two distinctly different initiatives. By not opting for highly specific descriptions and demarcations, but for a somewhat ‘loose’ handling of terms and notions, it is possible to describe and interpret the phenomenon of EBM in the broadest sense, with its many different facets and aspects, as well as its internal tensions and contradictions. To a certain extent, the same applies to notions such as (clinical) epidemiology, statistics, numerical methods, et cetera.

Thirdly, it is customary to present and formulate historical findings and interpretations into a *narrative structure*. It is annoying when the historical narrative is repeatedly interrupted by definitions. In addition, the point is usually not to clarify the significance of the phenomena described by means of a definition, but in terms of (and in the course of) the narrative. This has everything to do with the *time perspective* that, as a rule, occupies an important place in historical stories.

Fourthly, it should also be mentioned here that many matters discussed in this book – and consequently their boundaries as well – have been continually subject to change over the course of time. This applies, for example, to notions such as ‘statistics’ and ‘numerical methods’ and the demarcation thereof with ‘epidemiology’. This moreover applies to the phenomenon of EBM itself too. Partly for this reason, perhaps the main objective of this dissertation is to provide an answer, via the route of the historical narrative and the

plicit references to diverging visions on or theories of disciplines and discipline formation. See for more on this: a special edition of the journal *Studium* on ‘discipline formation’ in the history of the sciences and humanities, with the following contributions: E. Jonker, ‘Van Relativisme naar Oordeelsvorming. Recente Tendensen in de Wetenschapsgeschiedschrijving’ *Studium* 4: 1 (2011), pp. 2-15; D. Wegener, ‘Wetenschapsgeschiedenis op Lange termijn. Flexibiliteit en Fragiliteit van Disciplines’, *Studium* 4: 1 (2011), pp. 16-30; G. J. Johannes, “Nationale Filologieën” en het Historische Onderzoek naar Disciplinenvorming in de Geesteswetenschappen. Een verkenning’, *Studium* 4: 1 (2011), pp. 31-46.

continuities and changes over the course of time described in it, to the question: What is EBM actually, and what is the (historical) significance of this phenomenon?

At the same time, it should be admitted that only a tentative and moreover very incomplete answer may be given to this question. This dissertation restricts itself mainly to several conspicuous aspects of EBM. In part I, above all, the increasing impact of statistical-epidemiological knowledge in medicine is thematised, which is further developed in part II on the basis of a description and analysis of the rise of clinical epidemiology in the Netherlands. In part III, the discussion of the EBM era in the Netherlands remains largely limited to the rise and impact of evidence-based *guidelines* in the context of the national healthcare policy – where the focus is also mainly concentrated on the guidelines for GPs. This is because, in the opinion of many, guidelines have become the main specific manifestation of EBM and, moreover, form a suitable first step to study the subject of EBM as mechanism of control as well as its consequences for the professional autonomy of physicians.

It is also important to mention that no attempt was made to be exhaustive in the case of, for example, listing all the persons and bodies that played an important role in the history of clinical epidemiology and/or evidence-based medicine in the Netherlands. This is not only to do with the practical necessity of demarcation and limitation. Providing an exhaustive overview was never the aim of this study, partly because such a pursuit of exhaustiveness soon leads to a listing of names, facts and events which is not pleasant to read and, except for among a number of insiders, is of little interest. Instead, the aim was to arrive at a useful historical interpretation and explanation of the phenomenon of EBM in the light of, in particular, Porter's work and that of Marks. In order to be able to arrive at this interpretation and explanation, a choice was made to develop the 'Netherlands case' on the basis of several specific stories about particular persons, situations or developments. The consequence of this is that some 'therapeutic reformers', including Borst-Eilers, Andries Querido and Niek Urbanus, receive a great deal of attention, while others who are possibly as much 'entitled' to be discussed at great length, are not, or are barely, dealt with.⁷⁴ Similarly, some sections of medicine, some facets of evidence-based practice and some parts of healthcare policy are discussed, while this is not the case, or a great deal less so, for other sections, facets and parts, which are possibly (at least) as relevant.

74. This applies, for example, to Marc Keirse, who, as a Dutchman, was an important figure in the genesis of the Cochrane Collaboration. Partly because this dissertation focuses less on the 'systematic review movement' than on the 'guideline movement', Keirse's role is not discussed here. Something similar also applies to Henk Visser, for example, who, as dean of the medical faculty in Rotterdam, allegedly played a role similar to that of Niek Urbanus as chairman of the Board of Directors and dean of the AMC in Amsterdam (see chapter 6). Yet this dissertation does extensively discuss the role of Urbanus but not that of Visser.

Another significant limitation is that no comparative analysis has been made, in which the rise and reception history of EBM in the Netherlands was compared to that in other countries. Within the time frame of this research, it proved impossible to launch a 'comparative project' in co-operation with foreign partners, in part because conducting proper comparative research is extraordinarily complicated and time-consuming. In this respect, the Dutch case study – which, incidentally, is explicitly placed in an international perspective and moreover in an internationally relevant theoretical framework in this dissertation – may be regarded as an invitation for other historians to also delve more deeply into the phenomenon of evidence-based medicine, as it materialised in various countries.

Put differently, the aim of this dissertation is by no means to have said the last word on EBM, but rather to open or further stimulate historical debate on it. Of course, several historians and social scientists have already published on subjects such as objectification and quantification, the rise of the Randomised Controlled Trial, the medical profession, healthcare policies and evidence-based medicine.⁷⁵ However, not one of the (still highly valuable) publications by these scholars contains an extensive historical account of the *phenomenon of evidence-based medicine*. The only extensive⁷⁶ studies specifically on EBM are written by sociologists,⁷⁷ who naturally ask sociological rather than historical questions. The historical works on the rise of quantification in medicine (as many books on the history of statistics and 'probabilism' in general) focus on developments in the nineteenth and early twentieth century, and do not, or only very briefly, address events in the second half of the twentieth century, and the phenomenon of EBM that emerged in that period.⁷⁸ The works of Porter and of Galison and Daston on objectivity are very influen-

75. See a.o.: J. Daly, *Evidence-Based Medicine and the Search for a Science of Clinical Care* (Berkeley/Los Angeles/London: University of California Press, 2005); G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005); E. Magnello & A. Hardy (eds.), *The Road to Medical Statistics* (Amsterdam/New York: Rodopi, 2002); Marks, *Progress of Experiment*; J. R. Matthews, *Quantification and the Quest for Medical Certainty* (Princeton, New Jersey: Princeton University Press, 1995); Porter, *Trust in Numbers*; S. Timmermans & M. Berg, *The Gold Standard. The Challenge of Evidence-Based Medicine and Standardization in Health Care* (Philadelphia: Temple University Press, 2003).

76. Usually the medical literature on the history of EBM is limited to very brief histories, which focus on the role of individual pioneers or address mainly methodological developments and issues. While a lot of this literature is valuable indeed, the aims and approaches are highly different from those of professional historians – who are, amongst others, far more interested in *context*. See for examples of the medical literature on the history of EBM: the contributions to the James Lind Library (<http://www.jameslindlibrary.org>) and the 'oral history of EBM' on the website of the Journal of the American Medical Association (<http://ebm.jamanetwork.com>).

77. In particular Daly and Timmermans & Berg (see n.75 above).

78. This applies to, a.o. the works (edited) by Jorland, Opinel & Weisz, Matthews, Magnello & Hardy, Matthews, and Porter, as well as to the articles and PhD thesis that are available at the James Lind Library. See n. 75 and n. 76 above.

tial, but discuss developments in healthcare and medicine only to a very limited extent. The scope of Marks's book is limited to the rise of one research method – the Randomised Controlled Trial – in the United States.

All this underlines the earlier comment that, out of necessity, this dissertation is, above all, probing in nature, partly because the field of contemporary medical history is still unexplored territory in many respects. It is only attempted here to open a window that offers an interesting view of, and food for thought about, the 'paradox of modern medicine'. Hopefully, many more of such 'windows' will be opened in the years to come.⁷⁹

79. For example, by my colleagues from the Utrecht/Maastricht research programme *Medicine in Transition*, Noortje Jacobs, Roland Bertens and Floor Haalboom, who, in the coming years, will open the 'windows' of medical research ethics, health law and (the prevention of the pandemic outbreak of) zoonoses, respectively.



Part I.

**Evidence-Based Medicine in
International and Historical
Perspective**



Chapter 1.

Evidence-Based Medicine and the Search for Certainty in the History of Medicine

At first glance, evidence-based medicine (EBM) has a remarkably short history. Less than 25 years ago, in 1992, the concept was internationally launched in an article in the *Journal of the American Medical Association* (JAMA), entitled ‘Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine’.¹ After that, it went incredibly quickly: within several years, EBM was omnipresent in health care throughout the world.

This momentous JAMA article was written by the ‘EBM working group’, consisting of a number of people – with David Sackett as undisputed leader – from the clinical epidemiology and biostatistics department of McMaster University in Hamilton, Canada. The authors presented evidence-based medicine as being no less than a new paradigm for medical education and clinical practice. Whether or not this claim is justified is highly debatable; in the literature there is major disagreement about this. It is beyond dispute, however, that the group at McMaster and many of its supporters were (and are) *convinced* of the paradigmatic significance of evidence-based medicine.²

That the concept ‘paradigm’ is frequently used nowadays, whether appropriately or not, is due to the influential work of the philosopher of science Thomas Kuhn. In his famous book *The Structure of Scientific Revolutions*, which will not be further discussed here, Kuhn establishes an interesting link between ‘scientific revolutions’ and dealings with history. He argues that, after a so-called paradigm shift, the history of the relevant branch of science is rewritten from the perspective of the new paradigm. The resulting new vision of the past, present and future of the scientific discipline(s) involved is subsequently recorded in the secondary literature. Kuhn emphasises the educational role of

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1. Evidence-Based Medicine Working Group, ‘Evidence-Based Medicine’.
 2. See a.o.: A. M. Cohen, P. Z. Stavri & W. R. Hersh, ‘A Categorization and Analysis of the Criticisms of Evidence-Based Medicine’, *International Journal of Medical Informatics* 73 (2004), pp. 35–43; R. B. Darlenski et al., ‘Evidence-Based Medicine: Facts and Controversies’, *Clinics in Dermatology* 28 (2010), pp. 553–7; J. Howick, *The Philosophy of Evidence-Based Medicine* (Oxford: Wiley-Blackwell, 2011), pp. 10–11; Sehon & Stanley, ‘A Philosophical Analysis’.

text books in particular: according to him, they serve as ‘pedagogic tools’ used to socialise new scientists within the dominant (or, after a scientific revolution: the new) paradigm.³

The phenomenon of the rewriting and selective use of history is also visible within the EBM movement and clinical epidemiology – the relatively young discipline from which evidence-based medicine originated. Clinical epidemiologists and proponents of EBM regularly demonstrate a propensity to discern historic ‘precursors’ in the sometimes distant past. Entirely in line with Kuhn’s argument about the ‘pedagogic’ use of history, this manifests itself most strongly in the context of education: in inaugural speeches, lectures to medical students and refresher courses for medical practitioners.⁴ This is illustrated by the report from a British physician from a workshop about evidence-based medicine in Oxford, which was supervised by David Sackett himself. This physician described how he and other participants were divided into small groups, with each group being named after an illustrious physician from history. He himself was placed in the ‘Pierre Louis group’.⁵

That the name of Pierre Louis (1787-1872) surfaced is not surprising. He is mentioned by clinical epidemiologists and EBM proponents as an important precursor like no other. With his ‘numerical method’, he is purported to have laid the philosophical and methodological foundations for both clinical epidemiology and EBM.⁶ An article about

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3. T. S. Kuhn, *The Structure of Scientific Revolutions* (Chicago: Chicago University Press, 1964), in particular pp. 136-44. See also Susser’s observation that, after ‘paradigm shifts’ within epidemiology, different historical examples were used in the teaching and text books of epidemiology than before: M. Susser, ‘Epidemiology in the United States After World War II: The Evolution of “Technique”’, *Epidemiologic Reviews* 7 (1985), pp. 147-77, on pp. 150-1.
 4. This corresponds with the author’s own experience with various courses of the master program Epidemiology of University Medical Centre Utrecht and with the summer course ‘History and Philosophy of Evidence-Based Health Care’ that was organized in July 2012 in Oxford by the Centre for Evidence-Based Medicine at Oxford University (TB has got the powerpoint presentations of and other information on these courses). See also the following inaugural lectures: E. Borst-Eilers, *Geneeskunde op Recept?* (Amsterdam: Universiteit van Amsterdam, 1993); Bossuyt, *Idolen van Kieslowski*; M. Offringa, *Met en Wegen. Klinische Epidemiologie in de Kindergeneeskunde* (Amsterdam: Vossiuspers UvA, 2002); J. P. Vandenbroucke, *Klinische Epidemiologie en de Geest der Hygiënisten* (Utrecht: Bunge, 1987). See also many contributions to the James Lind Library on: <http://www.jameslindlibrary.org>
 5. M. Crilly, ‘Evidence Based Bloodletting’, *British Medical Journal* 322 (2001), p. 854.
 6. Bossuyt & Offringa, ‘Wortels van Evidence Based Medicine’; A. R. Feinstein, *Clinical Epidemiology. The Architecture of Clinical Research* (Philadelphia: W. B. Saunders, 1985), p. 5; A. R. Feinstein, ‘Two Centuries of Conflict-Collaboration between Medicine and Mathematics’, *Journal of Clinical Epidemiology* 49 (1996), pp. 1339-43; J. van Gijn, ‘De Macht van het Getal’, *Nederlands Tijdschrift voor Geneeskunde* 144 (2000), pp. 1-3; A. Hofman, D. E. Grobbee & J. Lubsen, *Klinische Epidemiologie* (Utrecht: Bunge, 1996), p. 2; A. Morabia, ‘P. C. A. Louis and the Birth of Clinical Epidemiology’, *Journal of Clinical Epidemiology* 49 (1996), pp. 1327-33; J. P. Vandenbroucke, ‘De Vele Gezichten van de Epidemiologie’, *Nederlands Tijdschrift voor Geneeskunde* 141 (1997), pp. 182-4; J. Vandenbroucke, ‘De Opkomst van de Medische Statistiek en Epidemiologie in het Klinisch Wetenschappelijk Onderzoek van de Afgelopen Eeuw’, *Nederlands Tijdschrift voor Geneeskunde* 143 (1999), pp. 2625-8; J. P. Vandenbroucke, ‘Evidence-Based Medicine and “Médecine d’Observation”’, *Journal of Clinical Epidemiology* 49 (1996), pp. 1335-8.

Louis in the *Journal of Clinical Epidemiology* ended with the conclusion: ‘It is reasonable to say that the scientific work of Louis has given birth to a new scientific discipline that today is referred to as clinical epidemiology.’⁷ Elsewhere, the French physician is explicitly typified as ‘father of evidence-based medicine.’⁸ Interestingly, not only is the parallel with Louis drawn by clinical epidemiologists and advocates of evidence-based medicine, but also by critics. While the former seek to obtain a certain historical legitimacy for themselves,⁹ their opponents believe they can prove the lack of originality of EBM. An example is an article entitled ‘Evidence-Based Medicine: Old French Wine with a New Canadian Label?’¹⁰

Professional historians are generally reluctant to draw such one-to-one comparisons between past and present. Nevertheless, several of them have seen enough cause to take a closer look at the numerical method of Louis and nineteenth century debates about it, precisely in the light of the recent emergence of evidence-based medicine.¹¹ As a result, there are quite a few publications about Louis, written from various angles. Together, these publications form a suitable starting point for an exploration of the place of EBM in the long history of the search for certainty in medicine.

In this chapter, a *historiographical* perspective will initially be used for this. First, it will be examined how and why Louis acquired the role of historical hero within the EBM movement. This primarily entails a discussion of medical sources and literature. Subsequently, the attention shifts to the professional historical and philosophical literature. There Louis and his opponents feature as symbols of different philosophical positions in medicine that are supposed to have been in conflict with each other since ancient times. From this some scholars deduce that the rise of evidence-based medicine too was just another episode in this ‘eternal debate’. The goal of these historiographical digressions is to show that neither the glorification of Louis (in medical literature) nor the image (in historical and philosophical literature) of a permanent struggle between competing philosophical positions provide a satisfactory historical understanding of the phenomenon of EBM.

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7. Morabia, ‘P. C. A. Louis’, p. 1333. See also: A. Morabia, ‘In Defense of Pierre Louis Who Pioneered the Epidemiological Approach to Medicine’, *Journal of Clinical Epidemiology* 62 (2009), pp. 1-4.
 8. R. Moorhead, ‘William Budd and Typhoid Fever’, *Journal of the Royal Society of Medicine* 95 (2002), pp. 561-4, on p. 561.
 9. See for example the highly influential *BMJ*-article by Sackett et al. from 1996, entitled ‘Evidence Based Medicine: What it Is and What it Isn’t’, in which they responded to some of their critics. The first sentence of the article was: ‘Evidence-based medicine, whose philosophical origins extend back to mid-19th century Paris and earlier [...]’. See: Sackett et al., ‘Evidence Based Medicine: What it Is and what it Isn’t’.
 10. P. K. Rangachari, ‘Evidence-Based Medicine: Old French Wine with a New Canadian Label?’, *Journal of the Royal Society of Medicine* 90 (1997), pp. 280-4. See also: Weisz, ‘From Clinical Counting’, p. 377.
 11. La Berge, ‘Medical Statistics’, pp. 89-108; Matthews, *Quantification*; G. Weisz, *The Medical Mandarins. The French Academy of Medicine in the Nineteenth and Early Twentieth Centuries* (New York/Oxford: Oxford University Press, 1995), pp. 159-88; Idem, ‘From Clinical Counting’, p. 377.

Therefore, in the second part of this chapter, a different *historical* perspective will be introduced. In short, both Louis' numerical method and evidence-based medicine will be placed against the historical background of an ongoing process of objectification and quantification in medicine. First, the narrative will shift from the *theoretical* and philosophical discussions on the fundamentals of medicine to the *practice* of medicine, in particular in hospitals. It will be argued that numbers and numerical methods – contrary to what is often supposed and despite a relatively low epistemological status – began to play an increasingly important role in hospitals in the nineteenth century. Next, the significance and impact of this development will be further explained by discussing the literature on the 'probabilistic revolution', the broader context of 'modernisation', and the work of medical historian Charles Rosenberg on the 'specificity revolution' in medicine and healthcare. This is followed, in the conclusion of this chapter, by a summarising outline of how the emergence of EBM may be placed in the longer-term perspective of the objectification, quantification and specificity revolution in medicine over the past two hundred years.

Pierre Louis as Part of the EBM Rhetoric

Louis was by no means the first to urge the necessity of careful observation and quantification in medicine. According to (clinical) epidemiologists, there were already 'precursors' in antiquity. Inevitably, Hippocrates is mentioned here,¹² but also, for example, Alexander of Aphrodisias, from the second century BC.¹³ In this bigger picture, Louis is not immediately a striking or original figure. Nor was it exceptional that his numerical method was not only empirical but also 'quantifying'. The eighteenth century 'British empiricists' and his slightly older fellow countryman Pinel, the famous reformer of psychiatry, among others, had already applied similar methods.¹⁴

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12. D. Cantor (ed.), *Reinventing Hippocrates* (Aldershot: Ashgate, 2002); Hofman, Grobbee & Lubsen, *Klinische Epidemiologie*, pp. 1-2; D. E. Lilienfeld & A. M. Lilienfeld, 'The French Influence on the Development of Epidemiology', in A. M. Lilienfeld (ed.), *Times, Places and Persons. Aspects of the History of Epidemiology* (Baltimore and London: Johns Hopkins University Press, 1980), pp. 28-38, on p. 28; H. A. Valkenburg & A. Hofman, *Een Kwart Eeuw Hippocratische Epidemiologie* (Utrecht: Bunge, 1995).
 13. K. Ierodiakonou & J. P. Vandenbroucke, 'Medicine as a Stochastic Art', *Lancet* 341 (1993), pp. 542-3; Vandenbroucke, 'Evidence-Based Medicine'. The different approaches of two very famous medical schools in classical antiquity, e.g. the schools of Knidos, could be mentioned here as well. See on that (a.o.): Mehmet Turgut, 'Ancient Medical Schools in Knidos and Kos', *Child's Nervous System* 27 (2011), pp. 197-200. However, Alfredo Morabia is of a different opinion and argues that the origins of epidemiology do not lie in classical antiquity but in the 17th century. See: A. Morabia, 'Epidemiology's 350th Anniversary: 1662-2012', *Epidemiology* 24 (2013), pp. 179-83.
 14. J. Cole, *The Power of Large Numbers: Population, Politics, and Gender in the Nineteenth-Century France* (New York: Cornell University Press, 2000), pp. 94-5; Matthews, *Quantification*, pp. 8-14; Rangachari, 'Evidence-Based Medicine', p. 283; U. Tröhler, "To Improve the Evidence of Medicine". *The 18th Century*

Like Pinel, Louis was an exponent of the so-called ‘Parisian clinical school’, which, in the first half of the nineteenth century, was internationally recognised as being the pinnacle of medicine. Within this ‘school’, there was resentment against theoretical ‘systems’. Instead, a strict empiricism was espoused. It was characteristic here for clinical observations in patients to be coupled to findings in autopsies. This happened systematically and on a large scale. Each of the various hospitals in Paris offered room to hundreds and sometimes thousands of patients, who were usually divided across the various departments in a very orderly way, on the basis of the (allegedly) affected organ. In addition, records were kept of numbers of births and deaths and of the occurrence of diseases and symptoms. Thus, in the French capital, all conditions were in place for the application of Louis’s numerical method: a strictly empiricist ‘culture’ of ‘unprejudiced’ observation, the opportunity to collect considerable numbers of observations in more or less homogeneous groups of patients, and familiarity with statistics.¹⁵

Louis managed to use these conditions in the best possible way. For seven years, he dedicated himself solely to the careful collection, registration and quantification of observations – both in the clinic and on the dissecting table – in the Hôpital de la Charité (Charity Hospital) in Paris. He subsequently published, among others, his famous work about the effectiveness of bloodletting in pneumonia. In it, he compared a group of 41 patients who had bloodletting administered to them shortly (within one to four days) after the first symptoms of pneumonia occurred, to a group of 36 patients who, only in a later stage of the condition, underwent this treatment. Here, he used two quantitative variables: duration of illness (in the ones who recovered) and number of deaths. His most important finding was that the patients undergoing ‘early treatment’, on the one hand, had a shorter average duration of illness – so recovered faster – yet, on the other hand, died more often. This led him to conclude that restraint had to be exercised with regard to bloodletting, but that this treatment was useful indeed in some cases. Thus, contrary to what is often claimed, Louis was not an outspoken opponent of bloodletting.¹⁶

It seems that, to Louis, the results of his research were less important than the method he wished to bring to the fore. In the second edition of his 1835 study on bloodletting, in particular, he discussed his ‘numerical method’ extensively. According to him, *only* with

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- British Origins of a Critical Approach*, electronic edn. (Edinburgh: Ulrich Tröhler and Royal College of Physicians of Edinburgh, 2012); Wiersma, *Twee Eeuwen*, p. 196; Weisz, ‘From Clinical Counting’, p. 378.
15. The classical historical work on the Parisian clinical school is: E. H. Ackerknecht, *Medicine at the Paris Hospital, 1794-1848* (Baltimore: Johns Hopkins Press, 1967). See for Louis’s place in this context pp. 9-10, 102-4, and: La Berge, ‘Medical Statistics’, pp. 89-108.
 16. P. Ch A. Louis, *Recherches sur les Effets de la Saigné dans Quelques Maladies Inflammatoires* (Paris: J.B. Baillière, 1835). See also the English translation from 1836: P. Ch A. Louis, *Researches on the Effects of Bloodletting in some Inflammatory Diseases, and on the Influence of Tartarized Antimony and Vesication in Pneumonitis* (Boston: Hilliard, Gray, and Company, 1836). See also: Matthews, *Quantification*, pp. 14-20; Morabia, ‘P. C. A. Louis’; Rangachari, ‘Evidence-Based Medicine’ pp. 280-4.

this method was it possible to make progress in the field of therapeutic knowledge. He was convinced that his ‘proposal’ would become common practice in the near future.¹⁷ He predicted:

‘[...] and then we shall hear no more of medical tact, of a kind of divining power of physicians. No treatise whatsoever will continue to be the sole development of an idea, or a romance; but an analysis of a more or less extensive series of exact, detailed facts; to the end that answers may be furnished to all possible questions: and then, and not till then, can therapeutics become a science.’¹⁸

This publication by Louis drew attention, partly because, in his time, there was a great deal of debate about bloodletting.¹⁹ However, it was mainly his plea for the numerical method that caused the greatest controversy. This was not because the method was new or innovative. This was not the case: in fact, all Louis did was compare groups of patients on the basis of ‘counted’ properties and means by clinical observation, as the eighteenth century British empiricists, among others, had already done.²⁰ Louis’ references to the probability theory, as developed, several decades before, by the mathematician Pierre-Simon Laplace (1749-1827) and others, were mainly a matter of rhetoric. Despite his claim of being ‘a master of the spirit of mathematical theory’,²¹ Louis demonstrated neither mathematical sophistication nor a real grasp of mathematical theory. Historian J. Rosser Matthews writes about this: ‘His numerical method reflected a concern more with the collection of empirical facts than with abstract theorizing.’²²

Nevertheless, Louis presented his method as the one and only scientific foundation for the medicine of the (near) future. He turned out to be a rather skilful propagandist in the process. Although he did not belong to the most prominent figures within Parisian medicine, he managed to promote his ‘programme’ with some degree of success. In addi-

17. See about Louis’s elaborations on his method: Louis, *Recherches*, pp. 70-87 (or pp. 55-70 in the English translation mentioned in n. 16 above, and see also the other references in that note).

18. This English translation is obtained from: Louis, *Researches*, p. 70. See for the original French formulation: Louis, *Recherches*, 86-7.

19. Ackerknecht, *Medicine at the Paris Hospital*, p. 75; Cole, *Power of Large Numbers*, pp. 96-7. Louis’ former teacher Broussais was a strong advocate for the drift of ‘excessive’ blood through bloodletting and/or leeches. For some time, the ‘doctrine of Broussais’ enjoyed great popularity. As a result tenth of millions of leeches were used by French physicians on a yearly basis. Critic spoke of ‘vampirism’. See (a.o.): R. G. W. Kirk & N. Pemberton, ‘Re-Imagining Bleeders: The Medical Leech in the Nineteenth Century Bloodletting Encounter’, *Medical History* 55 (2011), pp. 355-60.

20. Tröhler, “*To Improve the Evidence of Medicine*”.

21. Louis, *Researches*, p. 63. This is a quote from the English translation from 1836, the literal meaning of the original French text is that Louis claimed to have ‘unraveled the spirit of the science of numbers’. See: Louis, *Recherches*, p. 79.

22. Matthews, *Quantification*, pp. 19-20. See also n. 23 below.

tion to his publications, his role as a teacher in the French capital was important here. He acquired the support of a small but loyal circle of students. In order to promote the numerical method, some of these disciples founded the Société de Médecine d'Observation ('Medical Society for Observation') in Geneva. Louis himself subsequently became the lifelong president of this society.²³

The almost militant way in which Louis propagated his programme, aroused the resentment of Benigno Risueño d'Amador (1802-1849), professor of pathology and general therapy at the medical faculty of Montpellier. On 25 April 1837, Risueño d'Amador gave a lecture for the Académie de Médecine (Academy of Medicine) in Paris, in which he argued that the probability theory could not be applied in medicine. His main argument was that a physician deals with individual patients, and therefore was not helped greatly by knowledge of means and statistical patterns. Instead, a physician was to perform the *art* of medicine. Only then was a physician able to obtain an accurate and complete picture of the individual patient, and treat them in the appropriate manner.²⁴

This lecture ignited a now classic 'Academic Debate'. For several months on end, the members of the Academy were tangled up in sometimes very heated discussions on the subjects introduced by Risueño d'Amador. Louis himself also participated.²⁵

Louis owes his present fame primarily to this famous Academic Debate. Many see similarities with the current 'battle' over evidence-based medicine, which is also often about the tension between the science and the art of medicine, and about the (alleged) contrast between practising on the basis of statistical-epidemiological knowledge of groups on the one hand, and a focus on the individual on the other hand.²⁶

The statements on these issues by Sackett and other EBM-proponents are highly reminiscent of the defence Louis mounted against his critics almost two centuries ago. The Parisian physician argued that his method made explicit what practising physicians had been doing implicitly all along. According to him, a clinician's judgment about the applicability of a certain diagnosis or treatment strategy with a patient was arrived at by previous experiences with similar patients. In other words, Louis argued: 'he reasons as if he has counted, without really having done this'.²⁷ What the numerical method contributed

23. Lilienfeld & Lilienfeld, 'French Influence', pp. 30-7; Matthews, *Quantification*, pp. 14-38; Rangachari, 'Evidence-Based Medicine'; Weisz, *Medical Mandarins*, p. 164; Wiersma, *Twee Eeuwen*, p. 197.

24. B. J. I. Risueño d'Amador, *Mémoire sur le Calcul des Probabilités Appliqué à la Médecine* (Paris: J. B. Baillière, 1837).

25. Cole, *Power of Large Numbers*, pp. 96-103; La Berge, 'Medical statistics'; Matthews, *Quantification*, pp. 28-30; Weisz, *Medical mandarins*, 159-88.

26. See a.o.: Cohen, Stavri & Hersh, 'Categorization', pp. 35-43; Darlenski et al., 'Evidence-Based Medicine', pp. 553-7.

27. The original French text is: 'C'est-à-dire qu'il argumente comme s'il avait compté, sans l'avoir fait'. See: Louis, *Recherches*, p. 83.

was that counting really did occur or, put differently: that observations were collected systematically and processed quantitatively. As a result, clinical judgment by physicians did not essentially change in character, yet did become increasingly accurate and certain, Louis maintained. According to him, the crucial point was that physicians who did not ‘count’ failed to progress beyond vague and ultimately useless indications such as ‘more’, ‘less’, ‘rarely’ and ‘frequently’. Only when people ‘counted’ was the numerical precision possible, that was required to provide medical practice with a scientific foundation. According to him, this same numerical precision led to a situation where *individual* differences were also exposed and clarified with the help of the numerical method.²⁸

This line of reasoning can also be identified in various writings by the leading figures within the EBM movement. Sackett et al., for example, wrote in the preface to their textbook *Clinical epidemiology*:

‘The important acts we carry out as clinicians require the particularization, to the individual patient, of our prior experiences (both as individual clinicians and collectively) with groups of similar patients. Thus, the rational evaluation of a symptom, sign, or laboratory test result in today’s patient demands our critical appraisal of how this clinical finding has behaved previously among groups of patients with the same differential diagnosis. Similarly, the rational selection of a treatment for today’s patient requires our appraisal of how similar patients have fared with various treatments in the past.’²⁹

This way, both Louis and spokespersons of the EBM movement were able to defend the thesis that their ‘numerical’ approach was not at all contrary to, but rather in line with clinical expertise and focus on the individual patient. Louis did this by remaining at a distance from more mathematically-minded contemporaries, such as the Belgian statistician, Quetelet. He emphasised that his method was not intended to acquire knowledge of Quetelet’s notion of an imaginary ‘average man’, but rather as a tool for the practising clinician to arrive at a more reliable assessment of the diagnostics and treatment of individual patients.³⁰ Sackett and his followers, in turn, repeatedly stressed that evidence-based medicine is about the *integration* of clinical expertise, patient preferences and the best available scientific evidence. Exemplary in this respect is the statement: ‘external evidence can inform, but never replace, individual clinical expertise.’³¹

28. Ibid., pp. 82-6. See also: La Berge, ‘Medical Statistics’, pp. 96-7.

29. D. L. Sackett, R. B. Haynes & P. Tugwell, *Clinical Epidemiology. A Basic Science for Clinical Medicine* (Boston/Toronto: Little, Brown and Company, 1985), p. x.

30. Louis, *Recherchers*, 82-86. See also: Matthews, *Quantification*, p. 29.

31. This has become a kind of ‘mantra’ within the EBM movement, since Sackett et al. wrote this, in response to criticisms of their initial claims, in: Sackett et al., ‘Evidence Based Medicine: What it Is’. See also chapter 3.

Another similarity between Louis and leading figures within the EBM movement is the ‘missionary zeal’ they manifested. David Sackett, in particular, was a good match for Louis in terms of his messianic performance. Like the Parisian physician, Sackett had the support of a veritable throng of ‘disciples’. This is why, in the literature, evidence-based medicine is regularly characterised as an ideological movement. Also, the ‘apostle-like’ demeanour of Sackett stirred up a lot of resistance, as was also the case with Louis in the nineteenth century. However, the almost holy fire with which Sackett and his followers conveyed their message was actually very appealing, and this possibly partly accounts for the success of EBM.³²

All in all, it is hardly surprising that the parallel is often drawn between the Academic Debate of 1837 and the discussions on evidence-based medicine since the 1990s. In a number of respects, there is, indeed, a striking similarity between then and now. It also fits in within the venerable ‘doxographical tradition’ in medicine to use examples from the past to support and clarify views from the present.³³ It does need to be noted, however, that in this case, the references to Louis and the Academic Debate usually seem to be entirely driven by current interests and considerations. The goal is often not to acquire insight into the historical significance of Louis or Risueño d’Amador, but to stress the correctness of personal convictions in the debate on evidence-based medicine.

This applies to both parties in the debate, yet it is most strikingly visible in the more or less fixed place Louis and Risueño d’Amador have acquired in conveying the ‘EBM message’. The former is mainly remembered for pointing out the ineffectiveness and danger of bloodletting, for having an aversion to vague notions such as ‘medical tact’ and for his efforts to provide medicine with a more robust, objective and quantitative foundation. In other words, the ‘correctness’ of Louis’s view on bloodletting is coupled with several of his premises that correspond with those of representatives of the EBM movement. The suggestion emanating from this is evident: just as Louis was right at the time, this now applies to advocates of EBM. It is not a coincidence that out of all of Louis’s scientific work, it is almost always exclusively his study on bloodletting that is quoted, as this speaks most to the imagination. In medical circles, the age-old belief of physicians in the benefits of this treatment method is widely regarded as one of the most incomprehensible lapses in judgement in the history of medicine. The ‘correctness’ of Louis’s view on bloodletting therefore provides the ideal vehicle to point out the (alleged) superiority of the numerical method – and thus of evidence-based medicine.

32. See a.o.: Daly, *Evidence-Based Medicine*. This was also discussed in the interview with Büller.

33. See about the ‘doxographic tradition’ a.o.: Ph. J. van der Eijk (ed.), *Ancient Histories of Medicine: Essays in Medical Doxography and Historiography in Classical Antiquity* (Leiden: Brill, 1999).

As a counterpoint, Risueño d'Amador's role in the rhetoric of EBM proponents is not to be underestimated. With statements such as 'the d'Amadors are still among us'³⁴, they label their critics representatives of traditional 'authority-based' and 'opinion-based' medicine. The venom of such remarks lies in the alleged end of the Academic Debate. According to the time honoured story, Louis, even though he was 'gloriously right'³⁵, had to succumb to Risueño d'Amador and his conservative supporters.

As a result, Louis is purported to have had a lasting influence on public health only. British and American physicians, in particular, including several students and admirers of Louis, applied the numerical method to demonstrate the need for all manner of sanitary, hygiene and preventive measures for the promotion of the general health of the population. This is why Louis – in addition to his (slightly younger) English contemporaries William Farr and John Snow³⁶, among others – is also regarded as one of the 'fathers' of general epidemiology or population epidemiology, which is generally associated with public health and preventive and social medicine.³⁷

Clinical medicine, however, is purported to have rejected the numerical method. After Louis's defeat in the Academic Debate, 'numbers' have allegedly disappeared from the heart of medical practice for a long time, only to return in the course of the twentieth century with the rise of medical statistics and the *randomised controlled trial*. In other words, due to the resistance of the 'anti-scientific' established order in French medicine, at least a century's worth of important scientific progress in clinical medicine appears to have been blocked.³⁸

34. This is a direct quote from the interview with Patrick Bossuyt, but the tenor of this statement is also present elsewhere. See for this: n. 38 below.

35. Vandenbroucke, 'Evidence-based medicine', p. 1335.

36. Alfredo Morabia, who published a lot on the history of epidemiology, has made the remark that the choice of 'historical hero' speaks volumes about the kind of epidemiologist someone is. Snow is usually the hero of American and aetiologically oriented epidemiologists, Farr is the hero of public health and statistically oriented epidemiologists, and Louis is in particular the hero of clinical epidemiologists (this information is based on a personal communication between prof. Jan Vandenbroucke and TB). See for a similar observation: Susser, 'Epidemiology in the United States', pp. 150-1.

37. See a.o.: Lilienfeld & Lilienfeld, 'French Influence', pp. 28-38; P. D. Stolley & T. Lasky, *Investigating Disease Patterns: The Science of Epidemiology* (New York: Scientific American Library, 1995); Cole, *Power of Large Numbers*, pp. 103-4. In particular, note the epidemiological 'family tree' on p. 33 in Lilienfeld's article, which illustrates 'the influence of P.C.A. Louis on the development of statistics and epidemiology through some of his students in England'.

38. See n. 37 above. This message was also explicitly put forward in the course 'clinical epidemiology', part of the master program 'Epidemiology' of UMC Utrecht, which I attended to in November 2011 (he then used powerpoint presentations are still in possession of TB). I came across several of similar rhetorical uses of the past, in particular in informal, verbal contacts and in educational settings. The workshop named after Louis, mentioned in the introduction of this chapter, is exemplary. All this fits remarkably well with Kuhn's notion of the 'educational' function of history as part of the process of socialization within the predominant (or new) paradigm. In addition, there are also some *written* examples of the rhetorical use of Louis and D'Amador, but these are generally (somewhat) more nuanced. See for some

This clarifies the rhetorical role of the comparison between the current discussions on evidence-based medicine and the Academic Debate of 1837 that EBM proponents are so happy to draw, as this carries a warning that nothing less than the progress of medicine is at stake. This way, it is made crystal-clear who are the ‘good guys’ and who are the ‘bad guys’, who are on the side of progress and who threaten to thwart this progress.

The Issue of Certainty in Medicine: a ‘Permanent Battle of Methods’?

The image of Louis, the brilliant hero, who was far ahead of his time, and Risueño d’Amador, the reactionary who stood in the way of scientific progress, is rather simplistic. It is therefore refuted in the historical and philosophical literature on the Academic Debate, which provides a more nuanced view of both figures – and especially of Risueño d’Amador.³⁹ Instead of applying the dichotomies right-wrong and modern-traditional to them, historians and philosophers depict Louis and Risueño d’Amador as exponents of fundamentally *different* approaches to medicine.

In order to be able to understand this view on matters and why it might be relevant for historicizing evidence-based medicine, it is necessary to elaborate somewhat more on both the content and the broader context of the Academic Debate.

Risueño d’Amador belonged to the (‘vitalistic’) medical school of Montpellier, which had prevailed in eighteenth century France, but was subsequently superseded by Parisian medicine. There is little doubt that his attacks on Louis were partly inspired by resentment of the metropolitan dominance in his profession. In 1835, another physician from Montpellier, François-Joseph Double, had already expressed his objections against the application of the probability theory in medicine. In a lecture for the *Académie des Sciences* (French Academy of Sciences) and using virtually the same arguments as Risueño d’Amador would use two years later, Double responded to a book by J. Civalé, a famous Parisian physician in his day who, on the basis of numerical data, made statements in it about what was the best surgical technique to remove bladder stones.⁴⁰

Dutch examples: Bossuyt, *De Idolen van Kieslowski*; Bossuyt & Offringa, ‘De Wortels van Evidence Based Medicine’, pp. 30-5; Hofman, Grobbee & Lubsen, *Klinische Epidemiologie*, p. 2; Offringa, *Meten en Wegen*, pp. 11-12. One of these examples is a textbook for medical students and two of them are inaugural lectures, which fits the statement above about the educational function of history. In addition, see the historian George Weisz’s comments on all this, in: Weisz, ‘From Clinical Counting’, p. 379.

39. See a.o.: Cole, *Power of Large Numbers*, pp. 98-9; La Berge, ‘Medical Statistics’, p. 101.

40. Cole, *Power of Large Numbers*, pp. 100-2; La Berge, ‘Medical Statistics’, pp. 91-2, 99-101; Matthews, *Quantification*, 20-3; U. Tröhler, ‘Commentary: “Medical Art” versus “Medical Science”’: J. Civalé’s Statis-

This does not mean, however, that the Academic Debate on the numerical method can simply be traced back to the competition between the two most important medical schools in France. There were also ‘vitalists’ who did not object to Louis’s method, while various renowned exponents of Parisian medicine broadly agreed with Risueño d’Amador.⁴¹ All this first and foremost makes clear that Louis’s work was not unique or in any way isolated and that the Academic Debate was part of a much broader discussion on the role of science in medicine.

What was this discussion actually about? Risueño d’Amador himself had a clear stance on this: ‘C’est la grande question de la certitude en médecine.’⁴² The ‘major issue of *certainty* in medicine’ was, indeed, high on the agenda in his day. Around 1800, there were several competing ‘systems’ in medicine, and there was no decisive answer as to what was the correct system. Partly as a result of this, there was a general feeling that medicine was in the doldrums. Combined with the ideals of the Enlightenment, this greatly encouraged people in the early nineteenth century to think, speak and write about the question of the extent to which and in what way it was possible to provide medicine with a more certain, more scientific foundation.⁴³

An important point of discussion here was whether living organisms could be studied in the same way as inanimate nature. Vitalists such as Risueño d’Amador argued that this was not the case, as special life forces were active in living nature. In his lecture at the Academy in 1837, the professor from Montpellier voiced an opinion that, in the decade before, had been regularly expressed by prominent professionals in the field of medicine, which was that it was impossible to discover ‘laws of disease’ in nature that could be compared to Newton’s universal law of gravity. He argued that, in illness and therapy, no regularity and uniformity could be found, for these concepts formed part of living nature, which was characterised by variability and variation. This ‘first law of life’ was completely ignored by figures such as Louis, with their attempts to discover order and regularity in medicine. ‘Numerists’ sought certainty where it did not exist, Risueño d’Amador argued.⁴⁴

tical Research on Conditions Caused by Calculi at the Paris Academy of Sciences in 1835’, *International Journal of Epidemiology* 30 (2001), pp. 1252-3.

41. See about all this: La Berge, ‘Medical Statistics’, pp. 92, 97, 99-101; Weisz, *Medical Mandarins*, pp. 165-6.
42. Risueño d’Amador, *Mémoire*, p. 11.
43. Ackerknecht, *Medicine at the Paris Hospital*, pp. 3-12, 101; La Berge, ‘Medical Statistics’, pp. 90-1, 94-5, 100; T. C. Murphy, ‘Medical Knowledge and Statistical Methods in Early Nineteenth-Century France’, *Medical History* 25 (1981), pp. 301-19; B. Theunissen & R. P. W. Visser, *De Wetten van het Leven: Historische Grondslagen van de Biologie, 1750-1950* (Baarn: Ambo, 1996), p. 278; B. Theunissen, “*Nut en Nog Eens Nut*”: *Wetenschapsbeelden van Nederlandse Natuuronderzoekers, 1800-1900* (Hilversum: Verloren, 2000), p. 220; I. Widdershoven-Heerding, *Geneeskunde als Wetenschap: Wetenschapsidealen in de Nederlandse Geneeskunde van 1840 tot 1970* (Maastricht: Universiteit van Maastricht, 2000); Wiersma, *Twee Eeuwen*, p. 31.
44. Risueño d’Amador, *Mémoire*, (a.o.) pp. 104-6. See also n. 43 above.

According to him, it was indeed possible to arrive at certain knowledge with respect to causes of disease and therapy, but via a completely different route. While the numerical method led to a situation where all attention was focused on the ‘outward manifestations’, Risueño d’Amador was of the opinion that the medical professional had to use these manifestations as a starting point in order to penetrate to the core of the underlying and not immediately visible ‘inner essence’ of the disease. This first and foremost required the physician to know as much as possible about the individual occurrence of the illness, about the patient and their (medical) history. The experienced physician subsequently obtained insight into the cause of the disease or certainty about the right therapy to be followed, usually as a result of an intuitive, ‘spontaneous conviction’. In addition, the physician had to apply inductive reasoning, using knowledge of similar cases from personal experience and from the ‘experience of centuries’. Risueño d’Amador emphasised that, by this, he meant something substantially different from the ‘adding up’ as done by the numerists. While induction was based on the *analogy* between cases or phenomena, which had common characteristics in some areas but were ultimately individually different, the numerists, according to him, made the mistake of believing these cases or phenomena to be *identical*, and lumping them together.⁴⁵

In summary, Risueño d’Amador pleaded for a combination of ‘art’ and ‘science’. Contrary to popular belief, he not only stressed the importance of matters such as clinical expertise and intuition, but he actually considered science, in the form of careful observation and induction, to be important for medicine as well.⁴⁶ Indeed, in his view, it was Louis who worked in an anti-scientific way, blocking progress in medicine. He argued in this context:

‘To invoke probability [...] is to invoke chance. It is the renunciation of all medical certainty, surrendering all the rational rules which are a part of induction, experiment, observation, and reason to the mechanical and inflexible operation of calculation. Instead of facts to analyze and compare, you will have nothing more than chances to calculate; medicine will no longer be an art, but a lottery.’⁴⁷

Risueño d’Amador’s attack on Louis’s ‘anti-scientific’ approach had everything to do with the controversial nature of the so-called Laplacian probability theory. During the major

45. Ibid., (a.o.) pp. 109-12.

46. J. Cole, ‘The Chaos of Particular Facts: Statistics, Medicine and the Social Body in Early 19th-Century France’, *History of the Human Sciences* 7:3 (1994), pp. 17-18.; Idem, *Power of Large Numbers*, pp. 98-100; La Berge, ‘Medical Statistics’, p. 99; Murphy, ‘Medical Knowledge’, p. 317; Weisz, *Medical Mandarins*, pp. 164-5.

47. See for the original French quote: Risueño d’Amador, *Mémoire*, p. 14. This English translation is obtained from: Cole, *Power of Large Numbers*, p. 98; Weisz, *Medical Mandarins*, p. 164.

part of the nineteenth century, the work of the French mathematician Laplace played a key role in the theory and practice of the probability theory, yet at the same time, it kept evoking a great deal of resistance throughout this period. The literature points to several problematic aspects of the Laplacian ‘system’, including the integration of the probability theory in a deterministic worldview, the *subjective* meaning of the notion of probability, and the implicit assumption that, *a priori*, all chances are equally probable,⁴⁸ forming the basis for the calculation of *inverse* (or: *a posteriori*) probabilities.⁴⁹

Any further elaboration here would go beyond imposed bounds. It is sufficient to establish that Risueño d’Amador not only rejected the application of the probability theory in medicine for, in his view, the physician was supposed to focus on the unique, individual patient, but also because he had fundamental, theoretical and epistemological objections. The core of his criticism was that the search for *certainty* – and, in particular, by definition, *certain* cause-consequence relationships with respect to disease and medical treatment – was not helped much by the assessment of *chances* and the *approximation* of reality by Laplace and Louis.⁵⁰

Contrary to the image of Risueño d’Amador as a hardened reactionary, for almost the entire nineteenth century, many of the theoretical and epistemological ideas he expressed were shared by numerous scientists and philosophers who were considered to be ‘progressive.’⁵¹

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48. This assumption is (more or less) in line with the so-called ‘theorem of Bayes’.
49. See about this in particular: Wiersma, *Twee Eeuwen*, pp. 211-17. In addition, see about the (debates on) the Laplacian calculation of probabilities: Cole, ‘Chaos of Particular Facts’, pp. 7-8; Idem, *Power of Large Numbers*, pp. 98-102; I. Hacking, *The Taming of Chance* (Cambridge: Cambridge University Press, 1990), pp. 11-15; A. Kamlah, ‘The Decline of the Laplacian Theory of Probability: A Study of Stumpf, Von Kries, and Meinong’, in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), pp. 91-116; L. Krüger, ‘The Slow Rise of Probabilism: Philosophical Arguments in the Nineteenth Century’, in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), pp. 59-89; Th. M. Porter, *The Rise of Statistical Thinking 1820-1900* (Princeton: Princeton University Press, 1986), p. 8.
50. See about this: Wiersma, *Twee Eeuwen*, pp. 214-7. See also several quotes from Risueño d’Amador’s lecture, for instance: ‘Dans le cas supposé, la relation de la cause à l’effet étant connue, on a le *certain*, et non plus le probable; car la probabilité, dans aucun cas, ne peut engendrer que la probabilité’, See: Risueño d’Amador, *Mémoire*, 22-3. See also on pp. 26-7: ‘Dès qu’on connaît la cause et la loi d’un fait, on sait qu’il se répétera non parce que il s’est répété tant et tant de fois, mais parce qu’il *doit* se répéter; ce qui est bien différent.’ Original italics.
51. I. B. Cohen, ‘Scientific Revolutions, Revolutions in Science, and a Probabilistic Revolution 1800-1930’, in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), pp. 38-40; W. Coleman, ‘Experimental Physiology and Statistical Inference: The Therapeutic Trial in Nineteenth-Century Germany’, in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 2: Ideas in the Sciences* (Cambridge MA/London: MIT Press, 1987), pp. 204-6; Wiersma, *Twee Eeuwen*, 216-23.

This also applied – but only to a certain extent – to Claude Bernard, one of the founding fathers of scientific, physiologically-oriented medicine, which strongly developed in the latter half of the nineteenth century. In 1865, almost thirty years after the Academic Debate, Bernard formulated his criticism of the numerical method, of which one essential element was very similar to that of Risueño d'Amador. Bernard argued, among other things, that statistics 'can actually show only *probability*, never *certainty*'. He stressed that he could not understand why results taken from statistics were called 'laws': 'for in my opinion scientific law can be based only on certainty, on absolute determinism, not on probability'.⁵² On taking averages, he furthermore wrote:

'Let us assume that a physician collects a great many individual observations of a disease and that he makes an average description of symptoms observed in the individual cases; he will thus have a description that will never be matched in nature. So in physiology, we must never make average descriptions of experiments, because the true relations of phenomena disappear in the average [...]. In the cases just considered, averages must therefore be rejected, because they confuse, while aiming to unify, and distort while aiming to simplify.'⁵³

The similarity between (part of) the argumentation of Bernard and that of Risueño d'Amador is striking, but should not be overestimated. They arrived at their criticism of Louis's numerical method from completely different angles. Bernard strongly rejected references to the *art* of medicine, as well as the vitalistic doctrine that special life forces were active in living nature. In addition, he thought the combination of observation, induction and intuition pleaded for by Risueño d'Amador, was a much too fragile basis for medical practice. His ambition was to make a proper natural science of medicine. In this respect, Bernard was closer to Louis than to Risueño d'Amador. Bernard also opined that statistics and numerical methods had their useful applications in practice, and used them himself as well.⁵⁴

52. See: C. Bernard, *Introduction à l'Étude Médecine Expérimentale* (Paris: J.B. Ballières et Fils, 1865), p. 239. The italics are from the original text. The English translation is obtained from: C. Bernard, *An Introduction to the Study of Experimental Medicine* (New York: Dover, 2012 [1865]), p. 136. See also: Matthews, *Quantification*, pp. 71-4; Wiersma, *Twee Eeuwen*, pp. 207-8, 218-19.

53. See: Bernard, *Introduction à l'Étude Médecine Expérimentale*, pp. 236-7. This English translation is obtained from: Matthews, *Quantification*, p. 73.

54. Compare this with: A. Morabia, 'Claude Bernard was a 19th Century Proponent of Medicine Based on Evidence', *Journal of Clinical Epidemiology* 59 (2006), pp. 1150-4. I believe Morabia is right to nuance the predominant image of Bernard as opponent of Louis and statistics. However, I also find he takes his argument too far as he depicts Bernard (as much) as a supporter of Louis and a 'co-precursor' of EBM. Too easily, Morabia ignores or at least underestimates the profoundly different philosophical and epistemological positions of Louis (and the EBM movement) on the one hand and Bernard on the other.

Although Bernard did use Louis' *method*, he disapproved of Louis' *programme*, in which the numerical method featured as the scientific basis of medicine and as the key to future progress in the field. Bernard wrote on this: 'I do not therefore reject the use of statistics in medicine, but I condemn not trying to get beyond them and believing in statistics as the foundation of medical science.'⁵⁵ This indicates that Bernard had a perception of science that was, in the end, essentially different to that of Louis. While, in his view, Louis's numerical approach implied that medicine was only a passive, observational science, Bernard thought it necessary to take a further step: to actively intervene in nature by experimentation. This is why he chose the laboratory, and not the hospital, as the location for medical science. It was there that, through experimental physiology, processes and laws in the human body were brought to light, which were the basis of sickness and health. Bernard believed that only with the help of this type of strict deterministic knowledge of (patho)physiology, could medicine acquire a certain, scientific foundation.⁵⁶

According to the historian Matthews, a fundamental difference of views manifests itself here, about what "objective" knowledge entails. Louis and his proponents thought they could arrive at objective knowledge by evading the idiosyncrasies and inconsistencies of the individual, focusing instead on the regularities that manifested themselves on the level of a (clinical) population. Bernard, on the other hand, sought objectivity in an absolute (micro-)determinism on the level of the individual. It was in the physiological laboratory that the causes, relations and laws of phenomena in individual organisms were to be unravelled.⁵⁷

Bernard's view was considerably influential, especially since physiologically-oriented 'laboratory science' gained momentum in the latter half of the nineteenth century. At the same time, many (practising) physicians remained committed to the views expressed by Risueño d'Amador. Thus, the numerical method came under pressure from two sides.⁵⁸

All in all, the predominant view in the philosophical and historical literature can be summarized as follows. The Academic Debate and the subsequent discussions in the nineteenth century on the application of statistics cannot be reduced to a conflict between modern and old-fashioned, between scientific progress and an anti-scientific

55. See: Bernard, *Introduction à l'Étude Médecine Expérimentale*, p. 243. This English translation is obtained from: Bernard, *An Introduction to the Study of Experimental Medicine*, p. 138.

56. Bynum et al., *Western Medical Tradition*, pp. 116-19; Cohen, 'Scientific Revolutions', p. 40; Coleman, 'Experimental Physiology', pp. 202-6; Matthews, *Quantification*, 71-4; Th. M. Porter, 'Medical Quantification: Science, Regulation and the State', in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005), pp. 397-8; Wiersma, *Twee Eeuwen*, 203-10.

57. Matthews, *Quantification*, pp. 74, 84-5. See also: Porter, 'Medical Quantification', pp. 397-8.

58. See a.o.: Coleman, 'Experimental Physiology', p. 202; C. Lawrence, 'Incommunicable Knowledge: Science, Technology and the Clinical Art in Britain 1850-1914', *Journal of Contemporary History* 20 (1985), pp. 503-20.

reference to 'art'. Rather, there was a thorough discussion on the proper foundation for medical practice, where *the views of Risueño d'Amador, Louis and Bernard represent three fundamentally different visions* with respect to 'the major issue of certainty in medicine'.⁵⁹

The tension between these divergent views with regard to the foundation of medicine is regularly used as a structuring and explanatory element in historiography. In particular, there is a widespread notion of theoretical and empirical approaches in medicine battling for precedence since antiquity.⁶⁰ Some scholars use such a scheme to place the recent rise of evidence-based medicine in a long-term perspective. The Dutch general practitioner and philosopher Tjerk Wiersma, for example, argues that both the Academic Debate of 1837 and the current discussions on EBM can be traced back to a 'permanent battle of methods' in which medicine is purported to have been involved for at least two centuries. He speaks of medicine having 'two faces', pointing to the ongoing tension between pathophysiological knowledge on the one hand, and statistical-epidemiological knowledge on the other.⁶¹

Similarly, the historian Matthews places the current debates about EBM in the broad framework of the eternal struggle between various approaches and philosophical positions in medicine: between rationalism and empiricism, between determinism and probabilism, between a focus on the individual or on groups and categories, between the art of medicine and the science of medicine. In this respect, despite the stormy developments in medicine during the last two centuries, remarkably little has changed, Matthews argues. He therefore ends his book *Quantification and the Quest for Medical Certainty* with the French saying: *plus ça change, plus c'est la même chose* (the more things change, the more they remain the same).⁶²

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59. See a.o.: Howick, *Philosophy of Evidence-Based Medicine*, p. 4 (and notes 6-9); A. Desrosières, 'Commensuration and Probabilism: Two Kinds of Controversies about Statistics (1850-1940)', in I. H. Stamhuis, P. M. M. Klep & J. G. S. J. van Maarseveen (eds.), *The Statistical Mind in Modern Society. The Netherlands 1850-1940. Volume II: Statistics and Scientific Work* (Amsterdam: Aksant, 2008), pp. 311-21, on p. 318. Morabia recognises these three visions as the three stages in the evolution of medicine, which were described by Bernard. The most primitive stage was that of 'irrational medicine', as Bernard labelled the practices of physicians who only went by their 'medical tact' and intuition. The 'intermediate stage' was the stage of 'empirical medicine', which was grounded on comparisons between groups of patients and probabilistic reasoning. The most advanced stage – which, according to Bernard, had not arrived (in full) yet – was the stage of 'scientific medicine', which was entirely grounded on the certain (and *deterministic*) knowledge of disease mechanisms that was produced by experiments in physiological laboratories. See on this: Bernard, *Introduction à l'Étude Médecine Expérimentale*; Morabia, 'Claude Bernard was a 19th Century Proponent'.
60. See for example: Borst-Eilers, *Geneeskunde op Recept?*; Ierodiakonou and Vandenbroucke, 'Medicine as a Stochastic Art'; Turgut, 'Ancient Medical Schools'; Vandenbroucke, 'Evidence-Based Medicine'.
61. Wiersma, *Twee Eeuwen*, pp. 12-20, 280-97, the quotes are on pp. 280 and 290.
62. Matthews, *Quantification*, see p. 149 for the original French quote. See also Matthews' lecture at the 'Nacht van Descartes', edition 2009: the powerpoint presentation and video recording of this lecture are available on: <http://www.sg.uu.nl/opnames/bewezen-beter-nacht-van-descartes/prof-dr-ted-porter-en-prof-dr-j-rosser-matthews>.

In itself, little may be said against this image of a permanent struggle between methods or philosophical viewpoints in medicine. However, the interpretations provided by Wiersma and Matthews, of both the Academic Debate of 1837 and the current discussions on EBM, are also slightly one-sided, ahistorical and 'transcendent'. The fact that medicine and healthcare have completely changed in the last two centuries in terms of scale, scope, curative potential, social position, technological development and so on, seems to have little or no influence on what they describe as the 'eternal' tension between the various methodological and epistemological approaches. This is not very satisfactory.

Moreover, the Academic Debate of 1837 did not merely concern an 'academic' discussion, in which only theoretical issues were addressed. The acrimonious nature of the debate suggests that there was a rhetoric battle here, in which a variety of interests, considerations and practices were at stake. It seems sensible, therefore, to not only scrutinise the philosophical and epistemological arguments of the people involved, as Matthews and Wiersma have done, but also to try and address the stakes *behind* the debate.

Here, the approach of the sociologist Thomas Gieryn, which was discussed in the general introduction, seems to be relevant. The battle of words between Louis and Risueño d'Amador, as well as the current EBM debate, is very similar to the disputes, analysed by Gieryn, on the 'boundaries of science'. Gieryn describes how parties embroiled in such disputes, constructed cultural maps of science, in which they determined the boundaries of (proper) science. In analysing cultural maps of science, Gieryn did not fix his gaze 'upstream' on the production and philosophical basis of scientific knowledge, but 'downstream': on the practical role of the cultural maps of science, and, in particular, on the way in which these were used to take or legitimise specific decisions.⁶³

In line with Gieryn's viewpoint, in the remainder of this chapter, attention will be shifted from the theoretical and epistemological reflections situated 'upstream' to the more 'practical', 'downstream-situated' issues that were raised in nineteenth-century debates on the use of numbers and statistics in medicine. On the basis of the works of historians such as George Weisz and Ann La Berge, in which such a 'downstream' perspective is adopted, it will be shown that numbers and numerical methods increasingly pervaded medicine in the course of the nineteenth and early twentieth centuries. In other words, a notable process of objectification and quantification took off in medicine. The backgrounds, characteristics and significance of this process will be further explored on, by discussing the literature on the so-called 'probabilistic revolution' and Rosenberg's work on the 'specificity revolution'. All this will not only shed a different light on the Academic Debate and, in particular, its aftermath, but also on the question of how evidence-based medicine can be placed in a longer term perspective.

63. Gieryn, *Cultural Boundaries*, see in particular pp. ix-xii, 1-35.

From Theory to Practice; 'Louis's Bifurcated Legacy'

According to the 'standard story', Louis was the big loser in the Academic Debate. From an 'upstream' perspective, as Gieryn would put it, a great deal may be said in favour of this. The theoretical, but also the many practical objections attached to it, prevented the numerical method from becoming the scientific basis for medical practice, as Louis had hoped and expected. Until far into the twentieth century, the epistemological status of 'statistics' would remain very low in medical circles.⁶⁴

This was a very different story, however, from a 'downstream' perspective. Statistics and 'numerical' methods did indeed penetrate to both medical science and medical practice. This happened fairly soon after the Academic Debate: from the 1850s, statistic tables and numerical methods were an increasingly present component of everyday routine in medicine.⁶⁵ This applied, above all, to the hospitals. Already in the first half of the nineteenth century, statistics were kept there of admission, dismissal and mortality figures. Over time, these hospital statistics were increasingly expanded and they also began to play an increasingly central role. They were used, for example, to compare various institutions to each other, or to check whether an organisational or therapeutic innovation actually led to changes in the figures.

The growing importance of hospital statistics had a number of causes. First of all, people simply needed time to collect sufficient numerical data in order to be able to set to work with statistical analysis. Around 1850, this point had been reached in most Western European countries. Secondly, it took quite a while before an efficient infrastructure was built up for the maintenance of hospital statistics. Apart from the fact that a great deal of organisation was required for this, it proved particularly difficult to get physicians to be more unequivocal in the use of concepts, diagnoses and classifications of disease. Thirdly, towards the end of the nineteenth century, hospitals started to occupy an increasingly important position within healthcare. Not only did they greatly increase in number and size but their role changed as well. They gradually developed from infirmaries, in which mainly poor people were nursed and looked after, into medical treatment institutions, to

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64. A. de Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek in het "Nederlandsch Tijdschrift voor Geneeskunde" rond de Eeuwwisseling', *Gewina* 15 (1992), pp. 163-81, on pp. 165-7, 171, 180; Matthews, *Quantification*, p. 65; Weisz, 'From Clinical Counting', pp. 379-80; Weisz, *Medical Mandarins*, p. 164. See also Matthews' account of the debate between the bacteriologist Wright and representatives of the biometrical school such as Pearson and Greenwood, that took place in the early twentieth century: Matthews, 'Almroth Wright', pp. 143-44; Matthews, *Quantification*, pp. 103, 107-9.
65. Weisz, 'From Clinical Counting', p. 379. See on the situation in The Netherlands: P. M. M. Klep & B. Kruithof, 'The Rise of Quantification and Statistics in Dutch Medical Research (1850-1940)', in I. H. Stamhuis, P. M. M. Klep & J. G. S. J. van Maarseveen (eds.), *The Statistical Mind in Modern Society. The Netherlands 1850-1940. Volume II: Statistics and Scientific Work* (Amsterdam: Aksant, 2008), pp. 9-37; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 163-81.

which an increasing number of people from the middle and higher classes were admitted as well.⁶⁶

Furthermore, to an increasing extent – and more so than in private practices – measuring instruments such as the thermometer and the sphygmomanometer (blood pressure meter) were introduced and used in hospitals. Taken together with the blood and urine tests that were developed over time, strong quantification thus occurred in medical practice, particularly where diagnostics were concerned. Towards the end of the nineteenth century, it had become common practice for physicians to express the condition of the patient, and its gravity, in measure and number, rather than in the more descriptive, qualitative terms used in former times. Numerical methods played an important role here, as they were used to determine what the significance of measured values actually was and, for example, what cut-off points had to be used.⁶⁷

In the area of therapy too, the application of statistics became more common, albeit somewhat less marked than in the field of diagnostics. This was especially the case in the field of surgery. In the latter half of the nineteenth century, surgery became increasingly significant due to the introduction of anaesthetics such as ether and chloroform as of the 1850s, antiseptic measures to disinfect wounds as of the 1870s, and asepsis – the provision of a sterile working environment and the use of sterile instruments for the prevention of infections – as of the 1890s. This stimulated the introduction of all manner of new surgical techniques and interventions, which were often evaluated with the help of methods very similar to Louis's. In addition, the discovery of pathogenic microorganisms and other bacteriological insights led, at the turn of the 19th century, to the development of a number of new serums and vaccines. The efficacy of these products was tested with

66. Bynum et al., *Western Medical Tradition*, pp. 150-1; Klep & Kruithof, 'Rise of Quantification', pp. 16, 18-19, 23; A. Klijn, *Verlangen naar Verbetering. 375 Jaar Academische Geneeskunde in Utrecht* (Amsterdam: Boom, 2010), pp. 86-90, 97, 102, 116, 121; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 172-173; E. Magnello, 'The Introduction of Mathematical Statistics into Medical Research: The Roles of Karl Pearson, Major Greenwood and Austin Bradford Hill', in E. Magnello & A. Hardy (eds.), *The Road to Medical Statistics* (Amsterdam/New York: Rodopi, 2002), pp. 95-123, on pp. 99-100; Weisz, *Medical Mandarins*, p. 166.

67. Bynum et al., *Western Medical Tradition*, pp. 167-173; V. Hess, 'Standardizing Body Temperature: Quantification in Hospitals and Daily Life, 1850-1900', in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts: Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005), pp. 109-126; Klep & Kruithof, 'Rise of Quantification', pp. 16, 34, 36; Matthews, *Quantification*, pp. 74, 77; Porter, 'Medical Quantification', p. 398; Weisz, 'From Clinical Counting', p. 378. See also: S. J. Reiser, 'Technology and the use of the Senses in Twentieth-Century Medicine', in W. F. Bynum & R. Porter (eds.), *Medicine and the Five Senses* (Cambridge: Cambridge University Press, 1993), pp. 262-73; Z. G. Swijtink, 'The Objectification of Observation: Measurement and Statistical Methods in the Nineteenth Century', in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), pp. 261-87.

the help of statistics, which was the obvious thing to do, because of the large number of people that could be treated with these products.⁶⁸

A host of other examples may be given to illustrate the increasing significance of quantitative data and numerical methods in medicine. During the last decades of the nineteenth century, for example, there was a great deal of debate on the effectiveness of electrotherapy in patients suffering from nervous diseases, where both proponents and opponents used statistic arguments.⁶⁹ This was also the case in disputes on homeopathy and other alternative treatment methods.⁷⁰ Moreover, in medical and scientific laboratory research a similar process of quantification took place. Here too, a major reason was the increasing importance of precision and measuring instruments. In addition, statistical methods were used for the evaluation of experimental results. In the Netherlands, for example, as of approximately 1900 medical dissertations and articles in the *Nederlands Tijdschrift voor Geneeskunde* (*Dutch Journal of Medicine*) were markedly frequently accompanied by statistical data.⁷¹

Highly questionable, therefore, is the persistent story that Louis was defeated by Risueño d'Amador and his proponents, with the result that, for over a century, statistical methods and numbers would no longer play a role in clinical medicine. The historian George Weisz argues: 'The claim that quantification was seriously set back by opposition to it during the 1830s (or by Claude Bernard's later critique) is difficult to credit.'⁷² He also points to a French medical dictionary from the 1870s in which the numerical method is even referred to as a 'cause gagnée' – a 'won case'.⁷³ Other historians draw similar conclusions. Porter, for example, writes: 'It would be a mistake to suppose that medicine was singularly resistant to quantification.'⁷⁴

68. Bynum et al., *Western Medical Tradition*, pp. 155-60; Klep & Kruithof, 'Rise of Quantification', pp. 23-4, 34, 36; Klijn, *Verlangen naar Verbetering*, pp. 102-4, 109, 120-1; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 176-9; Matthews, *Quantification*, p. 69; Benjamin Toth, 'Clinical Trials in British Medicine 1858-1948, with Special Reference to the Development of the Randomised Controlled Trial' (PhD dissertation, University of Bristol, 1998), pp. 93-112; Weisz, 'From Clinical Counting', p. 378; Weisz, *Medical Mandarins*, pp. 166-73.

69. Klep & Kruithof, 'Rise of Quantification', p. 25; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', p. 177; J. Senior, 'Metrological Awakenings: Rationalising the Body Electric in Nineteenth-Century Medicine', in E. Magnello & A. Hardy (eds.), *The Road to Medical Statistics* (Amsterdam: Rodopi, 2002), pp. 77-94.

70. Bossuyt, *De Idolen van Kieslowski*, p. 7.

71. Klep & Kruithof, 'Rise of Quantification', pp. 9-37; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 163-181; A. Morabia, 'Claude Bernard, Statistics, and Comparative Trials', *JLL Bulletin* (2007); Swijtink, 'Objectification of Observation', pp. 261-87.

72. Weisz, *Medical Mandarins*, p. 182.

73. *Ibid.*

74. Porter, 'Medical Quantification', p. 397.

At the same time, historians point out that the influence of statistical data and methods must not be overestimated. Weisz speaks of a 'conditional and limited embrace' and of the 'selective use' of 'clinical counting'.⁷⁵ Weisz very consciously use the term 'clinical counting' to indicate that, in medicine, only very simple statistic methods were used. Matters did not progress beyond the adding up of observations and data, where the manipulations usually remained at the level of calculation of means and percentages. In other words, only descriptive statistics were used. The probability theory was hardly used. Mathematical statistics, which developed in the period 1890-1930 under the influence of the work of Francis Galton, Karl Pearson and their 'biometric school', did not initially change this situation, and were only very slowly accepted in medicine.⁷⁶

This may in part be explained by the fact that medical professionals were generally barely skilled in mathematics. The more complex statistical methods and techniques applied within the biometric school, were simply too difficult for most physicians to grasp. At least as important a factor, however, is that the probability theory was widely considered unsuitable for medicine. The principal starting point that the individual patient needed to be central, remained paramount. In addition, there were objections of a more practical nature. Insufficient data could be collected in clinical medicine, for example, or the classification was often too precarious to justify the application of probability calculation and statistical inference. Moreover, most medical professionals thought it too cumbersome to apply all sorts of mathematical calculations to the observations collected. In their view, 'common sense' and the clinical judgment of the experienced practitioner offered a much simpler and also more reliable route to arrive at sensible conclusions. In addition, numerical data and methods did not enjoy the status or authority of 'science'. They were simply considered to be useful tools that could be used heuristically in order to acquire more insight into the effectiveness of treatment methods. This was mainly the case in fairly uncomplicated issues, in which both the ailment and the effect of the treatment that was to be determined, could be ascertained easily and unequivocally. If the situation was more complicated, or if clinical expertise and interpretation played a more important part, then numerical methods represented a negligible role. In short, 'statistics' formed only one of the many elements that could be part of the formation of a medical judgement, and remained subordinate to the clinical expertise of the physician.⁷⁷

75. Weisz, *Medical Mandarins*, pp. 166, 182.

76. Klep & Kruithof, 'Rise of Quantification', pp. 28, 30-1, 36; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 167, 171-2; Toth, 'Clinical Trials in British Medicine', pp. 91-7; Weisz, 'From Clinical Counting', pp. 379-81.

77. Klep & Kruithof, 'Rise of Quantification', pp. 17, 25, 36; Knecht-van Eekelen, 'Opvattingen over Geneeskundige Statistiek', pp. 171, 178-80; Matthews, *Quantification*, pp. 68-70, 75-7; Weisz, 'From Clinical Counting', pp. 379-80; Weisz, *Medical Mandarins*, pp. 166-83.

In broad terms, the same development occurred in experimental biomedical laboratory research. Here too, numerical data and methods were not regarded as ‘proper science’ but as useful tools. The historian Coleman notices in this regard: ‘Even the most insistent deterministic physiologist could admit the utility of statistics, provided he was not compelled to acknowledge that nature herself was indeterministic.’⁷⁸ Among physiologists, there was no great need for the application of more complex, mathematical methods. In experimental physiology and other preclinical sciences, quantification mainly played a role in the collection of experimental data. However, the assessment of these data and the conclusion drawn from them barely had a quantitative character. There was a search for causal links, and there was therefore no interest in a statistical analysis of the distribution and variation in the results of experiments.⁷⁹ Moreover, statistical inferences and formal procedures were not very useful, according to laboratory researchers, for the results of their experiments first and foremost required expert interpretation. In the same way as the professional judgement of the physician was held in higher regard than statistical analysis in the clinic, the expertise and ‘tacit knowledge’ of the researcher were dominant in the laboratory.⁸⁰

Thus, an ambivalent image emerges of the role of ‘statistics’ in medicine in the nineteenth and early twentieth century. On the one hand, statistical data and the application of simple numerical methods began to be very prominent in this period, both in clinical practice and in biomedical research. On the other hand, the meaning and significance of these methods were not held in anything like the same esteem as the professional expertise of the practising physician or of the researcher. Therefore, judging by the developments in the subsequent century, the Academic Debate of 1837 did not produce clear winners or losers.

This is why Matthews speaks of ‘Louis’s bifurcated legacy’.⁸¹ He argues that, over time, the numerical method became detached from Louis’s programme for the scientific foundation of medicine. Admittedly, the method became ‘standard’ in the latter half of the nineteenth century, but it was no longer associated with Louis’s vision for the future with regard to medicine as science. On this point, from the latter half of the nineteenth century, the hopes and expectations of the vast majority of physicians were placed upon experimental biomedical research in the laboratory.⁸²

78. Coleman, *Experimental Physiology*, p. 220 See also: Morabia, ‘Claude Bernard, Statistics, and Comparative Trials’.

79. Weisz, ‘From Clinical Counting’, pp. 380-81 Weisz’s argument is based on Matthew’s account of the famous debate between Wright and Pearson in Greenwood, see: Matthews, ‘Almroth Wright’, pp. 125-47; Matthews, *Quantification*, pp. 97-114, see also p. 62. See also: Porter, ‘Medical Quantification’, pp. 397-9.

80. Coleman, ‘Experimental Physiology’, pp. 201-26; Klep & Kruithof, ‘Rise of Quantification’, pp. 9-37; Matthews, *Quantification*, pp. 77-85; Porter, ‘Medical Quantification’, pp. 397-8.

81. Matthews, *Quantification*, p. 62.

82. *Ibid.*, pp. 62, 65-6, 69. See also (a.o.): Toth, ‘Clinical Trials in British Medicine’, pp. 104-6; Weisz, ‘From Clinical Counting’, p. 380.

All this makes it difficult to assess the actual influence of numerical data and methods in the nineteenth and early twentieth century. They were ubiquitous in the practice of the clinic and the laboratory, but what was the significance and importance of this? In order to obtain greater clarity in this respect, it is useful to explore more thoroughly the process of objectification and quantification, which manifested itself in numerous fields in this period. In the following sections, the developments in medicine will be placed in a broader context, and they will be further interpreted, amongst others with the help of the literature on the ‘probabilistic revolution’, the broader context of modernisation and the ‘specificity revolution’.

The ‘Probabilistic Revolution’

The notion of a ‘probabilistic revolution’ originated from the ascertainment that numbers, statistics and applications of the probability theory are omnipresent in today’s world. In science, quantitative procedures and data are dominant, and, in many disciplines, complex statistical techniques are used. Public bureaucracy and government policies are, to a large extent, determined by statistics such as unemployment figures, data on the Gross National Product, crime figures, figures on traffic casualties, et cetera. In the economy and in daily life, statistical details and a wide variety of applications of ‘numerical’ methods are also omnipresent, in the shape of intelligence tests, market surveys and opinion polls.⁸³

However self-evident these matters may seem nowadays, over two centuries ago, around 1800, all this was (virtually) non-existent. Statistics and probability calculation played absolutely no role whatsoever in science, the state apparatus, the economy and in daily life. This is the reason that, in the meantime, an important change must have occurred, which is referred to as the ‘probabilistic revolution’ in the literature.⁸⁴ Other terms used for this include: ‘the rise of statistical thinking’,⁸⁵ ‘the taming of chance’,⁸⁶ the development of a ‘statistical *Lebensgefühl*’⁸⁷ and the establishment of an ‘empire of chance’.⁸⁸ The ‘probabilistic revolution’ – to use this term, for the sake of convenience – is generally placed in the nineteenth and early twentieth century. Roughly in the period be-

83. G. Gigerenzer et al., *The Empire of Chance: How Probability Changed Science and Everyday Life* (Cambridge: Cambridge University Press, 1989); I. Hacking, ‘Was there a Probabilistic Revolution 1800-1930?’ in L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), p. 45-55.

84. See a.o. L. Krüger, L. J. Daston & M. Heidelberger (eds.), *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA: MIT Press, 1987); L. Krüger, G. Gigerenzer and M. S. Morgan (eds.), *The Probabilistic Revolution. Volume 2: Ideas in the Sciences* (Cambridge MA: MIT Press, 1987).

85. Porter, *Rise of Statistical Thinking*.

86. Hacking, *Taming of Chance*.

87. Gigerenzer et al., *Empire of Chance*, p. 289.

88. Ibid.

tween 1800 and 1930, a number of crucial transformations heralded the present ‘statistical era’. While the ‘empire of chance’ saw an enormous expansion, particularly after 1950, the foundation for it had already been laid in the preceding period.

In the literature, there is a great deal of debate on the question whether a ‘probabilistic revolution’ really did occur. Some authors wonder whether or not the period of 130 years is way too long in order to be able to speak of a ‘revolution’. Others doubt if the characteristics of a scientific revolution, for example in the sense of a Kuhnian paradigm shift, were present at all. It is undisputed, however, that, with the rise of statistics and statistical methods in the course of the nineteenth and early twentieth century, an important change took place, which may be regarded as ‘revolutionary’ in everyday language.⁸⁹

In various publications on the ‘probabilistic revolution’, it becomes clear that the concept of ‘statistics’ has had countless meanings in the course of time. In the eighteenth century, statistics first and foremost meant ‘politics’, or ‘the political description of a state’. Initially, this did not necessarily concern a (purely) quantitative political description. It is only in the course of the nineteenth century that statistics gradually acquired the meaning of ‘the representation of conditions through *numbers*’. At the same time, the close interrelation with politics disappeared, and ‘conditions’ of a highly varying nature were expressed numerically with the help of statistics. In medicine and in biology, among other disciplines, these so-called *descriptive* statistics were frequently applied in order to classify and quantify data. Louis’s and similar numerical methods too, should, above all, be understood as descriptive statistics: two or more ‘conditions’ were described numerically, and subsequently compared to each other. In the nineteenth century, the term *comparative* statistics was used for this as well. Mathematics, in its shape as probability calculation, played a limited role here. *Inferential* or *mathematical statistics* only developed through the work of Galton, Pearson and the biometric school, who, particularly in the period 1890-1930, introduced numerous innovations, starting with the notions of correlation and regression to the mean. This formed the conceptual basis, in the latter half of the twentieth century, for the emergence of statistics as the specialised mathematical discipline as it is known today.⁹⁰

89. See a.o.: Cohen, ‘Scientific Revolutions’, pp. 23-44; Cole, *Power of Large Numbers*; Hacking, ‘Was there a Probabilistic Revolution 1800-1930?’.

90. See a.o.: V. L. Hilts, ‘Epidemiology and the Statistical Movement’, in A.M. Lilienfeld (ed.), *Times, Places and Persons. Aspects of the History of Epidemiology* (Baltimore and London: Johns Hopkins University Press, 1980), pp. 43-55; Kamlah, ‘Decline of the Laplacian Theory’, pp. 91-116; J. G. S. J. van Maarseveen, P. M. M. Klep & I. H. Stamhuis, ‘Introduction’, in J. G. S. J. van Maarseveen, Paul M. M. Klep & Ida H. Stamhuis (eds.), *The Statistical Mind in Modern Society. The Netherlands 1850-1940. Volume I: Official Statistics, Social Progress and Modern Enterprise* (Amsterdam: Aksant, 2008), pp. 11-41, on pp. 12-14; Porter, *Rise of Statistical Thinking*, pp. 11-12, 231-2, 286-318; I. H. Stamhuis, “*Cijfers en Aequaties*” en “*Kennis der Staatskrachten*”. *Statistiek in Nederland in de Negentiende Eeuw* (Amsterdam and Atlanta: Rodopi, 1989), pp. 2-6; I. H. Stamhuis, ‘De “Probabilistic Revolution” in de Wetenschappen’, *Gewina* 15 (1992), pp. 141-52.

As long as the increasingly widespread application of statistics remained limited to the descriptive and comparative variants, there was no undermining whatsoever of the dominant determinism due to an emerging probabilism. The Laplacian principle that statistical laws were based on an underlying causal structure remained in use. Statistics and probability calculation served as tools to shed light on this causal structure – and were thus only of derivative significance. It was not until the end of the nineteenth century that, due to the works of the biometric school, statistical laws *themselves* began to say something about reality. In this context, Hacking speaks of the introduction of a new phenomenon: ‘the autonomy of statistical law’. One of the consequences of this was, that the Laplacian probability notion made way for a frequentist view of reality, which, at least, allowed for the theoretical possibility of a *non*-determined world.⁹¹

In many fields and in many scientific disciplines, however, this conceptual switch from determinism to probabilism in the period 1800-1930 was not or hardly made. Various authors emphasise that the ‘probabilistic revolution’ was first and foremost driven by more practical and mundane matters, such as the collection of ever more numerical data, the increasing use of measuring instruments and the application of (usually simple) statistical techniques and probability calculations in an increasing number of areas.⁹² I. B. Cohen speaks of ‘a revolution by [and in] application.’⁹³ L. Krüger establishes that there was a ‘remarkable time lag between the rise of statistical practice and the recognition of probability.’⁹⁴ According to him, during the nineteenth century, statistical practices spread across various scientific disciplines at a rapid pace, but the vast majority of scientists remained ‘opposed to taking probability as fundamental or irreducible.’⁹⁵

In this context, Desrosières and Klep make a useful distinction between ‘two quite different statistical mindsets.’ The first mindset concerned: ‘only measurement, commensuration, quantification, and the use of numbers.’ In other words, this ‘mindset’ only involved the *use* of numerical data and methods without there being, what Krüger refers to as: the recognition of probability. Only with the second ‘mindset’, is there a (partial) displacement of determinism in the form of a truly ‘probabilistic mindset’, which Des-

91. See also the different stages of the ‘probabilistic revolution’ as described by Hacking: Hacking, ‘Was there a Probabilistic Revolution 1800-1930?’, pp. 52-3. See for a more comprehensive account: Hacking’s book *The Taming of Chance*. See also: Wiersma, *Twee Eeuwen*, pp. 211-43.

92. John Beatty et al., ‘Introduction to Volume 2,’ in L. Krüger, G. Gigerenzer & M. S. Morgan (eds.), *The Probabilistic Revolution. Volume 2: Ideas in the Sciences*. (Cambridge MA/London: MIT Press, 1987), pp. 1-4.; Gigerenzer et al., *Empire of Chance*, pp. xii-xiv; Magnello & Hardy (eds.), *Road to Medical Statistics*, p. iv.; Porter, *Rise of Statistical Thinking*, pp. 8, 10-11, 23; Swijtink, ‘Objectification of Observation’, pp. 261-87 See also: Stamhuis, “‘Probabilistic Revolution’”, p. 151.

93. Cohen, ‘Scientific Revolutions’, pp. 37-40. On p. 37 Cohen writes ‘by application’ and on p. 40 ‘in application.’

94. Krüger, ‘Slow Rise of Probabilism’, pp. 59-60.

95. *Ibid.*, 60.

rosières and Klep describe as: ‘the stochastic style of reasoning: Bernoulli’s urn model, the law of large numbers, probability, inferential statistics.’⁹⁶

In medicine – just as in many other disciplines – the developments in the period 1800-1930 almost entirely involved the first ‘statistical mindset’. While the application of descriptive and comparative statistics was in full flight in the medical world, inferential statistics had not (yet) gained a foothold there. With regard to medicine in the nineteenth century and the first half of the twentieth century, it is therefore more sensible to speak of a process of objectification and quantification rather than of a ‘probabilistic revolution’.

Modernisation, Numbers and Control

This process of objectification and quantification (to maintain this terminology) was closely related to the host of developments in the Western world and often referred to with the catch-all term ‘modernisation’. The economic and social changes that occurred under the influence of industrialisation and urbanisation, fostered support for the study of mass phenomena and the application of the ‘law of large numbers’. This was further enhanced by the belief in social progress, the striving for social reform, the strong expansion of public administration and the mutual interpenetration of state and society. Due to gradual social and political democratisation, there was an increasing demand for justification and underpinning of government interventions. All these factors contributed to the fact that greater importance was attached to ‘objective’ information – often in the form of numbers and statistics – on the condition of society, with the help of which political debates could be had and (policy-)decisions could be taken. In the Netherlands, for example, in the discussions on the so-called ‘school struggle’ and the ‘social issue’ – themes that were at the top of the political agenda for decades in the late nineteenth and early twentieth century – numerical data were frequently referred to by virtually all parties involved.⁹⁷

Under the influence of this interplay between ‘statistics’ and modernisation, a specific type of ‘objectivity’ became more important. It concerned an objectivity that was defined

96. Desrosières, ‘Commensuration and Probabilism’, p. 311. See also: P. M. M. Klep, “‘May the Devil and Statistics Get them!’ Controversy and Criticism about Statistics in the Netherlands (1850-1940)”, in I. H. Stamhuis, Paul M. M. Klep & Jacques G. S. J. van Maarseveen (eds.), *The Statistical Mind in Modern Society. The Netherlands 1850-1940. Volume II: Statistics and Scientific Work* (Amsterdam: Aksant, 2008), pp. 323-340, on pp. 323-324; Magnello & Hardy (eds.), *Road to Medical Statistics*, p. iv.

97. Cole, *Power of Large Numbers*; Hacking, ‘Was there a Probabilistic Revolution 1800-1930?’, p. 51; Hacking, *Taming of Chance*, p. 5; Maarseveen, Klep & Stamhuis, ‘Introduction’, pp. 31-3; K. H. Metz, ‘Paupers and Numbers: The Statistical Argument for Social Reform in Britain during the Period of Industrialization’, in L. Krüger, L. J. Daston & M. Heidelberger *The Probabilistic Revolution. Volume 1: Ideas in History* (Cambridge MA/London: MIT Press, 1987), pp. 337-50.

by what it was *not*: it concerned *impersonal* and *non-subjective* forms of information. Figures and statistics in particular were considered to be ‘objective’ in this respect. The demand for ‘objective’ knowledge was related to the gradual political democratisation and the importance attached to matters such as accountability, fairness, avoiding arbitrariness, and so on. Another important factor was the upscaling of social, economic and political life. As a result, quantification could come in useful as communication strategy. Porter writes about this:

‘Reliance on numbers and quantitative manipulation minimizes the need for intimate knowledge and personal trust. Quantification is well suited for communication that goes beyond the boundaries of locality and community.’⁹⁸

According to several authors, qualitative, intuitive and traditional sources of knowledge came under pressure this way. In science, for example, the subjective judgement of the expert was to increasingly succumb to quantitative or statistical ‘objectivity’.⁹⁹

The use of measuring instruments, figures and statistics here had consequences that reached much further than just the collection and processing of numerical data. A numerical approach required that phenomena be classified, that matters be measured in a specific way, and that procedures be standardised. As quantitative methods became ever more commonplace, they also increasingly influenced the way in which questions, problems or objectives were formulated. In short, the process of objectification and quantification greatly influenced the way in which people began to look at the world.¹⁰⁰

It is against this background that a profound influence, as *structural* elements of modernity, is attributed to statistics, objectification and quantification. In this context, the French historian La Berge notes that Risueño d’Amador may have understood more keenly than Louis and the numerists what far-reaching consequences the application of the numerical method could have for medicine. She explicitly distances herself from the soothing argument of Louis, and recently of the proponents of evidence-based medicine as well, that the numerical approach is an extension of what physicians have been doing for ages in clinical practice. According to La Berge, (medical) statistics should rather be

98. Porter, *Trust in Numbers*, p. ix.

99. Daston & Galison, *Objectivity*, pp. 371-82; Desrosières, ‘Commensuration and Probabilism’, p. 311; Gigerenzer, ‘Probabilistic Thinking and the Fight Against Subjectivity’, in L. Krüger, G. Gigerenzer & M. S. Morgan (eds.), *The Probabilistic Revolution. Volume 2: Ideas in the Sciences*. (Cambridge MA/London: MIT Press, 1987), pp. 11-34; Porter, *Trust in Numbers*; Swijtink, ‘Objectification of Observation’, pp. 261, 280-81; Toth, ‘Clinical Trials in British Medicine’, pp. 21-2.

100. Cole, *Power of Large Numbers*; Gigerenzer et al., *Empire of Chance*, pp. xiv-xv; Hacking, ‘Was there a Probabilistic Revolution 1800-1930?’, p. 51; Klep, ‘“May the Devil and Statistics Get them!”’, p. 326; Maar-seveen, Klep and Stamhuis, ‘Introduction’, p. 16; Metz, ‘Paupers and Numbers’, p. 357.

analysed as a social *technology* that – just like for example the scalpel, the stethoscope, the hospital and microscopy – may be an instrument of *transformation*. Risueño d'Amador understood better than his opponents that numbers embodied the values of order, precision, rationalisation, standardisation and control, La Berge argues.¹⁰¹ She concludes:

‘The numerical method was not just an extension of the observational method, not just business as usual, as some of the numerists contended. Rather, the introduction of quantification threatened to change the fundamentals of medicine.’¹⁰²

Indeed, there is a strong case to be made for the fact that Louis's method was met with so much resistance among his contemporaries, for it had the potential to fundamentally change medicine. For this reason, according to the historian Weisz, the numerical method was much more controversial than other innovations that were introduced in medicine in the early nineteenth century. Animal experiments and pathological anatomy, for example, did not represent a real threat to the freedom of the clinical judgement of the physician, for the transition still had to be made from animal to human or from post-mortem findings to the individual, living patient. However, the approach Louis advocated, touched ‘the heart of traditional therapeutic judgment’.¹⁰³

Weisz's argument is exemplary for the broadly shared view among historians that Louis's method created a great deal of resistance, for in the view of his opponents, it threatened to affect the *essence of being a doctor*. In addition to the professional status and autonomy of the physician, ethical and ideological elements from the ‘self-definition’ of both individual physicians and the medical profession were at stake. For example, the professional ethics of Risueño d'Amador and many other medical professionals in the nineteenth century were geared towards the setting of the private physician's office, in which the highly individual, private and confidential relationship between the physician and the patient was central. The more public Parisian hospital medicine was at odds with this, and this seemed to apply all the more to the method championed by Louis. In the view of Risueño d'Amador and his proponents, the numerical method represented a utilitarian approach to clinical practice that would irrevocably lead to dehumanisation of both patients and physicians.¹⁰⁴

101. La Berge, ‘Medical Statistics’, pp. 90, 98-101.

102. *Ibid.*, p. 101.

103. Weisz, *Medical Mandarins*, pp. 161-7, the quote is on p. 163.

104. Cole, *Power of Large Numbers*, in particular pp. 212-14; La Berge, ‘Medical Statistics’, pp. 89-108; Lawrence, ‘Incommunicable Knowledge’, pp. 503-20; Matthews, *Quantification*, pp. 22-38; Murphy, ‘Medical Knowledge’, p. 311; Porter, ‘Medical Quantification’, p. 394. See also Risueño d'Amador's argument in: Risueño d'Amador, *Mémoire*, pp. 14, 92, 112, 125.

However, the extent to which the threats that Louis's critics perceived actually became reality in the nineteenth and early twentieth century can certainly be questioned. Both in clinical practice and in laboratory research, the expertise of the professional in the nineteenth and early twentieth century was *not* essentially threatened under the influence of increasing objectification and quantification. Descriptive statistics and the results of measurements with measuring instruments were rather *at the service* of the judgement by the expert than representing a threat to it. At the same time, medical practitioners increasingly began to organise and profile themselves as a professional group. As a result, there was no erosion of the 'professional judgement' of the physician or medical scientist whatsoever (yet). On the contrary, more than ever, the expertise of the professional was emphasised.¹⁰⁵

Thus, the question of how, when and to what extent the 'traditional', subjective judgement of the medical professional was (nevertheless) undermined proves difficult to answer. Nevertheless, in the course of the nineteenth century, the process of objectification and quantification in medicine was already accompanied by a fundamental transformation which, following the example of the medical historian Rosenberg, may be termed the 'specificity revolution'.

The 'Specificity Revolution'

The central subject in Rosenberg's publications on the 'specificity revolution' is 'disease specificity', described by him as: 'the notion that diseases can and should be thought of as entities existing outside the unique manifestations of illness in particular men and women'.¹⁰⁶

Nowadays, it is almost self-evident to look at disease in such a way, but until approximately 1800, the situation was very different. Rosenberg argues that the ideas on the body and on disease were much more 'fluid' and 'non-specific' then. During his research of patient files from the early nineteenth century, it struck him that either a diagnosis was often missing from them, or that they only included general descriptive terms such as 'fever', 'fit', or 'dropsy'. This was illustrative for traditional medicine, which was not so much focused on the disease or diagnosis as on the individual sufferer and their prognosis. The perception of disease as a (humoral) imbalance was accompanied by an approach that would be called 'holistic' today. The balance in the human body could be disturbed

105. See a.o.: Klijn, *Verlangen naar Verbetering*, pp. 79-86; Toth, 'Clinical Trials in British Medicine', pp. 61-6.

106. C. E. Rosenberg, 'The Tyranny of Diagnosis: Specific Entities and Individual Experience', *Milbank Quarterly* 80 (2002), p. 237-260, on p. 237. See also: C. E. Rosenberg & J. Golden (eds.), *Framing Disease: Studies in Cultural History* (New Brunswick NJ: Rutgers University Press, 1992); Rosenberg, *Our Present Complaint*.

by individual peculiarities and all manner of contingent (environmental) factors. Each case of disease largely occurred on its own as the unique product of the constitution and personality of the individual patient, their specific material and social circumstances, and their (medical) biography.¹⁰⁷

As of 1800, fundamentally different ideas on disease slowly gained terrain. Rosenberg writes about this:

‘Pathological anatomy with its emphasis on localized lesions, physical diagnosis, the beginnings of chemical pathology, and studies of normal and abnormal physiological function all pointed toward the articulation of stable disease entities that could be – and were – imagined outside their embodiment in particular individuals and explained in terms of specific causal mechanisms within the sufferer’s body.’¹⁰⁸

Rosenberg emphasises that this development took place before 1860, and thus before the era of the germ theory. However, the view of disease as a specific entity certainly intensified under the influence of the germ theory. Disease entities were increasingly ‘abstracted away’ from the specific manifestations in patients and, to an increasing extent, acquired the status of ideal types. This was expressed by terms such as ‘atypical symptoms’ and ‘complications’, which were introduced as indications of deviations from the ideal type.¹⁰⁹

This way, an ‘ontological’¹¹⁰ concept of disease developed, in which disease is considered an entity that exists, as it were, outside the body of the patient. In other words, disease became separated from the individual patient, and thus became *objectified*. Rosenberg explicitly relates this objectification to *quantification* in medicine which, as described before, occurred as of 1850. Precision instruments such as the thermometer, the chemical analysis of blood and urine samples and other innovations not only contributed to ‘objective’ diagnostics, but also enabled disease conditions to be expressed in actual numbers – and, as Rosenberg phrases it: in standard units. According to him, numbers and measurement results promised the possibility of an objective and precise diagnosis and definition of disease as entities. Conversely, thinking in terms of disease entities was a prerequisite for quantification and the application of statistics in medicine and in the field of public

107. Rosenberg, ‘Tyranny of Diagnosis’, pp. 237-42.

108. *Ibid.*, p. 242.

109. *Ibid.*, pp. 242-243. See also: O. Temkin, ‘Comment’, in A.M. Lilienfeld (ed.), *Times, Places and Persons. Aspects of the History of Epidemiology* (Baltimore and London: Johns Hopkins University Press, 1980), p. 61.

110. See on the ‘ontological’ conception of disease: Rosenberg & Golden (eds.), *Framing Disease*, xxii-xiii; O. Temkin, ‘The Scientific Approach to Disease: Specific Entity and Individual Sickness’, in A. C. Crombie (ed.), *Scientific Change: Historical Studies in the Intellectual, Social and Technical Conditions for Scientific Discovery and Technical Invention from Antiquity to the Present* (New York: Basic Books, 1963), pp. 629-47.

health. Without the acceptance of standardised disease categories, as applied in statistics featuring disease and mortality figures, modern epidemiology would not even have been possible.¹¹¹ In many respects, the same applies to the use of numerical data and statistics in hospitals. In short, there was a clear interplay between objectification, quantification and changing views on disease.¹¹²

In his argument concerning the specificity revolution, Rosenberg is indebted to the sociologist Jewson, who, in 1976, published a now classic article entitled ‘The Disappearance of the Sick Man from Medical Cosmology, 1770-1870’. In it, Jewson distinguished three medical ‘cosmologies’ that coincided with three consecutive periods in the history of medicine, during which the position of the ‘sick human’ changed dramatically. In the era of *bedside medicine*, between approximately 1770-1800, there was a close, interpersonal relationship between the physician and their client. They usually met ‘at the *bedside*’ at the patient’s home. The latter was the ‘patron’ of their physician, and therefore influenced the way in which diagnostics and treatment were put into practice. This was accompanied by a holistic and strongly individualising approach to disease. According to Jewson, this changed due to the emergence of *hospital medicine* between approximately 1800 and 1840. Drawing from the work of the historian Erwin Ackerknecht on the Parisian clinical school,¹¹³ Jewson stated that disease was no longer considered to be something to do with the patient as a whole, but was now specifically localised *in* the body as anatomical lesions in one of the organs. Moreover, due to the admission of the patient from their private domain to the domain of the physician or the hospital, the power balance in the mutual relationship shifted in favour of the physician. However, the latter lost a great deal of this power when *laboratory medicine* started to develop in the period 1840-1870. Particularly as a result of progress in physiology, control on the production of medical knowledge shifted toward the medical scientist. The causes of disease were sought even ‘deeper’ in the body, namely in micro-processes at cellular level. According to Jewson, the ‘sick man’, who had been in control before 1800, and had been approached in his totality as a unique individual, thus totally disappeared from view.¹¹⁴

The overlap between the work of Jewson and that of Rosenberg may be clear, yet the latter emphasises a number of essentially different points. He explicitly distances himself

111. This is not only stressed by Rosenberg, but also by Morabia in: Morabia, ‘Epidemiology’s 350th Anniversary’, pp. 179-83.

112. Rosenberg, ‘Tyranny of Diagnosis’, pp. 243-7. See also: Reiser, ‘Technology’, pp. 262-73; Rosenberg & Golden (eds.), *Framing Disease*; Temkin, ‘Comment’, p. 61.

113. Ackerknecht, *Medicine at the Paris Hospital*.

114. N. D. Jewson, ‘The Disappearance of the Sick-Man from Medical Cosmology, 1770-1870’, *Sociology* 10 (1976), pp. 225-244. Despite its marxistic and schematic approach, Jewson’s thesis is still highly topical. It was, for example, reprinted and elaborately discussed in five commentaries in: *International Journal of Epidemiology* 38 (2009) pp. 622-649.

from the anti-reductionist criticism of the objectification of the patient in the diagnostic process. In his view, specific disease entities may certainly be perceived as being holistic and integrative. He stresses that diagnoses and disease categories fulfil a very important social role:

‘[They] provide both meaning and a tool for managing the elusive relationships that link the individual and the collective, for assimilating the incoherence and arbitrariness of human experience to the larger system of institutions, relationships, and meanings in which we all exist as social beings.’¹¹⁵

Following on from the social role of diagnoses and specific disease entities, Rosenberg also points at what he terms ‘the bureaucratic imperative.’¹¹⁶ Around 1900, it was already clearly visible how the internal order and the management of hospitals were strongly based on the distinction of individual disease categories. The most striking example of this was the way in which patient statuses were standardised and used. In addition, thinking in terms of ‘objective’ and specific disease entities in all manner of areas, such as life insurances, epidemiology and public health, played a crucial ‘bureaucratic’ role as organising and regulating principle.¹¹⁷

In this respect, the specificity revolution was much more than a conceptual change in views on disease. In addition, there was (at least the onset of) a substantial transformation of practice, education and research, as well as of social relationships, organisational structures and (work) processes in healthcare. This makes the specificity revolution a salient example of the link, as often established in the literature, between objectification and quantification on the one hand, and matters such as order, precision, rationalisation, standardisation, control, regulation and transparency on the other hand.¹¹⁸

Conclusion: EBM from a Historical Perspective

With the ‘specificity revolution’, precisely that which Risueño d’Amador feared seems to have happened. Referring to the work of Rosenberg, La Berge writes about this:

115. Rosenberg, ‘Tyranny of Diagnosis’, p. 257, see also p. 256. See also: Rosenberg and Golden (eds.), *Framing Disease*.

116. Rosenberg, ‘Tyranny of Diagnosis’, p. 246.

117. *Ibid.*, pp. 246-7, see also pp. 249-50, 254-5. See about the standardization of patient files also: Timmermans and Berg, *Gold Standard*, pp. 30-54.

118. See also: La Berge, ‘Medical Statistics’, pp. 99-101; Porter, *Trust in Numbers*.

‘The goal of the “specificity revolution” was to transcend the subjective, the local, the idiosyncratic, in order to embrace the universal, to strive for the replicability of disease entities, regardless of culture. This approach was completely at odds with Risueño d’Amador’s understanding of Hippocratic medicine and his view of society.’¹¹⁹

Yet this does not mean that the professor from Montpellier (and not Louis) should be regarded as the big loser of the Academic Debate of 1837. Instead, a more ambivalent conclusion is justified here.

On the one hand, the epistemological status of ‘statistics’ was low within medicine of the nineteenth and early twentieth century. In this respect, the experimental physiological approach and the professional expertise of the clinician or the scientific researcher were clearly valued more highly. Against this background, it is understandable (to an extent) that it is often argued that Louis’s mission to make a veritable science of medicine with the help of the numerical method, completely failed. In a certain sense, Louis’s programme had to succumb to the competing visions of figures such as Risueño d’Amador and Bernard. While this presentation of the state of affairs has been adjusted in a number of respects in this chapter, it remains the case that ‘statistics’ in the nineteenth and early twentieth centuries did not have the impact in medicine Louis hoped for and Risueño d’Amador feared so much. The professional self-definition that seemed to be at stake, remained largely intact. The professional authority of the clinician or scientific researcher was not (yet) under pressure from ‘objective’ quantitative data and methods.

On the other hand, particularly after 1850, there was an undeniable, rather spectacular rise of measurements, numbers and statistics in medicine, and in all manner of other areas. Qualifications in the literature such as ‘the nineteenth century covered by numbers’¹²⁰ make it clear that this was a development that could not be ignored. Since this particularly concerned descriptive statistics, the use of measuring instruments and simple probability calculations, while the more complex methods of mathematical statistics were hardly accepted yet in the medical world, it seems better not to speak of a ‘probabilistic revolution’ here, but of a process of objectification and quantification – where ‘objective’ means ‘impersonal’ and ‘non-subjective’ and numbers particularly have the status of being ‘objective’ in this sense.

The application of statistical data and numerical methods was not neutral here, but also had consequences for the way in which data were collected and ordered, the way in which questions, problems and objectives were formulated, and for countless other issues. The ‘specificity revolution’, which was closely related to the process of objectifica-

119. La Berge, ‘Medical Statistics’, p. 99.

120. A. de Knecht-van Eekelen & I. H. Stamhuis, ‘De met Cijfers Bedekte Negentiende Eeuw’, *Gewina* 15 (1992), pp. 137-9.

tion and quantification in medicine, as well as the important social and bureaucratic role that Rosenberg attributes to (thinking in terms of) specific disease entities point in the direction of (the onset of) a substantial transformation. However, it is difficult to assess how far-reaching this change was. There is little doubt that the low epistemological status 'statistics' had in medicine for a long time, and the relatively large degree of professional autonomy clinicians enjoyed, worked as a constraining or counteracting influence.

All in all, an ambivalent image emerges of the role of numbers and quantitative methods in medicine in the century after the Academic Debate of 1837. 'Upstream', there was the search for certainty, which was characterised by an ongoing struggle between various theoretical and philosophical positions, as embodied by Louis, Risueño d'Amador and Bernard – where the viewpoint of the former had to succumb to the visions of the latter two for the time being. 'Downstream', there was rather a trend of ongoing objectification and quantification in medicine, as a result of which practice in both clinic and laboratory was gradually flooded with statistical data and methods. As a result, an impetus was provided for a dramatic change in medicine.

This conclusion casts its shadow ahead towards the developments of the latter half of the twentieth century. These developments too may be interpreted in two ways. 'Upstream', the scientific and epistemological status of statistical methods clearly increased after 1950, with, perhaps, the EBM movement as culmination. In the hierarchies of evidence used within evidence-based medicine, statistical-epidemiological knowledge ranks at the top, while clinical expertise and pathophysiological reasoning based on knowledge from laboratory research rank lowest. The 'success' of clinical epidemiology and subsequently EBM contrasts with the minor impact of previous attempts to gain a foothold for numerical methods in medicine.

This requires a historical explanation. However, such an explanation cannot really be found with the historian, Matthews. Above all, he projects an image of continuous struggle, as a result of which he does not have a good eye for change.¹²¹ Moreover, Matthews virtually entirely limits himself to the period before approximately 1950, while it was not until after this year that the rise of statistical analysis in medicine began. Partly for this reason, his book is considered 'seriously incomplete'.¹²²

Other authors, including Wiersma and Vandenbroucke, view the history of medicine as a pendulum movement between theoretical and empirical orientations, and, in the last two centuries, between pathophysiological and statistical-epidemiological knowledge. Before approximately 1950, pathophysiological reasoning is purported to have been

121. Matthews, *Quantification*, pp. 141-9.

122. G. Jorland & G. Weisz, 'Introduction: Who Counts?', in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005), pp. 3-15, on p. 4.

prevailing, but afterwards the pendulum supposedly swung the other way, as a result of which statistical-epidemiological reasoning is predominant nowadays. Wiersma and Vandenbroucke expect the pendulum to swing the other way again in the more or less near future.¹²³ This vision is more historical than that of Matthews, as it prompts the demand for explanations for the ‘pendulum movements’, which, among others, may be searched in the specific historical circumstances. However, it is important to not only exclusively look ‘upstream’ at philosophical and epistemological aspects, for if we do, the continuous pendulum movement between theory and empirics is more or less the same as the ‘transcendent’ eternal battle described by Matthews.

‘Downstream’, the process of objectification and quantification in medicine seems to have continued after the Second World War. It could also be argued that a ‘probabilistic revolution’ did occur this time, particularly in terms of practice and methodology. Due to the emergence of clinical epidemiology and EBM, statistical-epidemiological knowledge acquired a central role within (clinical) medicine. This was another step in the process of objectification of the patient and of disease. In theory, ‘laboratory medicine’ could be made to comply with the traditional holistic approach focused on the unique, individual patient. After all, knowledge of physiological micro-processes in the body of the patient could be integrated in the entire biography of the individual patient. In clinical epidemiology and EBM, however, it is about aggregated evidence of (clinical) populations, and no longer about matters taking place in the body of the individual.¹²⁴

In this context, Rosenberg makes it clear that clinical epidemiology and EBM would be inconceivable without an ontological understanding of disease, in which diseases are perceived as specific entities that, to a certain extent, exist in isolation from (the body of) the individual patient. Whether diagnostic, etiological, prognostic or intervention research is concerned, in clinical-epidemiological research, the disease is the starting point every time, and a given that is not questioned further. It is just a matter of, for example, whether a new diagnostic test accurately predicts the presence of the disease, and so on.¹²⁵ Evidence-based clinical guidelines too are ‘disease-oriented’ as a rule.¹²⁶ Rosenberg therefore concludes:

123. Vandenbroucke, ‘Evidence-Based Medicine’, pp. 1335-8; Wiersma, *Twee Eeuwen*, pp. 11-13, 17-19, 280-97.

124. See a.o.: Magnello & Hardy (eds.), *Road to Medical Statistics*, p. iv; S. Nettleton, ‘Commentary: The Appearance of New Medical Cosmologies and the Re-Appearance of Sick and Healthy Men and Women: A Comment on the Merits of Social Theorizing’, *International Journal of Epidemiology* 38 (2009), pp. 633-6, on p. 635; J. V. Pickstone, *Ways of Knowing: A New History of Science, Technology and Medicine* (Manchester: Manchester University Press, 2000), pp. 113-14, 213.

125. This was one of the things I (TB) noted when I attended the course ‘clinical epidemiology’ of the master program ‘epidemiology’ of UMC Utrecht and the weekly clinical epidemiological seminars of the Julius Centre of UMC Utrecht. See also, for example: D. E. Grobbee & A. W. Hoes, *Clinical Epidemiology: Principles, Methods, and Applications for Clinical Research* (Sudbury, MA: Jones and Bartlett, 2009).

126. Rosenberg, ‘Tyranny of Diagnosis’, p. 239.

‘The logic of clinical epidemiology and randomized clinical trials has also turned historically on the ordering of data in terms of entities, as does much of what has come to be called evidence-based medicine.’¹²⁷

Thus, the ever further-reaching impact of the specificity revolution is expressed in clinical epidemiology and evidence-based medicine. Rosenberg argues that specific disease entities have become all-decisive in the course of the twentieth century, and that, as a result the social and bureaucratic significance of diagnosis is greater than ever. He also makes a connection with ongoing objectification and quantification. According to him, the bureaucratic system, which healthcare has become in many respects, is increasingly dependent on the use of ‘objective’ numbers and disease categories.¹²⁸ He writes about this:

‘Everywhere we see specific disease concepts being used to manage deviance, rationalize health policies, plan health care, and structure specialty relationships within the medical profession.’¹²⁹

Thus, the outlines emerge of a historical interpretation of the ‘pendulum movement’ in medicine in the latter half of the twentieth century. The emergence of statistical analysis, clinical epidemiology and EBM seems to be closely related to processes such as quantification, objectification and the ‘specificity revolution’, and by extension, to matters such as regulation, organisation, control and the ‘bureaucratic imperative’. Within this framework, the introduction and impact of epidemiology of chronic diseases, the randomised controlled trial, clinical epidemiology and evidence-based medicine will be described and analysed in the following chapters. Here, among others, the issue raised at the beginning of this chapter will be addressed: Is EBM something essentially new or merely old wine in new bottles?

127. *Ibid.*, 248. See also: Temkin, ‘Comment’, p. 61.

128. Rosenberg, ‘Tyranny of Diagnosis’, p. 249.

129. *Ibid.*, p. 238.



Chapter 2.

On an Incomplete Revolution: Epidemiology of Chronic Diseases, the RCT and the 'Statistical Era' in Medicine

Few developments have had as much impact on medicine, healthcare and (public) health policies of the latter half of the twentieth century as the so-called 'epidemiological transition'. This term refers to a shift in the disease pattern among the populations of Western countries that had already manifested itself early in this century. Infectious diseases began to exact a less heavy toll, while chronic diseases such as cancer and cardiovascular diseases were increasingly prominent features of 'modern life'. This had a profound effect on medical-scientific research, medical practice and government policy. In all these areas, particularly after the Second World War, a strong shift in emphasis occurred from the combating of infectious diseases to tracing, preventing and treating chronic diseases. In this context, essential changes occurred in thinking about and dealing with disease and health.

Another development in the latter half of the twentieth century was of a similar outstanding importance to medicine and healthcare. This is the rise of the Randomised Controlled Trial (RCT). In 1998, in a *BMJ*-editorial, the question was posed: 'Was the randomised controlled trial *the most important development in medicine this century?*'¹ The answer followed immediately:

'Some say yes. Others scoff. Whatever your view, it has clearly been essential for moving to a type of medicine where treatment is expected to be based more on firm evidence of benefit than on the treating doctor's opinion.'²

This editorial was part of a special issue of the *BMJ*, which appeared on the occasion of the '50th anniversary' of what is generally considered to be the 'very first' RCT. It concerned a study, conducted under the auspices of the British Medical Research Council (MRC),

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1. R. Smith, 'Fifty Years of Randomised Controlled Trials,' *British Medical Journal*, 317 (1998), p. 1167. TB's italics.
 2. Ibid.

into the efficacy of the antibiotic streptomycin on tuberculosis, which was reported on in an article in the *British Medical Journal* of 30 October 1948.³ The way in which the streptomycin trial was set up was then already presented by the MRC as an important innovation.⁴ To this day, commentators praise the detailed and lucid description of the way in which patients, with the help of a system with sealed envelopes, were allocated ‘at random’ to the streptomycin or the control group, and, moreover, how it was ensured that those who were involved in the selection of patients for the trial could not know in advance in which of the two groups they would end up.⁵

The canonical status of the MRC trial is mostly due to the leading position the RCT has acquired over the course of time. From as early as the 1970s, regulating authorities required that new medicines be tested in RCTs before they could be launched on the market at all. In the last 30 years, the double-blind, randomised and (placebo-) controlled clinical experiment has developed into the ‘gold standard’ for determining the efficacy of all sorts of medical treatments – and no longer just medicinal treatment. That physicians have to base their therapeutic decisions as much as possible on evidence from randomised trials – one of the key messages of the EBM movement – is now a widely accepted principle.

On the face of it, the rise of RCT on the one hand and the aforementioned epidemiological transition and the accompanying changes on the other, have little or nothing to do with one another. Yet there is an important common factor. Both developments contributed significantly to a considerable increase in the application of statistical methods and techniques in clinical and epidemiological research. Professional statisticians became increasingly involved in the organisation and planning of studies, as well as in the analysis of the collected data. Among medical professionals themselves as well, it became ever more common that they possessed statistical knowledge and skills. Barely embraced by medicine before the Second World War, inferential statistics thus seem to have advanced spectacularly in this area. In the literature, there is mention of the rise of ‘the statistical era in medicine’, with evidence-based medicine as one of its main manifestations.⁶

By extension, it could be argued that the epidemiological transition and the RCT have shaped a number of the prerequisites for the (subsequent) rise of the EBM movement. In the epidemiological study of chronic diseases, concepts, methods and techniques were

3. Medical Research Council, ‘Streptomycin Treatment of Pulmonary Tuberculosis,’ *British Medical Journal*, 2 (1948), pp. 769-82.

4. See a.o.: M. Edwards, *Control and the Therapeutic Trial*, p. 10.

5. See a.o.: I. Chalmers, ‘Unbiased, Relevant, and Reliable Assessments in Health Care,’ *British Medical Journal*, 317 (1998), pp. 1167-8; I. Chalmers et al., ‘The Advent of Fair Treatment Allocation Schedules in Clinical Trials during the 19th and Early 20th Centuries,’ *Journal of the Royal Society of Medicine* 105 (2012), pp. 221-7.

6. See a.o.: Marks, *Progress of Experiment*, pp. 129-30.; Magnello and Hardy (eds.), *Road to Medical Statistics*, p. x; Porter, *Trust in Numbers*, pp. 202-9.

developed that were subsequently also applied within *clinical* epidemiology – the discipline from which EBM originated and which, within the EBM movement, is regarded as the most important producer of reliable evidence. The RCT in turn, occupies a special position within the EBM-philosophy. Not only is it ranked high in the 'hierarchies of evidence'. It is also depicted as a paradigmatic model of how bias and subjectivity can be eliminated, which may also offer guidance in situations in which a randomised experiment is not feasible.

These two important elements of the 'prior history' of EBM form the subject matter of this chapter. An outline will be provided, first of the emergence of the epidemiology of chronic diseases and the relating changes in dealing with disease and health. Then the background of the 'first' modern RCT from 1948 will be described, followed by a brief account of how this experimental research design conquered the world in the ensuing decades. This narrative serves to provide insight into two issues: first, the extent to which the latter half of the twentieth century can (indeed) be considered to be the (onset of) 'the statistical era' in medicine and healthcare; and second, how the development of epidemiology of chronic diseases and the rise of the RCT link up with the themes of objectification and quantification discussed in the previous chapter.

It must be noted here that the relevant secondary literature, upon which this chapter is based, relates virtually exclusively to the developments in Great Britain and the United States. This admittedly constitutes a significant limitation, but it is also true that the epidemiology of chronic diseases and the RCT initially originated mainly in said countries, and were 'exported' to other parts of the world.

Epidemiology of Chronic Diseases⁷

Countless factors have contributed to the epidemiological transition, including greater prosperity, improved sanitary facilities and demographic changes. How this transition

7. This section is based on: M. Parascandola, 'Epidemiology in Transition: Tobacco and Lung Cancer in the 1950s,' in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen's University Press, 2005), pp. 226-48; D. Porter, 'Calculating Health and Social Change: An Essay on Jerry Morris and *Late-Modernist* epidemiology,' *International Journal of Epidemiology* 36 (2007), pp. 1180-4; Stolley & T. Lasky, *Investigating Disease Patterns*; F. Sturmans, 'Epidemiologie en Ziekte-oorzaken: van Monocausaal naar Multicausaal,' *Medisch Contact* 32:11 (1977), pp. 343-9; Susser, 'Epidemiology in the United States,' pp. 147-77; M. Terris, 'The Scope and the Methods of Epidemiology,' *Journal of Public Health* 52 (1962), pp. 1371-6; M. Terris, 'Approaches to an Epidemiology of Health,' *Epidemiology of Health* 65 (1975), pp. 1037-45; P. Weindling, 'From Infectious to Chronic Diseases: Changing Patterns of Sickness in the Nineteenth and Twentieth Centuries,' in A. Wear (ed.), *Medicine in Society: Historical Essays* (Cambridge: Cambridge University Press, 1992), pp. 303-16; C. White, 'Research on Smoking and Lung Cancer: A Landmark in the History of Chronic Disease Epidemiology,' *Yale Journal of Biology and Medicine* 63 (1990), pp. 29-46.

may be accounted for exactly, however, remains unclear. Several authors argue that the term itself is slightly misleading and even an oversimplification. They point out that chronic diseases also frequently occurred in former times, although they were not always recognised as such, but described as signs of ageing. The increasing interest in chronic diseases after the Second World War can therefore not only be attributed to objective changes in population, mortality and morbidity statistics. In addition, the way in which chronic diseases were *viewed* has changed considerably.

In the 1920s and 1930s, chronic conditions were still regarded as degenerative diseases, inevitably occurring in ageing, decaying bodies. Referring to the decrease in child mortality and the greatly increased average life expectancy in Western countries, people also spoke of ‘diseases of civilisation’ or ‘ailments of the modern age’. This view of chronic diseases resulted in there being no cause for preventive or therapeutic measures, even though the increase in cardiovascular diseases was already recognised early in the twentieth century. After the Second World War, a completely different ‘paradigm’ started to develop, in which chronic diseases were understood as being as preventable and treatable as any other condition. Only then did scientists, professionals in healthcare and governments see cause for activism with regard to cardiovascular diseases and cancer.

Two epidemiological research programmes were of crucial importance here. The first programme pertained to the relationship between smoking and lung cancer. An (alleged) heavy increase in the number of cases of lung cancer formed the impetus for a series of mainly British and American studies into the possible relationship with the smoking of cigarettes. In 1950, Richard Doll and Austin Bradford Hill (who was also the ‘inventor’ of the RCT) in England and Ernst Wynder and Evarts Graham in the United States published the results of their so-called ‘case-control studies’, where they tentatively concluded that people who smoked were at higher risk of developing lung cancer than people who did not smoke. In the 1950s and 1960s, more studies followed in which the relationship between smoking and lung cancer emerged even more clearly.

The second research programme related to cardiovascular diseases. In 1910, they already formed the main cause of death in the United States, but in the decades that followed, mortality due to heart disease increased significantly. Between 1900 and the negative high point that was achieved in 1968, the number of casualties attributable to heart disease increased from 8 to 35 per cent. In absolute numbers, a peak was achieved in 1963 with 541,000 deaths.⁸ In the period immediately after the Second World War, the American government, science and society were strongly preoccupied with this ‘epidemic’ of heart disease. In 1948, epidemiologists started tracking a cohort of approximately six thousand

8. Stolley & Lasky, *Investigating Disease Patterns*, p. 85, see also pp. 105-7 on the ‘epidemiological victory’ of the *decrease* of mortality due to heart disease after 1968. The authors claim that, (only) between 1968 en 1976, 630.000 lives were saved as a result of epidemiological insights.

(still) healthy inhabitants of the town of Framingham in Massachusetts over a longer period of time, where it was recorded every two years whether cardiovascular diseases had developed. This Framingham Study, which is running to this day, was soon recognised as the prototype of large-scale, long-term research within a community, and in particular of the so-called 'prospective cohort study'. In 1957, when the first, preliminary results were announced, a number of predictive 'pre-pathological' categories were mentioned, such as age, gender, family history, smoking, high blood pressure and high cholesterol values. In the first official report of the Framingham Study from 1961 the term 'risk factors' was coined for these categories: factors increasing the chance (the 'risk') of the development of cardiovascular diseases. Some of these risk factors were related to 'lifestyle' and, thus, seemed to be influenceable. This implied that chronic diseases no longer needed to be understood as inevitable phenomena of ageing, but were (to a certain degree) controllable and preventable.

This 'paradigm shift' did not come about without a struggle. The findings of both the studies into the relationship between smoking and lung cancer and the Framingham Study were not blindly accepted by the medical-scientific community. Since the end of the nineteenth century, thinking on the origin of diseases had been dominated by the germ theory. This had everything to do with revolutionary developments in bacteriology and microbiology, such as the discovery and identification of pathogenic micro-organisms, followed a while later by unprecedented successes with vaccination and serum therapy. The germ theory and the notions and criteria from the laboratory also made their mark on the way in which the issue of causality was approached within medicine. Very influential were the so-called 'Henle-Koch postulates' for determining whether a specific (suspected) germ was the cause of a certain infectious disease. According to these postulates, among others, the germ had to cause *only* this specific disease, and there could be no other pathogens causing the same disease.

However, with the notion of multiple risk factors for the development of chronic diseases, something of a completely different order was introduced. Not only were several causal factors assumed, rather than one cause, in addition, these factors were thought to only increase the risk of the development of a chronic condition, they were not *necessary* for this. Non-smokers too could develop lung cancer. In addition, smoking was anything but specific as a pathogen, but was associated with almost all important chronic diseases. All this did not correspond at all with the Henle-Koch postulates, and this made the results of both research programmes very controversial. As an answer to this, at the end of the 1950s, epidemiologists and statisticians, including (again) Hill, Lillienfeld, Yerushalmy and Sartwell, formulated alternative criteria for determining causality in chronic diseases. These included strength of association, consistency, a positive dose-response relationship and biological plausibility. However, it would take several decades and many battles before the new ideas became predominant.

In the medical and historical literature, the controversies regarding the relationship between smoking and lung cancer and the multiple risk factors for cardiovascular dis-

eases are often portrayed as a battle between (the deterministic approach of) biomedical laboratory science on the one hand and (the statistical-probabilistic mind set of) epidemiology on the other. In view of the tension between two entirely different conceptualizations of causality, there is some reason for this representation of matters. Yet, it ignores the huge divisions within the fields of epidemiology and biostatistics themselves. Up to and including the 1930s, epidemiology had been a discipline that limited itself to the study of infectious diseases where, in this discipline too, the influence of germ theory was far-reaching. For epidemiologists too, the post-war expansion of their working area with the study of chronic conditions and the new concepts and methods that were created here, were new and far from self-evident. This led to disagreement about the direction in which epidemiology was supposed to move, about who was actually allowed to practice epidemiology (only medical professionals or non-medical professionals too?) and about whether epidemiology was actually a scientific discipline with a domain of its own or nothing but a toolbox with methods and techniques. In brief, in the first decades after the Second World War, all the signs of a barely established discipline in transition and confusion were present.

It is therefore not surprising that a fierce debate arose among epidemiologists and biostatisticians as they were confronted with the new developments in cardiovascular and smoking-lung cancer research. The famed statistician Fisher, for example, did not believe that smoking increased the risk of lung cancer. He argued that a different mechanism had to be at work and suggested that there was a genetic cause that led to a greater disposition to addiction to smoking as well as to the development of lung cancer. In addition, there were many epidemiologists and biostatisticians who believed that there was not an actual increase in the number of cases of lung cancer, but an 'artefact' that, among others, had been created due to improvements in detection and diagnostics. There was also a great deal of debate on the methodological shortcomings of case-control and cohort studies as research designs, the statistics used and the way in which statistical inferences could be derived from them. These highly methodologically tinged debates not only lead to division, but to innovation as well. Mainly due to the contributions of statisticians and social scientists, existing methods and techniques were refined and new ones developed. For example, in 1951 the statistician Cornfield came up with the so-called 'odds ratio', which has played an important role in the interpretation of results of case-control studies ever since.⁹

Thus, the developments within epidemiology went much further than just an expansion of the traditional research area of infectious diseases with the study of non-infectious, chronic conditions. On a conceptual level, the approach to causality changed. This

9. In case-control studies, the 'relative risk' cannot be calculated (as there is no denominator), but the odds-ratio provides a fairly reliable estimate thereof.

was accompanied by a revival of the focus on the interaction between disease and environment, which had been characteristic for nineteenth century 'epidemiology', but had subsequently become somewhat obscured under the influence of the germ theory. In the 1950s and 1960s, epidemiologists frequently used the term 'ecology' to characterise their discipline. This was accompanied by a renewed and strong orientation towards studying health and disease *at the population level*. Partly as a result of this, the application of (ever more complex) statistical methods could advance rapidly. To an increasing extent, epidemiologists had to possess specific statistical knowledge and skills. This was also reflected in how they viewed themselves and their discipline. In the 1970s, the previous references to 'ecology' made way for more 'technical' descriptions of epidemiology in which terms such as 'distribution patterns' or 'occurrence relations' were used. The share of non-medical professionals among epidemiologists – in particular statisticians and social scientists – increased proportionally.

On an institutional level too, epidemiology went through a transformation. Shortly after the Second World War, in 1946 and 1947 respectively, the *British Journal of Preventive and Social Medicine* and the *Journal of Chronic Diseases* were established to meet the needs that arose due to the study of chronic diseases. Partly for the same reason, the name of the *American Journal of Hygiene* was changed to *American Journal of Epidemiology* in 1965, and the *International Journal of Epidemiology* was launched in 1972. Starting in 1960, a whole new 'generation' of epidemiological textbooks was published, which not only focused on chronic diseases, but also included many new methods and techniques, which thus acquired an established status. Epidemiology itself too, increasingly resembled an established discipline, judging by the increase in the number of epidemiologists in academic roles and the increase of university training opportunities.

Changes in Health Attitudes and Practices

The epidemiological transition was accompanied by the development of attitudes and practices with regard to disease and health, which did not exist or barely existed before the latter half of the twentieth century. Originally, medicine was complaint-oriented. As a rule, the symptoms from which patients suffered were the reason for a visit to the physician, who, in turn, made a diagnosis based on the complaints of the patient as well as on signs of disease, often not observed by the patient in question, but which the physician detected with the help of anamnesis, physical examination and, over time, an expanding arsenal of diagnostic tests and screening methods.

With thinking in terms of risk factors for chronic diseases, the 'playing field' of medicine changed entirely. It was no longer restricted to conditions which were already present, but also included diseases which might occur somewhere in the future. A 'patient' with an increased risk of cardiovascular disease did not yet have this disease and was thus

‘healthy’. Yet, they could receive all manner of advice as regards a healthier lifestyle and long-term preventive treatment with medication in the form of blood pressure and cholesterol-lowering medications. This means the line blurred between sick and healthy. Not only sick people, but basically anybody could become the target of medical and preventive intervention. Moreover, a remarkable new phenomenon emerged: *diseases without symptoms*, such as high blood pressure and high cholesterol.¹⁰

These asymptomatic ‘conditions’ were increasingly determined on the basis of numerical measurements using threshold values established by statistical methods. A blood pressure of above 130/80 mm Hg could, for instance, give rise to the diagnosis ‘hypertension’. The American historian Jeremy Greene speaks of the introduction of a ‘third person perspective’ in diagnostic practice. The first and second person perspective – the perceptions of the patient and the physician – became increasingly less relevant. Instead, ‘numerical definitions’ of pathology and risk, which were based on measurements, epidemiological databases, probabilistic calculations and guidelines established by experts, became ever more influential.¹¹

Greene’s analysis largely overlaps with the insights of authors such as Reiser and Rosenberg.¹² In addition, his argument is in line with the remarks made at the end of chapter 1, on the processes of objectification and quantification in medicine, and on the ‘specificity revolution’. As regards the latter, Greene speaks, for example, of: ‘the centrality of disease categories in contemporary concepts of health.’¹³ However, he does add a significant fact here (– as do several other authors for that matter¹⁴): as a result of thinking in terms of risk factors, statistical methods and the concepts of chance and probability gained a much more prominent place than before in attitudes and practice with respect to disease and health.¹⁵ This went hand in hand with the classification of people

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10. See on all this: J. A. Greene, *Prescribing by Numbers. Drugs and the Definition of Disease* (Baltimore: Johns Hopkins University Press, 2007), in particular pp. 6-11; K. Horstman, G. H. de Vries & O. Haveman, *Gezondheidspolitiek in een Risicocultuur. Burgerschap in het Tijdperk van de Voorspellende Geneeskunde* (Den Haag: Rathenau Instituut, 1999), pp. 11, 21-2.
 11. See n. 10 above.
 12. Reiser, ‘Technology’, pp. 262-273; Rosenberg & Golden (eds.), *Framing Disease*; Rosenberg, ‘Tyranny of Diagnosis’, pp. 237-60.
 13. Greene, *Prescribing by Numbers*, p. 5.
 14. See a.o. D. Armstrong, ‘The Rise of Surveillance Medicine’, *Sociology of Health & Illness* 17 (1995), pp. 393-404; Horstman, De Vries & Haveman, *Gezondheidspolitiek in een Risicocultuur*.
 15. The term ‘risk’ was derived from the world of insurance – and had, consequently, strong financial connotations. Ted Porter, among others, has showed how life and (occupational) disability insurers were instrumental in the development of probabilistic concepts and methods. See a.o.: Greene, *Prescribing by Numbers*, p. 12; Horstman, De Vries & Haveman, *Gezondheidspolitiek in een Risicocultuur*, pp. 64-6; M. S. Morgan, ‘The Probabilistic Revolution in Economics – an Overview’, in L. Krüger, G. Gigerenzer & M. S. Morgan (eds.), *The Probabilistic Revolution. Volume 2: Ideas in the Sciences* (Cambridge MA/London: MIT Press, 1987), pp. 135-7.; Porter, *Rise of Statistical Thinking*; Porter, *Trust in Numbers*. See also n. 16 below.

in subgroups or subpopulations. The concept of risk was meaningless if the individual concerned was not considered to be a member of a certain (risk) group. After all, the 'risk' they ran was assessed on the basis of available statistical-epidemiological information on this (sub)population.¹⁶

The notion of risk factors that could be detected and calculated was almost inextricably linked to the conviction that they could be managed as well. In the latter half of the twentieth century all kinds of measures were taken and new forms of (preventive) healthcare were invented to combat cardiovascular and lung diseases. This activism based on 'risk reduction' differed from the public health policy before the Second World War because the emphasis shifted from collective protective measures, such as the building of sewers and the improvement of housing, to personal interventions. Individual citizens were tested for a possible increased risk of cardiovascular diseases, received assistance in stopping smoking or improving their diet, and were urged (towards the end of the twentieth century) to participate in screening programs for the prevention of breast and cervical cancer. The initiative for these interventions usually did not originate from the patients themselves or their attending physician, but from a (public) healthcare agency.¹⁷

In the 1970s in particular, this gave rise to the criticism that the government and the medical profession interfered too much in the lives of individuals, and thus exercised social control. As the philosophy of risk reduction focused on (still) healthy people and thus actually expanded the target group for medical intervention to the entire population, the medical profession was also accused of having an expansionist, hegemonic approach. Usually terms such as 'medicalisation' and 'normalisation' are employed for this.¹⁸ The sociologist David Armstrong, inspired by the work of Jewson on *Bedside, Hospital and Laboratory Medicine*, prefers using the term *Surveillance Medicine*. He points to the emergence of structures and techniques of 'surveillance' and 'monitoring', such as screening, questionnaires and public health campaigns which, in his view, have become an inevitable part of the daily life of citizens.¹⁹ In addition, several other authors refer to the work of Ulrich Beck on the emergence of a 'risk society' or 'risk culture'.²⁰

16. Armstrong, 'Rise of Surveillance Medicine', 399-402; Greene, *Prescribing by Numbers*, pp. 10-14; Horstman, De Vries & Haveman, *Gezondheidspolitiek in een Risicocultuur*, pp. 11, 13, 21-2, 45-52, 71-3; S. Nettleton, 'The Emergence of E-Scaped Medicine?', *Sociology* 38 (2004), pp. 661-79, on p. 670; Nettleton, 'Commentary'.

17. Armstrong, 'Rise of Surveillance Medicine'; Greene, *Prescribing by Numbers*, pp. 11-14, 239; Horstman, De Vries & Haveman, *Gezondheidspolitiek in een Risicocultuur*, pp. 16, 22, 34, 45, 70-3.

18. See on this a.o.: Greene, *Prescribing by Numbers*, p. 5; Horstman, De Vries and Haveman, *Gezondheidspolitiek in een Risicocultuur*, pp. 34, 37, 70, 123-42; Nettleton, 'Commentary'.

19. Armstrong, 'Rise of Surveillance Medicine'. See also: Nettleton, 'Emergence of E-Scaped Medicine', pp. 633, 670, 672; Nettleton, 'Commentary'.

20. See for example: M. Hajer & M. Schwarz, 'Contouren van de Risicomaatschappij', in M. Hajer & M. Schwarz (eds.), *De Wereld als Risicomaatschappij* (Amsterdam: De Balie, 1997), pp. 7-22; Horstman, De Vries & Haveman, *Gezondheidspolitiek in een Risicocultuur*; F. Huisman & H. Oosterhuis (eds.), *Health*

It would be going too far to elaborate in detail on the (mutually different) concepts of 'risk culture' and 'surveillance medicine' here. Two general points may suffice. It is first and foremost important to note that these concepts indicate that *considerable and complex changes* have occurred in the relationship between health and illness; between doctor, patient and society; and between government, the public and the medical profession. These changes cannot be reduced to a deliberately executed 'plan' of governments and the medical profession to increase their power and influence in society. Similarly, a triumphalist explanation, in which the developments described above are perceived as the result of the progress of medical knowledge and technological possibilities, does not hold as well. Contrary to how matters are sometimes represented in the medical literature, there was no straightforward, rectilinear process, in which an objective demographic shift in disease patterns was followed by scientific, epidemiological research into its causes, after which, on the basis of the acquired scientific knowledge, preventive interventions were developed, which resulted in far-reaching changes in the system of medical provisions and public health policies. Instead, the literature on the origin of 'surveillance medicine' and on a 'risk culture' creates an image of a difficult-to-disentangle collection of changes and developments, occurring partly intentionally and partly unintentionally.

Secondly, it is important to realize that many features and problems of current health care are related to these changes and developments.²¹ This applies, for example, to the paradox between a prolonged life expectancy at birth on the one hand and an increased anxiety about health hazards on the other. Furthermore, there is little doubt that the problem of scarcity of health care resources has become practically insoluble, partly because the aforementioned "risk-reduction activism" has put health care systems under tremendous pressure. In addition, as mentioned earlier, the prominent role of statistical-epidemiological reasoning and clinical epidemiology in evidence-based medicine could, in part, be traced back to the conceptual and methodological innovations of the epidemiological study of chronic diseases.

However, it would be wrong to draw too direct lines here. The epidemiology of chronic diseases and the resulting societal trends mainly had an impact in the area of public health and preventive and social medicine. Epidemiology in the United States, the United Kingdom and Canada was not included in the *medical schools*, but in the *schools of public health*. Within 'hard-core' medicine, the prestige and influence of epidemiology and the accompanying statistical methods remained limited. Instead, clinical medicine was strongly focused on biomedical laboratory research, which also rapidly developed in the period after the Second World War, enjoying a very high status.

and *Citizenship: Political Cultures of Health in Modern Europe* (London: Pickering and Chatto, 2013), pp. 35-7.

21. See about this: Rosenberg, *Our Present Complaint*; see also n. 20 above.

Yet the 'paradigm' of risk factors for chronic diseases did eventually penetrate the heart of clinical medicine. This happened partly via the introduction of medicines for the prevention of chronic conditions – most notably cardiovascular diseases – followed by its actual application in medical practice. This had significant consequences for the way in which diagnoses and indications for therapeutic practice were established. Physicians had to balance the potential drawbacks of preventive treatment of (more or less) healthy people against the opportunities for risk reduction. In other words, they had to estimate chances and risks. Probably more than ever, they had to take their decisions 'in the consultation room' on the basis of *statistical-probabilistic reasoning*.

The treatment of people with, for example, blood pressure and cholesterol-lowering drugs was, as Greene and others have demonstrated, not simply the logical and inevitable *result* of the epidemiological knowledge that was acquired on hypertension and high cholesterol as being risk factors for cardiovascular diseases. The development of these medicines rather occurred *in tandem* with epidemiological research in the field of chronic diseases. Already at an early stage, pharmaceutical companies saw the potential of chronic conditions and their prevention as possible sales markets. These sales markets were interesting for they promised almost endless growth, as people would have to take their medication for a prolonged period of time, and often all their lives – as opposed to medication against infectious diseases that was used for a short time as a rule. In addition, the pharmaceutical companies actively tried to expand the scope of the application of, among others, blood pressure and cholesterol-lowering medicines by exercising influence on the definition of cut-off points and indication areas. Thus, the availability of medication could determine the way in which diagnostic practices were shaped.²²

Greene warns that this course of events should not be understood as being the result of a 'monolithic strategy emanating from the board room of a pharmaceutical company or the American Medical Association.'²³ Instead, he speaks of an interaction between several closely linked changes occurring since the 1950s. He refers to changes in demography and epidemiology, in policy structures with regard to biomedical scientific research, in the regulation of the pharmaceuticals market, in clinical practice, in the research and marketing practices of the pharmaceutical industry, and in 'disease-centred activism'.²⁴

Here, the randomised controlled trials (financed by the industry) played a central role in the 'complex nexus of drug and disease, risk and diagnosis, medicine and marketplace', as Greene phrases it.²⁵ This worked both ways. On the one hand, the trials were of great

22. Greene, *Prescribing by Numbers*, pp. 8-17, 225-32. See also: R. Vos, *Drugs Looking for Diseases. A Descriptive Model for the Process of Innovative Drugs Research with Special Reference to the Development of Beta Blockers and the Calcium Antagonists* (Groningen: Rijksuniversiteit Groningen, 1989).

23. Greene, *Prescribing by Numbers*, p. 5.

24. *Ibid.*, pp. 5-6, 10, 14, 17, 225, 233.

25. *Ibid.*, p. xi.

importance to the profiling and launching on the market of new pharmaceuticals and the determination of their indication areas. On the other hand, the RCT itself also benefited, as it were, from the growing market of preventive medication for chronic diseases. In the literature, it is argued that the development of medication such as blood pressure and cholesterol-lowering medicines greatly contributed to the ‘maturation of the RCT’.²⁶

The ‘mature’ RCT subsequently gained a central position in the ideology and practice of evidence-based medicine. All the more reason, therefore, to take a close look at the origins and rise of the RCT.

Therapeutic Evaluation before the RCT Era

A great deal of new information on the history of the evaluation of medical treatments has come to the surface in the last few years, mainly due to the activities of the James Lind Library, founded in 1998. This online library is named after the English ship’s surgeon, James Lind who, halfway through the eighteenth century carried out a sort of mini-trial in which he compared the efficacy of various interventions against scurvy with one another. This study was far from unique. In the James Lind Library, hundreds of examples have been collected of clinical studies from the eighteenth, nineteenth and early twentieth century – i.e. well before the ‘very first RCT’ from 1948 – where there were ‘fair tests of treatments’.²⁷

As yet, a proper synthesis is lacking in which the historical significance of all these ‘proto RCTs’ is identified,²⁸ but it is clear that the methodology of the randomised controlled trial did not come out of thin air. Historical research by, among others, Ted J. Kaptchuk and Ulrich Tröhler has demonstrated that most methodological principles of the RCT were already known in the eighteenth century and were applied as well (to a certain extent).²⁹

However, the ‘proto trials’ from the eighteenth, nineteenth and early twentieth centuries did not enjoy anything like the position the RCT does nowadays. These kinds of studies were mainly performed by ‘marginal men’.³⁰ In addition, clinical experiments were frequently performed to expose quacks. Some alternative healers in turn, went on to

26. Ibid., 232-235; Stolley and Lasky, *Investigating Disease Patterns*, pp. 94-8.

27. See: <http://www.jameslindlibrary.org>

28. See on the need for more historical research on this: Chalmers et al., ‘Advent of Fair Treatment Allocation’, pp. 225-6.

29. T. J. Kaptchuk, ‘Intentional Ignorance: A History of Blind Assessment and Placebo Controls in Medicine’, *Bulletin of the History of Medicine* 72 (1998), pp. 389-433. Tröhler, “To Improve the Evidence of Medicine”; U. Tröhler, ‘The Introduction of Numerical Methods to Assess the Effects of Medical Interventions during the 18th Century: A Brief History’, *Journal of the Royal Society of Medicine* 104 (2011), pp. 465-74.

30. See the publications of Tröhler, referred to in n. 29 above.

conduct such studies themselves in order to substantiate their claims. But in 'mainstream' medicine, 'proto trials' played a very modest role.³¹

There are various explanations for this. For example, the randomised trial, as the medical-historian Meldrum states, is 'by no means a straightforward solution'.³² In this context, she sums up various methodological and ethical implications attached to the RCT.³³ In addition, for a long time, comparative clinical studies were not really in line with the dominant epistemological ideas in medicine. For example, it was difficult to reconcile them with a holistic, humoral vision on disease and health.³⁴ Furthermore, until well into the twentieth century, the expertise and experience of the professional clinician – and not the (numerical) method – were recognised as the bedrock on which the acquisition of medical knowledge was supposed to rest. This ran counter to the methodological principles of the RCT, in which the researcher, with the help of blinding and randomising, is consciously made as 'ignorant' as possible.³⁵

From the late nineteenth century, moreover, laboratory research began to be more highly acclaimed than clinical research. In this period, a stream of new medication and treatment methods started flowing, spurred on by experimental research in physiological and bacteriological laboratories. It was therefore natural to also determine the efficacy and safety of these therapies with the methods of the laboratory.³⁶ New medication was also tested on human subjects now and again, but such clinical studies at most, performed a secondary role.³⁷ It generally concerned small-scale studies, with low numbers of subjects, performed by individual medical professionals, who were more or less interested in evaluating a certain medicine or other intervention. Already in the nineteenth century, it

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31. Edwards, *Control and the Therapeutic Trial*, pp. 12-13; Kaptchuk, 'Intentional Ignorance'; M. L. Meldrum, 'A Brief History of the Randomized Controlled Trial. From Oranges and Lemons to the Gold Standard', *Hematology/oncology Clinics of North America* 14 (2000), pp. 747-9; Porter, *Trust in Numbers*, pp. 202-3.
 32. Meldrum, 'Brief History', p. 746.
 33. See also: V. K. Y. Ho, 'Medicine, Methodology, and Values: Trade-Offs in Clinical Science and Practice', *Perspectives in Biology and Medicine* 54 (2011), pp. 243-55; Toth, 'Clinical Trials in British Medicine', p. 40; A. Yoshioka, 'Use of Randomisation in the Medical Research Council's Clinical Trial of Streptomycin in Pulmonary Tuberculosis in the 1940s', *British Medical Journal* 317 (1998), pp. 1220-3.
 34. See a.o.: Edwards, *Control and the Therapeutic Trial*, p. 12; G. B. Hill, 'Controlled Clinical Trials – the Emergence of a Paradigm', *Clinical & Investigative Medicine* 6 (1983), pp. 25-32, on p. 26.; Toth, 'Clinical Trials in British Medicine', pp. 82-3.
 35. Toth, 'Clinical Trials in British Medicine', p. 256, and see for more on this pp. 85-112. See also: Edwards, *Control and the Therapeutic Trial*, p. 12; Hill, 'Controlled Clinical Trials', pp. 748-9. See also chapter 1.
 36. Toth, 'Clinical Trials in British Medicine', p. 137. See also: L. Byder, 'The Medical Research Council and Clinical Trial Methodologies before the 1940s: The Failure to Develop a "Scientific" Approach', *JLL Bulletin* (2010); Edwards, *Control and the Therapeutic Trial*, pp. 16-21; Marks, *Progress of Experiment*, pp. 21, 28, 32-3; Meldrum, 'Brief History', p. 749.
 37. See n. 36 above.

was widely recognised that the findings of these individual observers with respect to the same treatment methods varied widely.³⁸

One of the underlying problems was that the infrastructure required for the organisation of clinical trials on a large scale was lacking.³⁹ However, this changed in the inter-war period. Two factors had a great impact here. Firstly, in the late nineteenth and early twentieth century, the pharmaceutical sector underwent a metamorphosis from ‘manufacture’ to ‘industry’. Partly influenced by the rapidly developing laboratory research, the manufacturers of pharmaceuticals established their own laboratories and research departments. This led to an explosive increase in the number of industrially produced laboratory-developed pharmaceuticals launched on the market. In their efforts to sell as many of these products as possible, manufacturers often made exaggerated and unfounded claims about their efficacy. Early in the twentieth century, the pharmaceutical industry was already regarded as ‘the great American fraud’ in public opinion in the United States.⁴⁰

Secondly, in the early twentieth century, the dividing lines within the medical profession became increasingly tangible and visible. Even the contemporary lay press reported on the ‘jealousy between physicians and scientists’ in medicine.⁴¹ Clinicians and general practitioners were critical of the increasing dominance of fundamental biomedical research for, in their opinion, it produced little of value to medical practice.⁴² ‘Academic’ medical professionals, in turn, did not conceal the fact that they were less worried about the ‘extravagant claims’ of pharmaceutical manufacturers than they were about the reckless, injudicious and financially-driven prescription practices of ‘peripheral’ physicians.⁴³

In this context, the necessity of more and better regulation of the pharmaceutical market was soon felt. In the United States, the Council on Pharmacy and Chemistry (CPC), founded in 1905 by the American Medical Association, took the lead here. In Great Britain, the Medical Research Council (MRC), a government body, stepped up as the independent arbitrator that could pass judgment on the authorisation of new pharmaceuti-

38. Edwards, *Control and the Therapeutic Trial*, pp. 16-17, 21; Marks, *Progress of Experiment*, pp. 42-53; Meldrum, ‘Brief History’, pp. 749-51; Toth, ‘Clinical Trials in British Medicine’, pp. 155-65.

39. Meldrum, ‘Brief History’, p. 749; Hill, ‘Controlled Clinical Trials’, p. 26.

40. Edwards, *Control and the Therapeutic Trial*, p. 15; Marks, *Progress of Experiment*, pp. 17-18, 21-7; Meldrum, ‘Brief History’, p. 749; Porter, *Trust in Numbers*, p. 207; K. J. Williams, ‘British Pharmaceutical Industry, Synthetic Drug Manufacture and the Clinical Testing of Novel Drugs 1895-1939’ (PhD thesis, University of Manchester, 2005), in particular pp. 229-33.

41. Cited in: Edwards, *Control and the Therapeutic Trial*, p. 20.

42. D. Cox-Maksimov, ‘The Making of the Clinical Trial in Britain, 1910-1945: Expertise, the State and the Public’ (PhD dissertation, University of Cambridge, 1997), pp. 138-82; Edwards, *Control and the Therapeutic Trial*, pp. 17-19, 110; Marks, *Progress of Experiment*, pp. 45-6.

43. Byder, ‘Medical Research Council’; Edwards, *Control and the Therapeutic Trial*, pp. 5-6, 39-66; Marks, *Progress of Experiment*, pp. 27-32.

cals on the market.⁴⁴ Both the CPC in the United States and the MRC in Great Britain first and foremost focused on the methods of the laboratory. The safety and efficacy of medicines had to be primarily demonstrated on the basis of chemical composition and physiological or bacteriological mechanisms. In addition, the biological standardisation of medical preparations was given high priority.⁴⁵

There was also a realisation, however, that clinical tests with human subjects were required as well. The laboratory could admittedly supply the most certain knowledge on the composition and performance of a preparation, but in order to acquire insight into the proper use, the prescribed dosage and possible unforeseen side-effects, clinical research involving real patients was indispensable. In itself, this was nothing new, but in the eyes of those involved, this had to be tackled differently and in a more structured way than had been the case up to that point, through the organisation of cooperative clinical studies.⁴⁶

In practice, however, this proved difficult to achieve. Attempts to systematically conduct such cooperative research were often met with all manner of financial and organisational hurdles. Not only material constraints were the reason for this. Social factors were at least as important. The success of cooperative studies depended greatly on the willingness of the participating researchers to stick to the pre-determined research plan. However, this did not fit well with the dominant 'medical culture that prized individual experience and judgment above all else'.⁴⁷ Individual researchers applied their own selection criteria and methods, each implementing their own treatment regime and using their preferred measuring methods and outcome values. The results of the cooperative clinical trials from the interwar period were therefore hardly less idiosyncratic and as difficult to generalise as those of the small-scale, individual studies from before the First World War.^{48, 49}

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44. Cox-Maksimov, 'Making of the Clinical Trial', pp. 96-137; Edwards, *Control and the Therapeutic Trial*, pp. 17-23; Marks, *Progress of Experiment*, pp. 23-24, 71-82; Meldrum, 'Brief History', pp. 749-50; Toth, 'Clinical Trials in British Medicine', pp. 113-15; Williams, 'British Pharmaceutical Industry', pp. 229-45, 257, 345-50.
45. Byder, 'Medical Research Council'; Edwards, *Control and the Therapeutic Trial*, pp. 16-21; Marks, *Progress of Experiment*, pp. 28, 32-3; Porter, *Trust in Numbers*, 207; Toth, 'Clinical Trials in British Medicine', pp. 114-25, 165-71; Williams, 'British Pharmaceutical Industry', pp. 229-45, 259-71.
46. Byder, 'Medical Research Council'; Edwards, *Control and the Therapeutic Trial*, pp. 16-17, 21, 96-7; Marks, *Progress of Experiment*, pp. 42-70; Meldrum, 'Brief History', pp. 749-51; Toth, 'Clinical Trials in British Medicine', pp. 132, 137, 145-65; Williams, 'British Pharmaceutical Industry', pp. 75-8, 137-41, 208-10, 254-57, 310-11, 345-50.
47. Marks, *Progress of Experiment*, p. 53.
48. Edwards, *Control and the Therapeutic Trial*, pp. 21-3, 100-12; Marks, *Progress of Experiment*, pp. 53-70; Meldrum, 'Brief History', p. 750; Toth, 'Clinical Trials in British Medicine', pp. 137, 155-65; Williams, 'British Pharmaceutical Industry', p. 33, see also pp. 345-420.
49. Historians (see n.48 above) are, for example, extremely critical about the 51 trials that were conducted in the 1930s under the auspices of Therapeutic Trials Committee (TTC), which was established in 1931 by the MRC. According to them, none of these trials were rigorously set up and the involvement of

The Second World War as a Catalyst for the ‘First RCT’

The 1940s heralded a ‘new era for clinical trials’⁵⁰. The outbreak of the Second World War was of crucial importance here. The war involved the mobilisation of the entire British population, a high degree of state control and the availability of financial means and other resources for matters that were deemed to be of national importance. This also applied to pharmaceutical and other medical research that could possibly contribute to sustaining the lives and deployability of as many soldiers as possible. In Great Britain, the MRC was given the opportunity to organise clinical trials on a scale and with a degree of central control ‘unlike any of the trials [...] conducted during the previous decade’.⁵¹ In the United States, a similar situation arose, where, among others, the National Research Council (NRC) was assigned a central role in medical research.⁵²

A first, specific opportunity presented itself through the introduction of penicillin. Already in 1940, there were clear signs that this was an exceptionally powerful medicine. In ordinary times, such reports would be followed by a series of pharmacological and clinical studies, which, only after many years, would provide clarity on the possibilities and correct application method of this medicine. War circumstances, however, required the highest possible acceleration of this process. In the First World War, millions of soldiers had been debilitated by venereal diseases such as syphilis. So it is hardly surprising that army doctors, before penicillin had been thoroughly clinically tested, prescribed the medicine in high dosages to soldiers suffering from syphilis. In the spring of 1943 the production of penicillin had been increased to such a degree that civil application could be considered as well. Overnight, there was a huge demand for this still scarce medicine, partly fuelled by reports in the press about this ‘wonder drug’.⁵³

The NRC committee for venereal diseases decided that, in this situation, cooperative studies with strict protocols were the best way to get a grip on the issue, and to gain clar-

the TTC did not lead to any methodological improvement at all. There is, however, a dissenting voice. Cox-Maksimov argues that the TTC has indeed been instrumental in shaping the conditions for the breakthrough of the randomized controlled trial after World War II. This divergent position is not due to a different assessment of the methodological quality of the TTC-trials, but to a different perspective. Cox-Maksimov is not interested in the scientific achievements of this committee, but in its socio-cultural and historical significance. She argues that the TTC and its parent organization, the MRC, succeeded, despite all the shortcomings of the trials conducted in the 1930s, in establishing an ‘ideology of fairness’. Within almost all stakeholders – the state, the pharmaceutical industry, the experts involved, and the British people – support grew for a more regulated, ‘mechanical’ system for testing and regulating access to the market of new drugs. See: Cox-Maksimov, ‘Making of the Clinical Trial’, pp. 12, 219-20. See for criticisms of Cox-Maksimovs thesis by other historians: Edwards, *Control and the Therapeutic Trial*, pp. 22-3; Williams, ‘British Pharmaceutical Industry’, pp. 29-34, 416-18.

50. Cox-Maksimov, ‘Making of the Clinical Trial’, p. 270.

51. *Ibid.*, p. 222. See also pp. 223-68.

52. Marks, *Progress of Experiment*, p. 99.

53. *Ibid.*, p. 105-9.

ity in the shortest possible time about the efficacy of penicillin as well as about dosages, applications and indications. Partly due to all the available financial and organisational resources, those in charge actually succeeded in generating the desired information relatively quickly. Yet the penicillin studies were disappointing. Never before had the circumstances for a trial carried out according to plan been so favourable but, again, the researchers involved proved unwilling to adhere strictly to the agreements. Participating clinicians found it especially hard to use the low dosages prescribed by the research protocol. Ultimately, nearly half of the researched cases could *not* be 'included' because of incomplete information or deviations from the protocol.⁵⁴

The introduction of streptomycin – an antibiotic against tuberculosis – offered new opportunities shortly before the end of the Second World War. The circumstances were very similar to those surrounding penicillin several years before. The new medicine seemed to be the solution to a major health problem – tuberculosis was one of the most common diseases and causes of death. The medicine was still in very short supply at that point in time while, partly due to publicity in the popular press, there was a huge demand for it. The army, pharmaceutical companies and government agencies were 'besieged by panic requests for the drug'.⁵⁵ At the same time, experts were worried about the 'possible toxicity of streptomycin' and the consequences of 'profligate misuse' of the medicine by 'uninformed physicians'.⁵⁶

This formed the context in which the 'very first RCT', the famous streptomycin study of the MRC in Great Britain, was conducted. Until 1949, streptomycin had only been produced in the United States, and initially it was not even available on the British market. Yet, after the first reports on the new 'wonder drug' had filtered through, the industry and government agencies were inundated with requests for the supply of streptomycin there too.⁵⁷

The unrest surrounding streptomycin began in 1946, the year in which the National Health Service Act came into force. Although there is no direct evidence to support this, it seems more than likely that this act influenced government policy with respect to streptomycin. It would go against the underlying principles of the National Health Service (NHS) to leave the introduction and distribution of the wonder drug to the free market. It was evident that the government needed to step up here. The British medical historian

54. *Ibid.*, p. 108-13 See also: Meldrum, 'Brief History', p. 751.

55. Cited in: Marks, *Progress of Experiment*, p. 114.

56. The quotes are taken from: *Ibid.*, p. 105. See also: Meldrum, 'Brief History', p. 751.

57. Toth, 'Clinical Trials in British Medicine', p. 232; A. Yoshioka, 'Streptomycin in Postwar Britain: A Cultural History of a Miracle Drug', in M. Gijswijt-Hofstra, G. M. van Heeteren & E. M. Tansey (eds.), *Biographies of Remedies: Drugs, Medicines and Contraceptives in Dutch and Anglo-American Healing Cultures* (Amsterdam/New York: Rodopi, 2002), pp. 203-27, on pp. 205-11; Yoshioka, 'Use of Randomisation'.

Benjamin Toth suggests that the streptomycin issue formed a test case of sorts for the Ministry of Health. Now the department needed to demonstrate that it was capable of building up a national health system, and of using the available resources in a rational and efficient way. Something similar applied to the MRC. It was still unclear what precise role this agency would fulfil within the NHS. The introduction of streptomycin offered an ideal opportunity to strongly position the MRC on the new playing field of British healthcare.⁵⁸

Within the Ministry of Health and the MRC, it was soon agreed that the organisation of a British cooperative clinical trial was the ideal means to get a grip on the streptomycin problem.⁵⁹ For the time being, public pressure could be resisted by referring to the ongoing scientific research – and for which the necessity was underlined by consistently pointing to the uncertainty about the efficacy and side-effects of the very toxic streptomycin.⁶⁰ Moreover, the distribution of the medicine could be centralised and regulated via the trial: only participating hospitals were given streptomycin. The latter was of great interest to the MRC in particular, as Toth stresses: ‘The impetus for organizing a trial in the middle of 1946 was the will of the MRC to be central to the roll-out of a powerful new drug in Britain.’⁶¹

Various methodological elements of the famed British streptomycin trial, which was published in 1948, have to be understood against this background. The comparison of a ‘streptomycin group’ with a control group, the double blinding and also the randomised allocation of subjects to either group is described by Toth as: ‘further and more specific ways to regulate the access of hospitals and doctors to streptomycin, and to draw together patients in diverse hospital settings while bypassing organisational and medical authority.’⁶² Randomisation was also a way of obtaining more control in the implementation of the trial itself, and, in particular, of ensuring that participating clinicians were not given the opportunity or tempted to deviate from the research protocols.⁶³

58. Toth, ‘Clinical Trials in British Medicine’, pp. 232-3.

59. *Ibid.*, pp. 234-236; Yoshioka, ‘Streptomycin in Postwar Britain’, pp. 204, 211-4.

60. The way this message was consistently put forward was, (according to Yoshioka:) ‘pessimistic to the point of being deliberately misleading’. See: Yoshioka, ‘Streptomycin in Postwar Britain’, p. 212.

61. Toth, ‘Clinical Trials in British Medicine’, p. 253, see also pp. 233-4, 251-4, 258-9. See also: Edwards, *Control and the Therapeutic Trial*, pp. 13-14; Yoshioka, ‘Streptomycin in Postwar Britain’, pp. 208, 214.

62. Toth, ‘Clinical Trials in British Medicine’, p. 254.

63. Edwards, *Control and the Therapeutic Trial*, pp. 13-14; Meldrum, ‘Brief History’, p. 753; Toth, ‘Clinical Trials in British Medicine’, pp. 254, 196-197, 242; Yoshioka, ‘Use of Randomisation’, p. 1223. See also: I. Chalmers, ‘Why the 1948 MRC Trial of Streptomycin used Treatment Allocation Based on Random Numbers’, *JLL Bulletin* (2010); I. Chalmers, ‘Statistical Theory was Not the Reason that Randomization was used in the British Medical Research Council’s Clinical Trial of Streptomycin for Pulmonary Tuberculosis’, in G. Jorland, A. Opinel & G. Weisz (eds.), *Body Counts. Medical Quantification in Historical and Sociological Perspective* (Montreal/Kingston: McGill-Queen’s University Press, 2005), pp. 309-33; I. Chalmers et al., ‘Advent of Fair Treatment Allocation’, pp. 221-27. See for a similar argument on the practical and organisational functions of blinding: Kaptchuk, ‘Intentional Ignorance’, pp. 421, 431-2.

Something similar applies to the 'first' *American* RCT as well. This was also a streptomycin study that, under the auspices of the Public Health Service (PHS), was carried out and published only a little later than that of the MRC. The background of this PHS study was studied and discussed extensively by historians Meldrum and (in particular) Marks.⁶⁴ They showed that the methodological innovations of the PHS study, including the application of 'centrally controlled randomisation', served *organisational* purposes as well. The problem of researchers not complying with pre-determined protocols, in particular, was largely resolved. Marks writes about this:

'By taking decisions about treatment assignment and outcome evaluation out of clinician's hands, the PHS provided researchers with a mechanism that reduced the investigator's opportunities to change his mind in midstream about the methods and purposes of a study.'⁶⁵

This 'administrative' explanation for the origin of the two 'first' RCT's is not intended to deny the importance of the methodological innovations of these streptomycin trials. Without a doubt, it was also important for the researchers involved to obtain reliable and robust knowledge about the efficacy of the medicine researched. However, the question of why 'the first RCT' was published precisely in 1948 (and not earlier) may only be answered from a broad historical perspective. The various principles of the randomised trial had, in themselves, been available for a longer period of time, yet their actual breakthrough did not materialise until various organisational, administrative and social developments and interests converged.⁶⁶

An Incomplete Revolution

In the above sketch of the origin of the RCT, the influence of mathematical statistics was not, or hardly, discussed. This is partly due to the 'organisational' angle that was chosen, but from a methodological and idea-historical perspective too, mathematical statistics played a much smaller role in the creation of the MRC trial than is often assumed.

This is demonstrated most clearly by Iain Chalmers, in an article entitled 'Statistical Theory was Not the Reason that Randomization was used in the British Medical Re-

64. Marks, *Progress of Experiment*, pp. 116-28; Meldrum, 'Brief history', pp. 752-3.

65. Marks, *Progress of Experiment*, pp. 127-8. See also: Meldrum, 'Brief history', p. 753.

66. Toth, 'Clinical Trials in British Medicine', p. 260; Yoshioka, 'Use of Randomisation', p. 1223; Kaptchuk, 'Intentional Ignorance', pp. 421, 432.

search Council's Clinical Trial of Streptomycin for Pulmonary Tuberculosis.⁶⁷ By 'statistical theory' Chalmers means the ideas of the statistician R.A. Fisher on the application of randomisation in agronomic field experiments. In the interwar period, Fisher's publications⁶⁸ presented randomisation as a way to determine the validity of significance tests and to quantify the degree of uncertainty. According to Chalmers, however, these kinds of 'esoteric statistical reasons' barely played a role in the introduction of randomisation in clinical trials by Austin Bradford Hill. As a statistician and key representative of the so-called 'biometric school', Hill was well aware of the work of Fisher.⁶⁹ However, his famous method with the sealed envelopes had little or nothing to do with the theoretical notions of Fisher but rather with 'the more fundamental and less technical concept of a fair – that is, unbiased – test'.⁷⁰

Chalmers argues that since the eighteenth century, clinical research scientists had already been preoccupied with the question of how to ensure that groups of subjects that were used in comparative studies were really comparable. In the first half of the twentieth century, the method of 'alternate allocation' increasingly became the standard method to reach this objective. Here, subjects were 'alternately' grouped into the treatment and control group, for example on the basis of entry.⁷¹

In Hill's view too, 'alternation' in itself was not inferior to randomisation as a way to ensure the largest possible comparability of intervention and control groups in a clinical trial. However, the precondition was that the researchers and clinicians involved would strictly adhere to the agreed schedule of alternation. Already in the thirties, Hill, as adviser to the MRC, had experienced that, precisely at this point, things would often go wrong. Clinicians who assessed whether a newly arrived patient could be included in a running trial could, when 'alternate allocation' was applied, know in advance if the patient in question would end up in the experimental group or the control group. For Hill – and many others in MRC circles – it had become overly clear in the course of the 1930s that such foreknowledge could consciously or unconsciously lead to the undermining of the agreed

67. Chalmers, 'Statistical Theory was Not the Reason'. See also: Chalmers, 'Why the 1948 MRC Trial'; Chalmers et al., 'The Advent of Fair Treatment Allocation'. The remainder of this section is mostly based on these three articles, but essentially the same is argued (in other words: Chalmers' view is supported in): Edwards, *Control and the Therapeutic Trial*, p. 13; Magnello, 'The Introduction of Mathematical Statistics', pp. 115-17; Marks, *Progress of Experiment*, pp. 141-8; Toth, 'Clinical Trials in British Medicine', pp. 195-7; Yoshioka, 'Use of Randomisation', p. 1221.

68. Respectively the article entitled 'The arrangement of field experiments' from 1926 in the highly influential book *The design of experiments* from 1935.

69. See on Hill and (his role within) the 'biometric school' a.o.: Magnello, 'Introduction of Mathematical Statistics'.

70. Chalmers, 'Statistical Theory was Not the Reason', p. 310.

71. Chalmers et al., 'The Advent of Fair Treatment Allocation'; U. Tröhler, 'Adolf Bingel's Blinded, Controlled Comparison of Different Anti-Diphtheric Sera in 1918', *Journal of the Royal Society of Medicine* 104 (2011), pp. 302-6. See for more on this: <http://www.jameslindlibrary.org>.

allocation schedule. It regularly occurred in clinical trials, for example, that the average age of the first group was considerably lower than that of the second group. Sometimes even the size of both groups differed, clear evidence that the 'alternate allocation' had not been strictly applied. According to Chalmers, this was the only reason why Hill started preferring randomisation to 'alternation'. Only in one crucial respect was 'random allocation' superior: it was much easier here to guarantee a successful 'concealment of allocation' and hence to prevent 'foreknowledge of allocations' on the part of researchers and clinicians participating in the trial.⁷²

That Hill was not the only one aware of this, became clear in 1943, when Philip D'Arcy Hart designed a trial for MRC on the efficacy of the medicine Patulin against the common cold. D'Arcy Hart devised a complicated system where subjects were divided over four (instead of two) groups, with the aim of creating 'confusion' with participating clinicians. Several years later, the same D'Arcy Hart was the secretary of the MRC committee in charge of the streptomycin trial.⁷³

All this suggests there is reason to doubt the 'standard interpretation' that the initial shortage of streptomycin in Great Britain has been crucial for the acceptance of the application of randomisation and a control group in the MRC trial. Hill is purported to have succeeded in overcoming ethical and other objections to his methodological innovations only because it was not possible to provide every patient included in the trial with the medicine. From D'Arcy Hart's role as well as from Toth's archival research cited above it appears that, in MRC circles, there was little resistance to Hill's methods to begin with.⁷⁴

Another point of revision, which is particularly emphasised by Chalmers is that, in the introduction of randomisation, the influence of Fisher and the (development of theory within) mathematical statistics was much less significant than assumed for a long time.⁷⁵ This is highly relevant because generations of medical professionals and medical research scientists were 'raised' with the ideas of Austin Bradford Hill on randomised trials and medical statistics in general. Already in 1937, Hill was asked to write a series of articles for *the Lancet* on the use of statistical methods and techniques in medicine. In the same year, these articles were also published in book form under the title *Principles of Medical*

72. See also n. 48 above.

73. See on D'Arcy Hart and the Patulin-trial, apart from Chalmers articles mentioned in n. 67 above: Cox-Maksimov, 'Making of the Clinical Trial', pp. 221-268, 273-274. See on the ideas, attitudes and activities of several members of the MRC-committee: Toth, 'Clinical Trials in British Medicine', pp. 237-9, 258.

74. See also, on the 'standard interpretation' and the need to revise it: Cox-Maksimov, 'Making of the Clinical Trial', pp. 5-18; Toth, 'Clinical Trials in British Medicine', pp. 258-61.

75. See on the 'standard account' of the role of Fisher and statistical theory: Chalmers, 'Statistical Theory was Not the Reason', p. 310. See also: Marks, *Progress of Experiment*, pp. 138-48. Compare this with: J. R. Matthews, *Quantification*, p. 128.

Statistics. This book became a great success and was reprinted and revised many times for over half a century. The twelfth and last edition appeared in 1992.⁷⁶

In the articles and the first edition of the book from 1937 randomisation was not yet addressed and only 'alternate allocation' was discussed. Hill himself later said about this:

'I deliberately left out the words 'randomisation' and 'random sampling numbers' at that time, because I was trying to persuade doctors to come into controlled trials in the very simplest form and I might have scared them off [...].I thought it would be better to get doctors to walk first, before I tried to get them to run.'⁷⁷

This quote is typical for the way in which Hill conquered the field of medicine for statistics. The great success of his articles and his book was largely the result of Hill's conscious strategy to write about statistics in the most accessible way, mainly underlining the practical relevance for medicine. It is to his great credit that he thus managed to 'open' medicine to statistical methods.⁷⁸

However, there is a downside which, in the course of time, has been regularly pointed out by statisticians and methodologists. It is thought that, partly due to the way in which Hill wrote about medical statistics, most medical professionals are not familiar with the underlying philosophical and theoretical principles and their problematic character. As a result, a situation is purported to have originated, in which researchers and physicians often do not properly understand what they are doing when using statistical techniques, with the result that they are inclined to misinterpret the results of statistical-epidemiological research.⁷⁹

According to several authors, this particularly applies to the randomised trial. In his publications that were intended for a broad audience, Hill offered no theoretical or logical, but only practical and psychological justifications for randomisation, including:

'It ensures that our personal feelings, or judgments, applied consciously or unconsciously, have not played any part in building up the various treatments groups; from that aspect, therefore, the groups are unbiased.'⁸⁰

This pragmatic, 'intuitive' justification for the RCT offered by Hill is, in the view of many statistical theorists, not so much wrong as insufficient. What is lacking is a generally ac-

76. V. Farewell & A. Johnson, 'The Origins of Austin Bradford Hill's Classical Textbook of Medical Statistics,' *JLL Bulletin* (2011).

77. Cited in: Chalmers, 'Statistical Theory was Not the Reason,' pp. 317-18.

78. See for Hill's own reflections on this: Marks, *Progress of Experiment*, p. 147.

79. See n. 81 below.

80. Cited in a.o.: Chalmers, 'Statistical Theory was Not the Reason,' p. 325.

cepted theoretical or logical foundation for randomisation. That many medical professionals and clinical research scientists are still unaware of this, or still do not contemplate this, has allegedly led to 'widespread inclination to overestimate the significance of the results of clinical trials.'⁸¹

Partly for this reason, the historian Marks argues that medicine underwent an *incomplete* statistical revolution at best. On the one hand, the randomised controlled trial has become to most medical professionals 'both symbol and substance of the statistical method in medicine.'⁸² On the other hand, the very same medical professionals generally know little about the driving intellectual force nor about the limitations of the RCT and of statistical methods, principles and techniques in general. According to Marks, this ambiguous situation underlies 'the unresolved conflicts between statisticians and physicians in their views of medical treatment and therapeutic research.'⁸³

The 'Gold Standard'

The comments by Marks and others do not detract from the fact that, in a relatively short time, the RCT was generally accepted as the most suitable method for determining the efficacy of medicines and other medical interventions. Already at the end of the 1950s, the RCT was considered to be the gold standard for therapeutic evaluation within the medical-scientific literature. A number of factors had contributed to this, including the influential writings of Hill, the active promotion of the RCT by the MRC in Great Britain and 'therapeutic reformers' in the United States, the publication of several very successful trials in both countries during the 1950s and an international conference in Vienna in 1959, devoted to the RCT, featuring Hill as one of the speakers.⁸⁴

The practice of drug research, however, did not keep pace with the quick acceptance of the RCT in the literature. Other methods for clinical studies remained popular in the

81. This quote is from: T. Wiersma, *Twee Eeuwen*, p. 280, see also pp. 258, 264-90. See also on all this: Coleman, 'Experimental Physiology', pp. 221-2.; T. Dehue, 'A Dutch Treat: Randomized Controlled Experimentation and the Case of Heroine-Maintenance in the Netherlands', *History of the Human Sciences* 15 (2002), pp. 75-98; Hill, 'Controlled Clinical Trials', pp. 28-9; Marks, *Progress of Experiment*, pp. 144-6, 154-5, 244; Toth, 'Clinical Trials in British Medicine', pp. 23-30, 37-44.

82. Marks, *Progress of Experiment*, p. 138.

83. *Ibid.*, p. 139, see also pp. 138-55. This view of an incomplete statistical revolution is (in essence) supported by Iain Chalmers in his review of Marks' book. In this review, Chalmers mentions several 'statistical issues' which are in his view not (sufficiently) appreciated by clinical investigators. The result is, according to Chalmers, a 'sorry state of affairs' in which 'clinical research remains bedevilled by false negative and selectively published false positive results'. See: I. Chalmers, 'The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900-1990 by Harry M. Marks', *Endeavour* 26 (2002), pp. 119-20.

84. Edwards, *Control and the Therapeutic Trial*, p. 172; Marks, *Progress of Experiment*, p. 133; Matthews, *Quantification*, pp. 133-8; Meldrum, 'Brief History', pp. 753-54.

first decades after the Second World War, while a degree of resistance to the randomised trial continued to exist among both researchers and clinicians. Marks understands why: to a physician – and many scientific researchers were physicians – acceptance of the RCT meant that they had to recognise how little they knew and how great the limitations of medical knowledge were.⁸⁵ For representatives of the authoritative medical profession this was not an easy hurdle to cross. Even in Great Britain, which had been leading in the promotion and application of RCTs for a long time,⁸⁶ according to the famous epidemiologist Richard Doll, it took ‘many years before randomisation was accepted as such a normal procedure.’ According to him, this point was not reached until towards the end of the 1980s.⁸⁷

While in Great Britain, the rise of the RCT occurred slowly but steadily, the developments in the United States were accelerated in the 1960s. The cause was the Thalidomide affair – (in the Netherlands) also known as the Softenon affair. At the end of the 1950s, Thalidomide was introduced as (among others) a medicine to treat morning sickness in pregnant women. Within a few years, alarming reports appeared about children being born with serious deformations as the result of the use of Thalidomide by the mother. In the United States, this medicine had not been allowed on the market yet, because the responsible officer of the Food and Drug Administration (FDA) had doubts about its safety. However, the reports from Germany, Australia and Japan about babies with deformities, which reached the United States in 1961, also had an enormous impact there. The Kennedy administration, Congress, the press and public opinion called for measures to protect the American people against possible similar tragedies in the future. To this end, congress adopted the Kefauver-Harris amendment in 1962, which amended the Food, Drug, and Cosmetic Act from 1938. The result was that the FDA transformed ‘from a modest agency to one of the world’s strongest and strictest regulatory bodies.’⁸⁸

In the years after the Thalidomide affair, the FDA developed a strict policy to which both new and existing medication was subjected. Contrary to before, evidence of the *efficacy* of a medicine was considered to be a prerequisite for the determination of its *safety*. When this policy led to the refusal of medication or its removal from the market, the manufacturers filed lawsuits against the FDA. In 1969, this forced the agency to clearly capture in rules and procedures what demands they imposed on the pharmaceutical industry. These rules and procedures explicitly required the double-blind randomised

85. Marks, *Progress of Experiment*, p. 156.

86. Edwards, *Control and the Therapeutic Trial*, p. 27; Matthews, *Quantification*, p. 27; Meldrum, ‘Brief History’, p. 754.

87. Cited in: Meldrum, ‘Brief History’, p. 754.

88. Timmermans & Berg, *Gold Standard*, p. 171. See on the (limited) role of the FDA before the Thalidomide-scandal: Marks, *Progress of Experiment*, pp. 71-97.

controlled clinical trial. Thus, a scientific procedure became embedded in political, legal and judicial frameworks.

In the course of the 1970s, most Western countries, including the Netherlands⁸⁹ (with Germany as striking exception), followed the American example and similar legislation was drafted. Here too, the Thalidomide affair – in addition to several other 'scandals'⁹⁰ – probably played a key role. Thalidomide has always remained a symbol for the necessity of good regulation of the pharmaceutical market. To the FDA, but to similar agencies in other countries too, the images of the maimed children from the early 1960s, have always defined their self-image and self-consciousness with respect to the important social task they have to fulfil. Thus, the symbolic effect of the Thalidomide affair transcended the direct consequences in the form of changes in laws and regulations.⁹¹

The pharmaceutical companies had no choice but to adapt to the changing circumstances. Despite initial protests, this is exactly what they did. In the 1970s, propelled by money from manufacturers of pharmaceuticals thus wishing to comply with the new requirements, a 'randomised trial industry' developed. The number of RCTs that were published, and which had increased steadily in the 1950s and 1960s, multiplied spectacularly in the 1970s and 1980s (and thereafter).⁹²

Conclusion

This chapter has shown that the RCT was not the self-evidently only right method for the evaluation of the efficacy of medical interventions. Administrative and organisational factors, such as the efforts by the MRC to get a better handle on both the introduction and on the clinical testing of new medication, as well as on the behaviour of individual researchers, were of crucial importance to the coming about of the 'very first' RCT. Such factors also played a key role in the further development of the randomised trial into a 'gold standard'.

The rise of the RCT as an instrument of regulation and control is analytically explored by Theodore Porter in his book *Trust in numbers*. Porter argues that the RCT became the 'standard' when, in many western countries, both public opinion and public officials lost trust in the claims of the pharmaceutical industry, the prescription practices of physicians

89. See for developments in The Netherlands (and the rather 'slow' rise of the RCT there): the forthcoming PhD-thesis of Noortje Jacobs, and: *Het College Ter Beoordeling van Geneesmiddelen: een Registratie* (Utrecht: College ter Beoordeling van de Geneesmiddelen, 1988).

90. See on this: Stolley & Lasky, *Investigating Disease Patterns*, pp. 143-63.

91. See a.o.: Edwards, *Control and the Therapeutic Trial*, pp. 172-3; Matthews, *Quantification*, pp. 138-9; Meldrum, 'Brief History', pp. 755-6; Stolley & Lasky, *Investigating Disease Patterns*, pp. 159-63; Timmermans & Berg, *Gold Standard*, pp. 170-2.

92. Edwards, *Control and the Therapeutic Trial*, p. 172; Meldrum, 'Brief History', pp. 755-6.

and in the trusted methods of evaluation of medicines based on ‘expert judgement’. He points to various factors underlying this loss of trust, such as the changes in the pharmaceutical industry from the early twentieth century, the infrastructure of standardisation and regulation that developed as a result, and he singles out the Thalidomide affair of 1962. Porter concludes: ‘the advances of statistics in medicine must be understood *as responses to problems of trust*, which have been most acute in the context of regulatory and disciplinary confrontations.’⁹³

Porter’s interpretation is influential and is cited by several authors specifically in relation to the randomised trial.⁹⁴ Marks has demonstrated, for example, that ‘therapeutic reformers’ during the interwar period put their trust in the judgment of researchers and clinicians, while their successors in the latter half of the twentieth century put more trust in ‘an impersonal standard of scientific integrity: the double-blind, randomized, controlled clinical trial.’⁹⁵ In this context, Marks speaks of a ‘transfer of authority from institutions to methods.’⁹⁶

Porter’s analysis, which mainly focuses on the influence of *external* pressure on the medical profession, is sensibly complemented by several other authors who focus more on the role of *internal* factors – and in particular on the dividing lines and social processes *within* the profession. For example, Marks places a strong emphasis on the need of academic medical professionals for an instrument enabling them to keep the ‘excessive’ prescription practices of their non-academic peers in check. The increased need for control over the pharmaceutical market and the performance of trials did not only influence medicine from the outside, but was also present within the medical profession itself and – to make matters even more complicated – with medical professionals employed by government agencies such as the MRC.⁹⁷

Marks and several other authors emphasise moreover, that there was not a fully-fledged revolution or a complete shift from disciplinary to mechanical objectivity. In relation to this, this chapter mainly touched on the (still) tense relationship between statisticians and medical professionals. In addition, statistical methods and techniques have never become all-decisive for the actual conduct of clinical studies. Within the design of a randomised trial too, there is ample space for political and social negotiations. This is because numerous choices have to be made – for example with respect to inclusion and exclusion criteria, outcome measures, duration of the experimental treatment and

93. Porter, *Trust in Numbers*, pp. 208-9, see also pp. vii-xii, 3-8, 199-209. TB’s italics. See also: Porter, ‘Medical Quantification’, p. 400.

94. See a.o.: Dehue, ‘Dutch Treat’; Edwards, *Control and the Therapeutic Trial*, p. 173; Marks, *Progress of Experiment*, p. 244; Matthews, *Quantification*, p. 175, n. 16; Wiersma, *Twee Eeuwen*, p. 261.

95. Marks, *Progress of Experiment*, p. 3.

96. *Ibid.*, p. 133, see also: pp. 3, 230, 235-6.

97. *Ibid.*, see in particular pp. 2-3, 27, 40-1, 150-2, 230-1, 236. See also on this: Edwards, *Control and the Therapeutic Trial*, p. 173.

follow-up – on the basis of implicit presuppositions, 'expert judgment', pathophysiological reasoning and practical and financial considerations.⁹⁸

Furthermore, the rise of the RCT (initially) occurred at a great distance from medical-therapeutic practice. In the 1970s, most western countries made the randomised trial compulsory for the admission of new medicines to the market, yet this did not mean that physicians began to base decisions on the treatment of individual patients on the results of RCTs. Most of them kept making therapeutic decisions on the basis of other 'resources', for example on the basis of intuition, clinical experience and expertise, of pathophysiological reasoning, of how they, during their training, had been taught to deal with specific medical problems, and of how they were "used to do things". Some physicians were simply not aware of the trial results or were not capable of proper interpretation of these results. Many however, had serious and substantiated doubts on the quality, generalisability and clinical relevance of many RCTs.⁹⁹

For the epidemiology of chronic diseases too, it is true to say that their influence on everyday medical practice has been limited for a long time. New concepts on the causality of (chronic) diseases, notions such as risk factors and new statistical methods and techniques moreover, made their mark on the 'peripheral' area of public health and research at the population level. Again, the qualification of a partial or incomplete 'statistical revolution' seems to be fitting here. On the one hand, this chapter referred to an essential change in dealing with disease and health, which expressed itself, among other things, in the phenomenon of 'asymptomatic conditions', the emergence of 'surveillance medicine' and a 'risk culture', and the rapidly growing importance of a statistical-probabilistic style of reasoning. On the other hand, (initially) this only seems to have marginally affected clinical medicine.

However, this situation seems to have changed towards the end of the twentieth century. Under the influence of a new clinical variant of epidemiology and the resulting EBM movement, statistical-epidemiological evidence – and in particular evidence from RCTs – was assigned an important place at the heart of medicine. This will be discussed in the next chapter.

98. See a.o.: Marks, *Progress of Experiment*, pp. 133-5, 196, 232, 240-1; Ho, 'Medicine, Methodology, and Values', pp. 243-55.

99. See a.o.: Marks, *Progress of Experiment*, pp. 133-5, 159-62; Meldrum, 'Brief History', p. 75.



Chapter 3.

From Clinical Epidemiology to Evidence-Based Healthcare

The general practitioner and philosopher Tjerk Wiersma typifies evidence-based medicine as a 'strongly clinically-epidemiologically oriented movement'.¹ Elsewhere in medical literature, clinical epidemiology and evidence-based medicine are often also bracketed together. The two seem inextricably linked, both in historical and methodological terms. As it happens, EBM *originated* from clinical epidemiology. In addition, within the EBM movement, clinical epidemiology has always been considered to be the main supplier of reliable evidence. Thus, the discipline symbolises one of the most important and controversial characteristics of EBM: the pronounced preference for 'numerical', statistical-epidemiological evidence over, for example, pathophysiological reasoning and clinical expertise.²

For a good understanding of the phenomenon of evidence-based medicine it is therefore necessary to have some knowledge of the history of clinical epidemiology. This chapter will provide a general outline of how this discipline originated at the end of the 1960s, and how it advanced considerably within academia from the 1980s onwards. The objective is not to provide a detailed overview of the key developments and the contribution of various key players that is as complete as possible, but to offer some insight into the conceptual background and the wider historical context of the rise of clinical epidemiology. In addition, the department of clinical epidemiology and biostatistics at McMaster University in Hamilton, Canada, will be discussed more specifically. This department was one of the most striking representatives of the 'success story' of clinical epidemiology. Moreover, this is where the EBM movement was born.

The second part of this chapter will contain a sketch of how evidence-based medicine itself originated and subsequently further developed in the 1990s and 2000s. It will be

1. Wiersma, *Twee Eeuwen*, p. 290.

2. See in particular: Evidence-Based Medicine Working Group, 'Evidence-Based Medicine'. See also: H. van Crevel, 'Van Evidence Naar Behandeling', *Nederlands Tijdschrift voor Geneeskunde* 140 (1996), pp. 1915-20; Daly, *Evidence-Based Medicine*, pp. viii, 4-5; R. Smith & D. Rennie, 'Evidence-Based Medicine – an Oral History', *JAMA* 311 (2014), pp. 365-7; Y. M. Smulders et al., 'De Rol van Epidemiologisch Bewijs in de Zorg voor Individuele Patiënten', *Nederlands Tijdschrift voor Geneeskunde* 154 (2010): A1910; Vandenbroucke, 'De Opkomst van de Medische Statistiek'; Idem, 'Vele Gezichten'; Wiersma, *Twee Eeuwen*.

come evident that, on the one hand, the clinical-epidemiological ‘roots’ remained crucial, while, on the other hand, there were essential shifts in emphasis and, moreover, a broadening out towards ‘evidence-based health care’ (EBHC). It will appear that these evolutions were related to a ‘merger’ of two (originally) separate movements. EBM emerged from the department of clinical epidemiology at McMaster University in Hamilton, Canada, but was soon to be highly influenced by a British initiative: the Cochrane Collaboration. The Cochrane Collaboration can be traced back to the work of the epidemiologist Archie Cochrane from the 1970s, which inspired the take-off of a ‘systematic review movement’. Whereas clinical epidemiology did not gain a strong position in Great Britain, this systematic review movement did. It can be regarded as the second, British ‘root’ or ‘pillar’ of EBM/EBHC, next to and equally important as the Canadian ‘root’ or ‘pillar’ from McMaster’.

In the last part of this chapter, external criticism of EBM and the way in which leading figures within the movement responded to this will be briefly looked into. This will be followed by a conclusion, in which it will be explained concisely how the entire development ‘from clinical epidemiology to EBHC’ may be seen in the light of the themes of objectification and quantification in medicine discussed in the previous chapters. Here, a preliminary answer will be given to the question of whether EBM represents something essentially new or is merely old wine in new bottles.

Emergence of Clinical Epidemiology: Conceptual

As far as is known, the term ‘clinical epidemiology’ was used for the first time in 1938 by John R. Paul, the then professor of preventive medicine at Yale University.³ He used this term to plead for an approach that was subsequently applied under headings such as ‘social medicine’ and ‘community medicine’ rather than under the ‘clinical epidemiology’ label. For this reason, Paul cannot really be regarded as the founder or a precursor of the latter discipline. This applies to Alvan Feinstein of Yale University and David L. Sackett of McMaster University who, at the end of the 1960s, reintroduced the term ‘clinical epidemiology’ more or less independently of one another.⁴

3. J. R. Paul, ‘Clinical Epidemiology’, *Journal of Clinical Investigation* 17 (1938), pp. 539-41.

4. A. Lilienfeld, ‘Clinical Epidemiology by John R. Paul. Book Review’, *Journal of Chronic Diseases* 9 (1959), pp. 694-5; A. R. Feinstein, ‘Clinical Epidemiology I: the Populational Experiments of Nature and of Man in Human Illness’, *Annals of Internal Medicine* 69 (1968), pp. 807-20; Idem, ‘Clinical Epidemiology II: the Identification Rates of Disease’, *Annals of Internal Medicine* 69 (1968), pp. 1037-61; Idem, ‘Clinical Epidemiology III: the Clinical Design of Statistics in Therapy’, *Annals of Internal Medicine* 69 (1968), pp. 1287-1312; D. L. Sackett, ‘Clinical Epidemiology’, *American Journal of Epidemiology* 89 (1969), pp. 125-8. See also on this: Daly, *Evidence-Based Medicine*, p. 15; D. L. Sackett, ‘Clinical Epidemiology: What, Who, and Whither’, *Journal of Clinical Epidemiology* 55 (2002), pp. 1161-6.

Both Feinstein and Sackett were very concerned about the domination of medicine by biomedical laboratory research, which had rapidly developed, particularly since the Second World War. They recognised that the developments in the field of molecular biology were impressive, yet the result of this, according to them, was the emergence of a considerable distance between the world of medical research and that of medical clinical practice.⁵ Feinstein and two co-authors illustrated this by providing an overview in a 1967 article in the *Annals of Internal Medicine* of the abstracts submitted between 1953 and 1965 for the annual meetings of the American Federation for Clinical Research, the American Society for Clinical Investigation and the American Association of Physicians. The number of abstracts oriented towards illnesses or patients appeared to have decreased considerably during this period, while the number of ‘non-human, non-disease-based abstracts’ had more than tripled. Feinstein and colleagues attributed this trend to an increasing obsession with ‘rat turd grinding in the laboratory’, yielding little to nothing from which practising physicians and their patients could really benefit.⁶

Feinstein and Sackett were of the opinion that the gap between science and practice could only be bridged with the help of *clinical* research focused on ‘intact people’ and on the problems of daily clinical practice. They argued that knowledge of causes and the underlying mechanisms of illnesses was of relatively little relevance for clinical practice. A physician receiving a patient in their consultation room was not so much concerned with aetiology as with making the right diagnosis, the proper assessment of the prognosis and the selection of an adequate treatment. In order to better equip physicians to perform these difficult tasks, there was, according to Feinstein and Sackett, a need for a new ‘basic science’ for medical practice: clinical epidemiology.⁷

The name of this new science referred to the objective of finding answers to *clinical* questions and problems with the help of quantitative and statistical methods from *epidemiology*. In this respect, the development of the epidemiology of chronic diseases (see chapter 2) was a prerequisite for the emergence of clinical epidemiology. The identity of the new discipline has always largely been based upon the application of research designs

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5. Daly, *Evidence-Based Medicine*, pp. 9, 21, 26, 30, 54.
 6. A. R. Feinstein, N. Koss & J. H. M. Austin, ‘The Changing Emphasis in Clinical Research: I. Topics Under Investigation: an Analysis of the Submitted Abstracts and Selected Programs at the Annual “Atlantic City Meetings” during 1953 through 1965’, *Annals of Internal Medicine* 66 (1967), pp. 396-419; A. R. Feinstein & N. Koss, ‘The Changing Emphasis in Clinical Research: II. Sites and Sources of Investigations’, *Annals of Internal Medicine* 66 (1967), pp. 420-34. See also on this: Daly, *Evidence-Based Medicine*, p. 21.
 7. Daly, *Evidence-Based Medicine*, p. 26-7, 54-6; Feinstein, ‘Clinical Epidemiology I’, in particular p. 809; Idem, *Clinical Epidemiology. The Architecture*; Sackett, Haynes & Tugwell, *Clinical Epidemiology*; D. L. Sackett, ‘Zlinkoff Honor Lecture: Basic Research, Clinical Research, Clinical Epidemiology, and General Internal Medicine’, *Journal of General Internal Medicine* 2 (1987), pp. 40-5; Sackett, ‘Clinical Epidemiology: What, Who, and Whither’.

and statistical techniques that originated from the epidemiological study of cancer and cardiovascular diseases.⁸

To a certain extent, Feinstein and Sackett recognised that they were indebted to the ‘mother discipline’. Yet they usually expressed themselves negatively and sometimes even with some contempt about ‘traditional’ population epidemiology. They were both trained to be internal medicine physicians – Feinstein also trained as a mathematician – and did not hide the fact that they were not in favour of the public health orientation of epidemiology. In addition, they regularly expressed their opinion on what they perceived to be the poor scientific quality of many epidemiological studies in which a relationship was established between chronic diseases and lifestyle factors. Their main objection, however, was that epidemiology had lost touch with direct patient care. Feinstein commented about prominent British epidemiologists, including Sir Richard Doll who had participated in famous studies on the relationship between smoking and lung cancer, that they did not know ‘which way up the patient is.’⁹ Sackett considered epidemiology, partly because of its focus on public health, to be ‘boring and irrelevant.’¹⁰ He repeatedly stated that medical students thought few subjects were as uninteresting and boring as epidemiology and public health.¹¹

By thus distancing themselves from both biomedical laboratory research and population epidemiology, Feinstein and Sackett tried to create room for clinical epidemiology.¹² However, they each put the new discipline into practice in their own unique way. When Feinstein used the term clinical epidemiology for the first time in 1968, he described it as a branch of science that dealt with ‘the occurrence rates and geographic distribution of disease; the patterns of natural and post-therapeutic events that constitute varying clinical courses in the diverse spectrum of disease; and the clinical appraisal of therapy.’¹³ This definition is indicative of a very substantive and methodological ori-

8. Feinstein, ‘Clinical Epidemiology I’, pp. 808-11; Daly, *Evidence-Based Medicine*, p. 16; C. D. Naylor et al., ‘Clinical and Population Epidemiology: Beyond Sibling Rivalry?’, *Journal of Clinical Epidemiology* 43 (1990), pp. 607-11; J. K. Tobacman & R. P. Wenzel, ‘Clinical Epidemiology: Further Consideration’, *Journal of Clinical Epidemiology* 43 (1990), pp. 633-5.

9. Daly, *Evidence-Based Medicine*, pp. 32-34, 150 (the quote is from both p. 32 and p. 150). See also: Feinstein, ‘Clinical Epidemiology I’, pp. 810, 819; Idem, *Clinical Epidemiology. The Architecture*, pp. viii-ix.

10. Daly, *Evidence-Based Medicine*, pp. 54.

11. See a.o.: Sackett, ‘Clinical Epidemiology’; Idem, ‘Three Cheers for Clinical Epidemiology’, *International Journal of Epidemiology* 13 (1984), pp. 117-9; Idem, ‘Zlinkoff Honor Lecture’; Idem, ‘Clinical Epidemiology: What, Who, and Whither’. See also: Daly, *Evidence-Based Medicine*, pp. 55-7; W. W. Holland, ‘Inappropriate Terminology’, *International Journal of Epidemiology* 12 (1983), pp. 5-7; Idem, ‘Epidemiology and the Use of Words’, *Journal of Clinical Epidemiology* 44 (1991), pp. 962-3; Naylor et al., ‘Clinical and Population Epidemiology’.

12. This was, in particular, very explicitly the case in: Sackett, ‘Zlinkoff Honor Lecture’.

13. Feinstein, ‘Clinical Epidemiology I’, p. 809.

entation, which has always remained characteristic of the way in which Feinstein approached his discipline.¹⁴

The contrast with Sackett could hardly be greater, as he was not so much focused on the content of the discipline of clinical epidemiology as on the characteristics of the clinical epidemiologist. This was manifested in the definition of clinical epidemiology that he consistently applied from 1969 onwards: ‘The application, *by a physician who provides direct patient care*, of epidemiological and biometric methods to the study of diagnostic and therapeutic processes in order to effect an improvement in health.’¹⁵ Sackett severely regretted the fact that the clinician-scientist threatened to become an ‘endangered species’. He attributed this to the revolutionary developments in both fundamental biomedical research and in epidemiology, which had led to a situation where more and more specific knowledge and skills were required in order to be able to participate in research in these areas. Thus, it had become increasingly difficult for physicians to develop sufficient expertise in both clinical medicine and in either of the two scientific domains. The result was that research in both the biomedical laboratory and epidemiology was increasingly carried out by people who had specialised to become scientists and, as a result, no longer worked in clinical practice, or who were not even trained to be medical professionals at all. According to Sackett, this was the main cause of the aforementioned ‘movement away from the bedside’ in both scientific areas, with as a serious consequence that many biomedical and epidemiological studies answered questions and produced results that were ‘clinically inappropriate’. Sackett wanted to solve this problem by training clinical epidemiologists who combined clinical expertise with knowledge of statistical-epidemiological methods and techniques. These people could establish a link between science and practice because they were equipped to ask meaningful questions and assess research results for their practical results as well as to comply with all requirements of scientific ‘rigor’.¹⁶

Sackett by no means failed to notice that his focus on the clinical epidemiologist was something essentially different from Feinstein’s view of clinical epidemiology.¹⁷ He

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14. See a.o.: A. R. Feinstein, *Clinical Judgment* (Baltimore: Williams and Wilkins, 1967); Idem, *Clinical Epidemiology. The Architecture*; Idem, *Clinimetrics* (New Haven: Yale University Press, 1987). See also: Daly, *Evidence-Based Medicine*, pp. 25-35; D. A. Kessler & R. I. Horwitz, ‘In Memoriam: Alvan R. Feinstein, MD (1925-2001)’, *American Journal of Medicine* 112 (2002), p. 501; J. A. Knottnerus & P. Tugwell, ‘After ARF’, *Journal of Clinical Epidemiology* 55 (2002), pp. 1159-60.; W. O. Spitzer, ‘The Teacher’s Teacher: A Personal Tribute to Alvan R. Feinstein’, *Journal of Epidemiology and Community Health* 56 (2002), pp. 328-9.
 15. Sackett, ‘Clinical Epidemiology’, p. 125. See also: Idem, ‘Zlinkoff Honor Lecture’; J. B. Wyngaarden, ‘The Clinical Investigator as an Endangered Species’, *New England Journal of Medicine* 301 (1979), pp. 1254-9.
 16. Sackett, ‘Clinical Epidemiology’; Idem, ‘Zlinkoff Honor Lecture’; Idem, ‘Clinical Epidemiology: What, Who, and Whither’.
 17. See on the various definitions of and approaches to clinical epidemiology (of Feinstein and Sackett, but also many others): Naylor et al., ‘Clinical and Population Epidemiology’, Sackett, ‘Clinical Epidemiology:

thought that Feinstein remained too close to ‘big E’ epidemiology and public health, only adding ‘clinical decision-making’ to it.¹⁸ Feinstein was no less critical of Sackett:

‘What Sackett proposed and what I proposed were utterly different, completely different. I was proposing a *specific intellectual domain* and trying to define its contents and challenges with clinical people. What Sackett proposed was that clinical epidemiology was classic public health epidemiology done by someone who happened to be a clinician. I thought that was idiotic.’¹⁹

For a good understanding of the ideas of Feinstein and Sackett, as well as of the mutual differences, an article by the sociologist Marc Berg may be helpful.²⁰ This article focuses on the various ways in which medical practice was (re)conceptualised in the latter half of the twentieth century. This is highly relevant, as both Feinstein and Sackett argued that many things went wrong in medical practice because physicians took decisions based on vagaries, intuition and authority. To them, clinical epidemiology was the perfect tool to make medical practice by physicians ‘more scientific’ and thereby improve it.²¹ However, from the mutual differences in approach to clinical epidemiology alone it may be deduced that Berg rightly argues reality was much more complex:

‘There was no single, unilinear process in which a previously ‘unscientific’ practice became ‘scientific’ [...]. What ‘scientific’ medical practice *is* according to medical authors, and, concurrently what medical practice’s problems *are*, took on different forms in different times and contexts.’²²

Berg substantiates this with an analysis of medical textbooks and the editorials of successive volumes of several leading medical journals. In the first decades after the Second World War medical practice was described in them as the ‘artful application of scientific knowledge.’ This presupposed a clear separation between the domains of science and practice, where the medical practice of physicians was admittedly based on a solid

What, Who, and Whither’; W. Spitzer, ‘Clinical Epidemiology’, *Journal of Chronic Diseases* 39 (1986), pp. 411-415.; Tobacman and Wenzel, ‘Clinical Epidemiology’.

18. Sackett, ‘Clinical Epidemiology: What, Who, and Whither’, p. 1162.

19. Quoted in: Daly, *Evidence-Based Medicine*, p. 56.

20. M. Berg, ‘Turning a Practice into Science: Reconceptualizing Postwar Medical Practice’, *Social Studies of Science* 25 (1995), pp. 437-76. This article is largely based on Berg’s PhD-thesis: Idem, *Rationalizing Medical Work: Decision Support Techniques and Medical Practices* (Maastricht: Rijksuniversiteit Limburg, 1995). Berg’s article will be summarized in the next couple of pages. Further references will not be given of this, except in the case of literal quotations.

21. See for example: D. L. Sackett, ‘A 1955 Clinical Trial Report that Changed My Career’, *JLL Bulletin* (2008).

22. Berg, ‘Turning a Practice into Science’, p. 438.

foundation of scientific knowledge, but was not perceived as 'science' *in its own right*. Pleas, such as those of Feinstein and Sackett, for a more scientific medical *practice* were therefore lacking in the period immediately after the Second World War. On the contrary, there were warnings of 'too much science' in medical practice. Of course, physicians were expected to apply medical knowledge, but in the practice of the *art of medicine* they were to avoid being dominated too much by science, becoming 'mindless technicians' in the process.²³

According to Berg, this somewhat ambivalent attitude towards science changed into a more pronounced positive attitude over time. Editorials from the 1950s and 1960s bore testimony to a clear awareness that medicine experienced a 'Golden Age', (partly) due to developments in biomedical research. Against this background, a shift occurred in thinking about the relationship between science and practice in medicine. Rather than there being a rather clear separation between the two domains, editors increasingly spoke of the penetration of practice by science. The term 'scientific medical *practice*' was introduced, but its meaning was by no means fixed. From the late 1960s onwards, *various* new 'discourses' originated on the relationship between medical science and medical practice.

A major contribution to one of these 'discourses' was made by Feinstein. Where medical practice was previously considered to be the (skilful) application of scientific knowledge, Feinstein was one of those who introduced the view that medical practice *itself* should be regarded as a scientific activity. In Berg's terminology, Feinstein situated science in the *structure* of medical practice. The shortcomings in medical practice identified by Feinstein occurred precisely in this area. He maintained that the meticulousness with which issues were defined, classified, clarified, recorded and evaluated in science was lacking in medical practice. From this, it followed that the solution to many problems in medical practice lay in making the terminology and procedures used 'more scientific', among other ways, through standardisation.

This is exactly what Feinstein attempted to do with his 'version' of clinical epidemiology. In his influential book *Clinical judgment* from 1967,²⁴ for example, he focused on the various steps physicians had to complete in the process of diagnosis, prognosis and treatment. He attached a great deal of importance here to the careful classification into subgroups of the 'heterogeneous lumps' of patients with the same diagnosis, but with many differences in respect of age, (severity of) symptoms, et cetera. Using several concrete examples and applying the mathematical methods of Boolean algebra and Venn diagrams, he showed that the effects and right choice of treatment could differ widely between such subgroups. In his view, the 'systematic clinical taxonomy', as Feinstein called

23. Ibid., p. 442.

24. Feinstein, *Clinical Judgment*.

his approach, was of essential importance for clinical practice. Physicians could only make the right decisions about the care for a patient if they were able to properly identify to which subcategory a patient belonged as well as the prognosis and the best treatment policy for this subcategory.²⁵

In the course of the 1970s and 1980s, the ‘discourse’ of which Feinstein was an important exponent, was increasingly overridden by another (re)conceptualisation of the relationship between medical science and medical practice. Science was not situated in the *structure* of medical practice here, but in the *‘head’* of the clinician. The emphasis was placed on intellectual capabilities such as ‘collecting information and synthesizing it into integrated concepts compatible with known diseases.’²⁶ Not only ‘science’, but also the causes of the problems of medical practice were localised in the mind of the physician within this ‘cognitivist discourse’, as Berg calls it. It became increasingly common to describe the behaviour of physicians as erratic and irrational. They were said to be ‘sloppy’ most of the time, driven by ‘wishful thinking’, have an opinion ready before they had collected all the facts and make many wrong choices because their statistical-probabilistic reasoning skills were severely inadequate. Various ‘decision-support techniques’ were developed as solutions, whether or not computer-assisted. Berg mentions, among others, the ‘rule-following expert systems’ and ‘clinical decision analysis’.

Although Berg does not refer to Sackett’s version of clinical epidemiology and evidence-based medicine,²⁷ Sackett may, in view of his focus on the clinical epidemiologist as a *clinician*, be regarded as a typical representative of the cognitivist ‘discourse.’²⁸ This sheds an illuminating light on a number of differences between Feinstein and Sackett. It applies, for example, to the difference in accessibility of their work. The sociologist Jeanne Daly writes that Feinstein’s work and, in particular, his later publications were so complicated and contained so many new concepts and mathematical methods that they were virtually illegible to ‘ordinary’ clinicians. As a result, Feinstein’s immediate impact

25. See (apart from Feinstein himself and Berg) also: Daly, *Evidence-Based Medicine*, pp. 28-31.

26. Quoted in: Berg, ‘Turning a Practice into Science’, p. 458.

27. An explanation for this might be that Berg published his article in 1995, only 3 years after the concept of evidence-based medicine was internationally launched. By then, it was probably still not fully clear whether or not this new concept was to have a significant impact on medicine, what it actually meant, and how it would evolve. Clinical Decision Analysis and the other ‘decision support techniques’ that Berg studied in his PhD research project were introduced earlier than EBM and therefore more feasible as subjects for assessment and analysis.

28. In 2004, both Clinical Decision Analysis and EBM were discussed in a way similar to Berg’s article (for example with respect to the influence of cognitive psychology) by Arthur Elstein, in: A. S. Elstein, ‘Decision Analysis, Evidence-Based Medicine and Medical Education: a Case-Study in the Diffusion of Innovation Within Academic Medicine’, in I. S. Kristiansen & G. Mooney (eds.), *Evidence-Based Medicine: in its Place* (London/New York: Routledge, 2004), pp. 106-23.

on clinical medicine is purported to have been limited although, as a ‘teachers’ teacher’²⁹, he indirectly significantly contributed to the dissemination of clinical epidemiological ideas.³⁰ Berg’s analysis of Feinstein’s conceptualisation of the relationship between science and medical practice makes clear that Feinstein was not primarily concerned with reaching clinicians either, but with the development of standardised, scientific procedures for the benefit of the medical process of diagnosis, prognosis and treatment.

Rather than this process, Sackett intended to make the practising physician ‘more scientific’. Clinicians formed his primary target group and partly for this reason, his work was much more accessible than Feinstein’s. Many of Sackett’s efforts were aimed at offering ‘tools’ enabling clinicians to make more rational decisions. By this, he meant, for example, that they were to base their treatment policy on evidence from ‘proper’ RCTs rather than on intuition, habit or on what had once been taught by their mentors. This ultimately resulted in evidence-based medicine.

Berg’s article raises a number of questions. Why, for example, did new ‘reconceptualisations’ of medical practice originate precisely from the late 1960s? And why was the ‘cognitivist discourse’ ultimately the most influential? In this respect, Berg refers to the more positive connotations of ‘science’ during the 1950s and 1960s, the ‘Golden Age’ for medicine. In addition, he mentions the impact of cognitive psychology, which was very much on the rise in the 1970s, and that of the computer as a model of the human brain. He furthermore argues that the cognitivist vision on the relationship between science and practice fits in well with the individualistic notions of professional autonomy, which were predominant in the medical world. The standardisation of procedures advocated by Feinstein, on the other hand, raised concerns that ‘third parties’, such as governments and insurers, were able to get too much of a grip on medical practice.

Berg only briefly addresses all these issues, for he is not primarily concerned with the abovementioned matters. He wishes to make a different point, namely that the rise of, among others, clinical epidemiology and clinical decision analysis should *not* be interpreted as a ‘gradual and unswerving process of turning an art into a science’.³¹ Instead, there were *several* (re)conceptualisations of medical practice and, hence, *various* problem definitions and solution strategies.

This implicitly presupposes that there was a hierarchical relationship between, on the one hand, the (re)conceptualisations and, on the other hand, the identification of prob-

29. This is how Feinstein has been typified several times, amongst others by Suzanne Fletcher in: Daly, *Evidence-Based Medicine*, both on p. 26 and p. 32. See also: Knottnerus & Tugwell, ‘After ARF’, pp. 1159-60; W.O. Spitzer, ‘The Apprenticeship of an Editor and the Secret Role of a Mentor’, *Journal of Clinical Epidemiology* 55 (2002), pp. 1173-5; Idem, ‘The Teacher’s Teacher’.

30. Daly, *Evidence-Based Medicine*, pp. 30-2.

31. Berg, ‘Turning a Practice into Science’, p. 438.

lems and solutions; with Berg, the former seem to *precede* the latter. It is also quite conceivable, however, that there was an opposite ‘movement’ as well, where the problems experienced and the solutions available influenced the manner in which the relationship between science and medical practice was (re)defined. It would therefore seem more appropriate to assume there was a complex interplay, two-way traffic rather than one-way traffic. It therefore follows that it is interesting to complement Berg’s conceptual analysis with a more contextual interpretation of the origin of clinical epidemiology.

Emergence of Clinical Epidemiology: Context

‘Clinical epidemiology was born during a time of ferment in health care and amid uncertainty about the processes of clinical decision-making.’³² This quote from Daly summarizes, in a nutshell, the historical context in which the emergence of clinical epidemiology and the ‘reconceptualisations’ of medical practice from Berg’s article may be placed. From the late 1960s onwards, a combination of internal and external challenges³³ to medicine appears to have triggered methodological self-reflection by (a number of) medical professionals.³⁴

Within medicine, more and more people started to realise that the tempestuous developments in their profession since the Second World War not only brought with them considerable progress but new problems too. In a matter of decades, the daily work of a practising physician had become a great deal more complex. All the new opportunities in the field of diagnostics and therapeutics, however much desired, resulted in physicians having to make a great many more decisions than before. Besides, they always had to arrive at a solution in the context of uncertainty (to a greater or lesser extent). This was primarily the case with the application of diagnostic or therapeutic *innovations*, for insufficient practical experience had been gained here to be fully convinced of their effectiveness and safety. Tragedies such as the Thalidomide affair, but also the less spectacular,

32. Daly, *Evidence-Based Medicine*, p. 25.

33. The distinction between internal and external challenges is highly artificial and is only used to establish some structure in the range of developments in healthcare and medicine in the latter half of the twentieth century.

34. Following is just a rough sketch of these ‘internal and external challenges’ facing medicine and of the manner in which the medical profession responded to this. Indeed, this issue will be examined in more detail in parts II and III. Although this analysis will pertain to the situation in the Netherlands then, the same factors and developments as briefly mentioned below will be addressed to a large extent. The sketch below of the ‘context’ of the emergence of clinical epidemiology is derived from, among others, the following literature: Daly, *Evidence-Based Medicine*, pp. 1-3, 9-11, 21, 27, 49; J. Lewis, ‘Providers, “Consumers”, the State and the Delivery of Health-Care Services in Twentieth-Century Britain’, in A. Wear (ed.), *Medicine in Society: Historical Essays* (Cambridge: Cambridge University Press, 1992), pp. 317-46; Timmermans & Berg, *Gold Standard*, pp. 13-18; G. Weisz et al., ‘Emergence’.

more mundane experiences with disappointing results and unexpected side-effects had taught physicians that *new* did not always equate to *better*. Another complicating factor was the growing specialisation in medicine. To an increasingly lesser extent, physicians were able to supervise and handle the treatment process of a patient by themselves, instead of having to collaborate ever more often with colleagues from other disciplines or from other healthcare institutions. Despite this specialisation, it became (virtually) impossible for physicians to keep up with all the developments in their profession in the field of their own specialism.

In the course of the 1960s and 1970s, concerns about all these ‘complicating factors’ were expressed in an increasing preoccupation with the phenomenon of ‘inter-physician variation’. It was regularly pointed out that different physicians often used widely varying criteria for determining a certain diagnosis or for the application of a certain treatment. The American epidemiologist Wennberg demonstrated at the beginning of the seventies that these differences not only existed between individual medical professionals, but also at the macro level between various regions. His research showed that certain surgical interventions in some areas in the United States were performed 3 to 9 times more often than in other areas. Shortly thereafter, other researchers demonstrated that similar patterns occurred in other countries as well. The differences in medical practices between individual countries appeared to be even greater, partly because there could be major differences in terms of ‘health culture’ and organisation of healthcare. All this variation between individual physicians, regions and countries implied that not every patient always received the best possible care.

The phenomenon of inter-physician-variation is probably symptomatic of all periods, but in the late 1960s and the 1970s it was considered to be a greater problem than ever. Firstly, it was thought that inter-physician-variation was more prevalent than before as a result of factors such as: (a) the increase in the number of options and decision moments in medical practice; (b) the specialisation and the resulting increased heterogeneity within the medical profession; and (c) the differences in the extent to which individual physicians, regions or countries could keep up with all the new (technological) developments in medicine. Secondly, it was widely thought that inter-physician variation had more serious consequences than before, as medicine was, due to all the new diagnostic and therapeutic possibilities, more powerful than ever. Therefore, physicians were not only capable of doing more good than in the past, but also of causing more harm when making wrong choices.

The debates on inter-physician variation focused attention on the way in which physicians arrived at their decisions in everyday practice. The question was emphatically raised as to whether these decisions were sufficiently rational and scientifically substantiated. It would therefore seem to be all but coincidental that the debates in the medical world on inter-physician variation coincided in time with the ‘reconceptualisations’ of the relationship between medical science and medical practice, addressed by Berg. Exponents of

these 'reconceptualisations' – Feinstein and Sackett, but also other influential commentators, such as the British epidemiologist Archie Cochrane and the Danish gastroenterologist Henrik Wulff – had one thing in common, despite all their mutual differences: they were all of the opinion that scientific knowledge from laboratory research was completely insufficient to be able to solve the problems of medical practice, such as inter-physician variation. According to them, not only had a gap emerged between fundamental laboratory research and clinical practice, but also had medical practice itself become much more complex, resulting in a need for a different, complementary 'basic science' for medical practice.

This 'reconceptualisation' of medical practice occurred in a period in which medicine was also under several *external* pressures. First and foremost, this had to do with the spiralling costs of healthcare. In this respect, there was essentially nothing new under the sun: early in the twentieth century and in the period immediately after the Second World War too, governments of Western countries were concerned about the need to contain the costs of healthcare. In the 1970s, however, an important new element was added to this. Increasingly, there were serious doubts as to whether ever-rising expenditure on healthcare had provided 'value for money', as it was suspected that health gains and life expectancy had not increased accordingly among the population. This doubt was fed by the seminal work by Thomas McKeown, a British professor of social medicine, who argued that increased life expectancy in Western countries since the nineteenth century was, above all, due to higher living standards and improvements with regard to nutrition, housing and sanitation. According to him, expensive curative healthcare had only contributed to this to a very limited extent. In a sense, McKeown provided governments with a strong argument to plead in favour of cutbacks – or in any event the dampening of expenditure increases – precisely in a time when, after decades of considerable growth, the economy had fallen on hard times in many Western countries, as a result of which the affordability of the welfare state was at stake as well.

The issue of the financial-economic boundaries of healthcare did not exist in isolation, but also had to be linked to broader social processes. According to Eric Hobsbawm, the famous British historian, a social and cultural revolution was unfolding in Western countries in the 1960s and 1970s.³⁵ He mentions a large number of developments that contributed to this or which were part of this, such as the enormous increase in the standard of living due to post-war economic growth, the development of the welfare state, the rise of 'consumerism', the increase in the average level of education among the population, the emergence of mass universities, changes in average size and composi-

35. E. Hobsbawm, *Age of Extremes: The Short Twentieth Century 1914-1991* (London: Abacus, 1994), pp. 287-343.

tion of families, secularisation and the changes in sexual morals. This social and cultural revolution was accompanied by a certain undermining of 'the establishment'. The power of traditional authorities was no longer considered to be self-evident. Instead, there was a call for democratisation, civic participation, transparency of procedures and decision-making processes, and accountability of directors and officers. Against this background, a great deal of criticism of 'professionals' and 'experts' was expressed from the 1970s onwards. Moreover, all this caused their political and social roles to change.

Within this trend, the medical profession occupied a special place. Few professions had so successfully gained power, autonomy and respect as the medical profession. It is therefore not strange that, when, in the 1970s, the position of traditional authorities and experts came under attack, the medical profession was one of the primary targets. In addition to the previously mentioned work of McKeown, there were also various other influential publications in which even more radical criticism of medicine and its practitioners was expressed. According to the philosopher Illich for example, the possible favourable effects of medical treatments could not counterbalance the (iatrogenic) damage medicine caused to patients. Other philosophers and sociologists, including Foucault, Zola and Laing, stated that medical professionals acted paternalistically, exercised social control and worked in a dehumanising manner.

Another theme that also enjoyed an increasing level of public interest from the seventies onwards was the rights of patients – who were increasingly referred to as 'consumers'. Patient and consumer organisations shot up like mushrooms and demanded their place at the 'negotiating table'. In this period, more attention than before was paid to issues such as (safeguarding) healthcare quality and the ethical boundaries to be observed by medical professionals, mainly for the protection of the patient. In many countries, this (ultimately) also led to new laws and legislation in these fields as well as to the institutionalisation of health law and medical ethics.

The above sketch of the context in which clinical epidemiology originated is cursory and incomplete, but sufficient to give an impression of the background to the growing concerns of a number of medical professionals about the state and societal position of medicine and their desire to do something about it. It is important to note here that the internal and external challenges facing medicine are not only mentioned in retrospect in the secondary literature,³⁶ but were also regularly discussed in the medical literature of the 1960s and 1970s themselves. In 1966 for example, the following analysis of the 'modern' problems of healthcare appeared in the *Milbank Quarterly*:

36. These 'challenges' are concisely summarized in: Timmermans & Berg, *Gold Standard*, p. 16.

‘In the past few decades the problems involved in the provision of health services have become increasingly complex, for various reasons – the increase of medical knowledge and techniques, leading to more complex and more expensive types of care; the increased diversity of interrelationships in society; the increase of urbanization; the changes in the age composition of populations; and, perhaps most importantly, the growing belief that everyone has the right to the “best” health care.’³⁷

It is also important to note that clinical epidemiology was only one of many solutions suggested to deal with the challenges described above. From the 1970s onwards, health services research, medical audit, clinical decision analysis, protocol medicine and medical technology assessment also emerged. Furthermore, not only were there major differences in the approach between Feinstein and Sackett; influential ‘kindred spirits’ such as Wulff³⁸ and Cochrane each also set their own accents.³⁹

In other words, what clinical epidemiology meant and in what direction this discipline would develop had by no means crystallised in the 1970s. Moreover, clinical epidemiology was only one of several initiatives within the medical profession and by no means a leading ‘voice’ in the debate on the future of medicine.⁴⁰ This changed in the 1980s, however, when clinical epidemiology experienced a remarkable ‘breakthrough’.

Breakthrough in the 1980s

In more than one way it was noticeable in the course of the 1980s that clinical epidemiology was ‘fashionable’ within academic medicine.⁴¹ Several textbooks on clinical epidemiology appeared, for example, some of which were reprinted several times. This ap-

37. Quoted in: Daly, *Evidence-Based Medicine*, p. 13.

38. See on Wulff a.o.: *Ibid.*, pp. 35-40. Wulff was highly influential in the Netherlands, so he will be mentioned several times in parts II and III.

39. See on the various definitions of and approaches to clinical epidemiology: Naylor et al., ‘Clinical and Population Epidemiology’; Sackett, ‘Clinical Epidemiology: What, Who, and Whither’; Spitzer, ‘Clinical Epidemiology’; Tobacman & Wenzel, ‘Clinical Epidemiology’.

40. Thus, in the 1970s, the ‘rise’ of clinical epidemiology remained limited to several local successes in Canada and the United States. Clinical epidemiology generated relatively little attention in the medical literature of that time, for more on this, see, among others: Daly, *Evidence-Based Medicine*, p. 75. The British epidemiologist W.W. Holland, an important critic of clinical epidemiology and, in particular, the ideas of Sackett, subtly raised this issue in 1983. He recalled that Sackett, when first launching the term ‘clinical epidemiology’ in the *American Journal of Epidemiology* in 1969, had explicitly mentioned that he hoped he would receive a lot of ‘feedback’. Holland had been looking for this ‘feedback’ but as he wrote, ‘I have not found any in the literature’. See: Holland, ‘Inappropriate Terminology’, p. 6; Sackett, ‘Clinical Epidemiology’, p. 128.

41. This is a paraphrase from: J. P. Vandenbroucke, ‘On the New Clinical Fashion in Epidemiology’, *Epidemiology and Infection* 102 (1989), pp. 191-8.

plied, among others, to the very first clinical epidemiological textbook, which appeared in 1982, entitled *Clinical Epidemiology: the Essentials*.⁴² The book was a reflection of the courses that the authors, Fletcher, Fletcher, & Wagner, had been teaching for several years at McGill University in Montreal, Canada and at the University of North-Carolina, and which were mainly inspired by the works of Feinstein and Wulff. When the authors were working on their book, it was not at all certain that they would use the title ‘clinical epidemiology’ for it. They knew that Feinstein and Sackett used this term, but this was ‘not yet the generally accepted term.’ Many people warned them not to use the term ‘epidemiology’ at all, for it would deter clinicians. When the book was completed in 1982, however, the situation had changed: ‘the term *clinical epidemiology* became attractive, a good thing, a nice label to attach to something.’⁴³ This also became apparent in 1985, when both Feinstein and Sackett (and colleagues) published their textbooks, entitled *Clinical Epidemiology. The Architecture of Clinical Research*,⁴⁴ and *Clinical Epidemiology. A Basic Science for Clinical Medicine*⁴⁵, respectively. In 1986 and 1988, two more textbooks on clinical epidemiology were published, written by professors from Seattle and Montreal⁴⁶, respectively.

Characteristic of the extent to which clinical epidemiology was gaining ground, was the name change of the *Journal of Chronic Diseases* in 1988 to *Journal of Clinical Epidemiology*. Already in the early 1980s, the journal – which was then headed by Feinstein (!) and a former student of his, Walter Spitzer of McGill University – had developed into the main platform for publications in the field of clinical epidemiology. This is why, for several years already, it had been proposed to change the name of the journal. However, both editors initially thought it was too early to decide on this name change, for clinical epidemiology was still an ‘uncertain entity’. By 1987 however, clinical epidemiology had become ‘well established and respected’, so that the new name could be introduced after all.⁴⁷

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42. R. H. Fletcher, S. W. Fletcher & E. H. Wagner, *Clinical Epidemiology: The Essentials* (Baltimore: Williams & Wilkins, 1982).
 43. Daly, *Evidence-Based Medicine*, p. 20-5, both quotes are on p. 24.
 44. Feinstein, *Clinical Epidemiology. The Architecture*.
 45. Sackett, Haynes & Tugwell, *Clinical Epidemiology*.
 46. These books were, respectively: N. S. Weiss, *Clinical Epidemiology: The Study of the Outcome of Illness* (New York [etc.]: Oxford University Press, 1986); M. S. Kramer, *Clinical epidemiology and biostatistics: a primer for clinical investigators and decision-makers* (Berlin: Springer, 1988). See also: Daly, *Evidence-Based Medicine*, pp. 71-3; Sackett, ‘Clinical Epidemiology: What, Who, and Whither’.
 47. D. P. Earle, ‘Biostatistics, Epidemiology, Clinical Trials and the *Journal of Chronic Diseases*’, *Journal of Chronic Diseases* 32 (1979), p. 345; D. P. Earle, ‘The Editor Says Farewell’, *Journal of Chronic Diseases* 34 (1981), pp. 573-4; A. R. Feinstein & W. O. Spitzer, ‘Happy Anniversary and an Impending Change of Name’, *Journal of Chronic Diseases* 40 (1987), pp. 1-2.; A. R. Feinstein & W. O. Spitzer, ‘The Journal of Clinical Epidemiology: Same Wine, New Label for the Journal of Chronic Diseases’, *Journal of Clinical Epidemiology* 41 (1988), pp. 1-7. In other journals too, there was an increasing attention for clinical epidemiology as from ca. 1980. See for example: A. Sherrington, ‘Adapting the Journal’s Scientific Section to the 1980s’, *Canada Medical Association Journal* 123 (1980), pp. 7-8.

The increasing use of the name 'clinical epidemiology' in textbooks, the *Journal of Clinical Epidemiology* and in countless publications in other medical journals as well, was a reflection of the extent to which this new discipline began to establish an important niche for itself within academic medicine. In the second edition of the textbook of Sackett and colleagues, which was published in 1991, the authors wrote about this with appropriate pride:

'Departments and divisions of clinical epidemiology have been created [...] all over the world, and the fasted growing specialty sections of several research societies are devoted to this area [...]. Clinical epidemiologists have been selected for chairs and chairmanships of departments of science and for senior editorship of major clinical journals.'⁴⁸

Sackett and his co-authors did have some reason for this triumphalism. Yet it must be seen in perspective. Clinical epidemiology had admittedly achieved some recognition as a scientific discipline, but this was nothing compared to the status of biomedical laboratory research. Moreover, the advance of clinical epidemiology was not equally successful everywhere. In North America and Australia, the position of the new discipline was possibly the strongest, but the extent to which clinical epidemiology was accepted varied greatly between the universities and medical schools concerned. In addition, the manner in which this discipline was interpreted differed from place to place.⁴⁹

Such a variation also occurred elsewhere in the world. In continental Europe, clinical epidemiology was particularly successful in the Netherlands, and to a certain extent in the Scandinavian countries, while this was hardly the case in countries such as France, Belgium and Germany.⁵⁰ In Great Britain too, clinical epidemiology barely took root, despite a series of pleas in favour of it, which appeared in *the Lancet* and the *British Medical Journal* around 1980 and the explicit 'campaign' conducted by E.D. Acheson, professor at the Environmental Epidemiology Unit of the University of Southampton. A possible explanation is that, after the reformation of the National Health Service in 1974, a new discipline, community medicine, was institutionalised in Great Britain which, to a certain extent, already fulfilled many of the roles clinical epidemiologists managed to

48. D. L. Sackett et al., *Clinical Epidemiology: A Basic Science for Clinical Medicine*. Second ed. (Boston/Toronto/London: Little, Brown and Company, 1991), p. xii. See also: Sackett, 'Clinical Epidemiology: What, Who, and Whither?'

49. This was acknowledged by Sackett himself, see: Sackett, 'Clinical Epidemiology: What, Who, and Whither?'

50. Interview with Bossuyt; A. Hofman, *Veertig Jaar Epidemiologie aan de Erasmus Universiteit 1969-2009* (Rotterdam: Erasmus Medisch Centrum Rotterdam, afdeling Epidemiologie, 2009), p. 29; Sackett, 'Clinical Epidemiology: What, Who, and Whither?'; W. O. Spitzer, 'The Future of Epidemiology', *Journal of Clinical Epidemiology* 49 (1996), pp. 705-9; K. H. Jöckel & A. Stang, 'Perspectives of Clinical Epidemiology in Germany', *Journal of Clinical Epidemiology* 52 (1999), pp. 375-8.

attract elsewhere. Consequently, the ‘playing field’ for clinical epidemiology was already occupied by community medicine.⁵¹

Besides, public health epidemiology had a long tradition and a relatively strong position in Great Britain. Research in this area – particularly according to British epidemiologists themselves – was far ahead internationally. In addition, the distance between traditional ‘population’ epidemiology and clinical medicine was less than in the United States. To clinicians working within the National Health Service, public health was far less remote a concept than it was, for example, for physicians operating in the privatised American healthcare system. Perhaps this was the reason why, in Great Britain, there was less need than elsewhere for a specific *clinical* variant of epidemiology. Furthermore, from a relatively strong starting position, British public health epidemiologists seem to have combated clinical epidemiology, and in particular Sackett’s version of it, with quite some success.⁵²

From a British perspective, the (pre)history of Evidence-Based Healthcare does not start so much with clinical epidemiology and figures such as Feinstein, Sackett and Wulff, as with the publication of the book, *Effectiveness and Efficiency: Random Reflections on Health Services* by Archie Cochrane in 1972, featuring an explicit call for the use of results from RCTs as a guideline for medical practice. In this respect, Cochrane was a kindred spirit of, for example, Sackett and Wulff, but still, his was a completely different approach. Where Wulff and Sackett primarily focused on the individual clinician, Cochrane was first and foremost concerned with safeguarding the quality, accessibility and affordability of British healthcare, in the long run too. With his book, he aimed to point the way to a more effective and efficient, and therefore sustainable *National Health Service*. This was in his view a prerequisite for his ultimate objective: *free access for all to all* (effective) health care. Thus, Cochrane’s work was more focussed at the ‘macro level’ of healthcare and, moreover, more (explicitly) politically motivated than that of clinical epidemiologists such as Sackett. While clinical epidemiology barely got off the ground in Great Britain, Cochrane’s ideas did catch on. With Cochrane as main inspiration, a ‘RCT and systematic review movement’ developed, which eventually resulted in the foundation

51. Daly, *Evidence-Based Medicine*, pp. 129-30, 139, 147-52. See also on the British context: ‘Epidemiology and the Clinician’, *Lancet* 316 (1980), p. 957; ‘A Plea for Clinical Epidemiology’, *Lancet* 281 (1980), p. 1163; E. D. Acheson, ‘Clinical Practice and Epidemiology: Two Worlds Or One’, *British Medical Journal* 1 (1979), pp. 723-6; Idem, ‘Clinical Practice and Community Medicine’, *British Medical Journal* 2 (1979), pp. 880-1.; Idem et al., ‘Epidemiology and Clinical Practice’, *British Medical Journal* 280 (1980), p. 1122; R. M. Acheson, ‘Community Medicine: Discipline or Topic? Profession or Endeavour?’, *Community Medicine* 2 (1980), pp. 2-6.; Berridge, ‘Changing Policy’; W. M. Garraway et al., ‘A Method of Teaching Epidemiology in a Clinical Setting’, *Medical Education* 10 (1976), pp. 496-502; Holland, ‘Inappropriate Terminology’, pp. 5-7; Lewis, ‘Providers’; T. J. Orchard, ‘Epidemiology in the 1980s’, *Lancet* 316 (1980), pp. 845-6; Sackett, ‘Clinical Epidemiology: What, Who, and Whither’; A. Smith, ‘Epidemiology and the Clinician’, *Lancet* 316 (1980), p. 1087.

52. See n. 51 above.

of the Cochrane Collaboration in 1992, which would prove to be enormously influential (– more about this later).⁵³

The major differences between countries and the example of the ‘deviating’ British pre-history of EBM mean that the ‘breakthrough’ of clinical epidemiology during the 1980s cannot be discussed in general terms. Each country has its own story as regards the introduction of clinical epidemiology.

That clinical epidemiology underwent a remarkable ‘breakthrough’ in a number of countries should, in addition to specific favourable circumstances, also be attributed to the drive of clinical epidemiologists themselves. Of crucial importance was that some of them were extraordinarily successful as *researchers*. They were able to produce new knowledge and, above all, publish in the most highly regarded journals – more so than, for example, ‘population epidemiologists’. This is perhaps the most important explanation for the rise of clinical epidemiology as an academic discipline in the 1980s. In research, precisely in this period, a trend of commercialisation and expansion was set, which is sometimes referred to as a transition from ‘little science’ to ‘big science’.⁵⁴ Part of this trend was that ‘research output’ in terms of publications in ‘high impact journals’ increasingly determined the policies of university boards and the unfolding of academic careers. Much more so than in the previous decades, professors, academics and university departments were judged by their productivity in the field of research. The contours of the current ‘publish or perish’ culture began to be visible.

There is clear evidence that, in this changed climate, clinical epidemiology thrived better than, for example, public health epidemiology and preventive and social medicine. Not only did clinical epidemiologists succeed in publishing in high impact journals and in collecting research funds. They also proved to be attractive to clinical departments of

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53. The term ‘RCT and systematic review movement’ is derived from the interview with Vandenbroucke. See also a.o. F. X. Bosch (ed.), *Archie Cochrane: Back to the Front* (Barcelona: 2003), see in particular pp. 243-53; I. Chalmers, L. V. Hedges & H. Cooper, ‘A Brief History of Research Synthesis’, *Evaluation & the Health Professions* 25 (2002), pp. 12-37; I. Chalmers, ‘Archie Cochrane (1909-1988)’, *JLL Bulletin* (2006); Daly, *Evidence-Based Medicine*, pp. 130-9; A. Maynard & I. Chalmers (eds.), *Non-Random Reflections on Health Services Research: On the 25th Anniversary of Archie Cochrane’s Effectiveness and Efficiency* (London: BMJ Publishing Group, 1997); Smith & Rennie, ‘Evidence-based medicine’ (see also the website of the EBM – oral history project: <http://ebm.jamanetwork.com>); Timmermans & Berg, *Gold Standard*, p. 14.
54. See a.o.: P. Galison & B. Hevly (eds.), *Big Science: The Growth of Large-Scale Research* (Stanford: Stanford University Press, 1992); J. Heilbron, M. van Bottenburg & I. Geesink, *Wetenschappelijk Onderzoek: Dilemma’s en Verleidingen* (Amsterdam: KNAW, 2000). This transition was already ‘predicted’ in: D. J. De Solla Price, *Little Science, Big Science* (New York & London: Columbia University Press, 1963); J. R. Ravetz, *Scientific Knowledge and its Social Problems* (Oxford: Clarendon Press, 1971).

medical faculties and academic hospitals in the role of advisors and partners in the setting up of research programmes.⁵⁵

In the field of academic *education* too, clinical epidemiology started to eclipse its ‘mother discipline’. It was no wrongful assertion by Sackett, Feinstein and several other clinical epidemiologists that medical students generally barely took an interest in education in public health epidemiology. They themselves were of the opinion that they could relate much better to the interests and experiences of these students, the vast majority of whom pursued a career in clinical medicine, for they applied the methods and techniques of epidemiology to clinical issues, acting ‘as clinicians with white coats, stethoscopes, and patients’.⁵⁶ And indeed, the training courses and workshops in the field of clinical epidemiology offered, among others, at Yale University, where Feinstein worked, the Johns Hopkins University, the University of North Carolina, McGill University and McMaster University tended to begin to flourish in the course of the 1970s. This also substantially contributed to the gradual spread of the ideas and methods of clinical epidemiology. Feinstein, Sackett and other pioneers in this area were very aware of the importance of this. The former, for example, spoke of the creation of a ‘new breed’ of clinicians and scientists.⁵⁷ Ultimately, evidence-based medicine also developed from clinical-epidemiological education.⁵⁸

55. This will be elaborated on in detail in part II with regard to the situation in the Netherlands. However, there are clear indications that this is also true for other countries. See a.o.: Daly, *Evidence-Based Medicine*, pp. 15, 24-25, 57, 64; Spitzer, ‘Clinical Epidemiology’; J. P. Vandenbroucke, ‘Epidemiology in Transition: A Historical Hypothesis’, *Epidemiology* 1 (1990), pp. 164-7.

56. Daly, *Evidence-Based Medicine*, p. 23.

57. Quoted in: *Ibid.*, p. 22.

58. Clinical-epidemiological education in North America and Australia received generous support from philanthropic organisations for that matter. In 1969, for example, the Clinical Scholars Program was launched, which was initially financed by the Carnegie Foundation and the Commonwealth Fund, and from 1974 onwards by the Robert Wood Johnson Foundation. Feinstein’s department at Yale University was one of the training centres for this programme, supervised by Feinstein himself. Other training programmes were supported by the Kaiser Family Foundation and the Milbank Memorial Fund. For more on this, see, among others: Daly, *Evidence-Based Medicine*, pp. 15, 21-3, 57; Sackett, ‘Three Cheers’. For more on the low status of, and lack of interest for public health epidemiology, see the ‘unsuspicious sources’: E. Barrett-Connor, ‘Epidemiology, National Boards and Medical Education’, *American Journal of Epidemiology* 112 (1980), pp. 732-5; Garraway et al., ‘A Method of Teaching Epidemiology’; L. Gordis, ‘Challenges to Epidemiology in the Coming Decade’, *American Journal of Epidemiology* 112 (1980), pp. 315-21; Orchard, ‘Epidemiology in the 1980s’; Susser, ‘Epidemiology in the United States’, p. 155.; M. Terris, ‘Epidemiology as a Basic Science in the Education of Health Professionals’, *International Journal of Epidemiology* 7 (1978), pp. 294-6.

Clinical Epidemiology at McMaster University

The department of clinical epidemiology (and biostatistics) that attracted the most attention was Sackett's at McMaster University in Hamilton, Canada.⁵⁹ This department was embedded in a still very young medical school, which had only been founded in 1965. The lack of any tradition in academic medicine in Hamilton at that point provided the founders of the new faculty with a unique opportunity to structure medical education in such a way as they saw fit.⁶⁰

There was a great need for an innovative design of the curriculum. The curricula of the established medical faculties had lost a great deal of their cohesion in the previous decades. As a result of the increasing specialisation in medicine and the rapid development of basic biomedical sciences, new subjects were continuously added to the curricula. This lack of cohesion was reinforced by the separation created in most curricula between a theoretical, pre-clinical part and a practical, clinical part. At the time of the foundation of the medical faculty of McMaster an increasingly broad body of opinion was in favour of breaking down this separation. Another problem related to the rapid progress in medicine was that knowledge gained by students in the course of their studies became outdated in no time at all. This is why they had to become 'lifelong learners': also after graduation, they had to keep learning and be able to continually integrate new knowledge and insights in their medical practice. This required a different didactic approach in medical education: the focus needed to shift from acquisition of knowledge to independently 'learning how to learn'.⁶¹

Against this background, the famous format of *problem-based learning* was introduced at the faculty of McMaster. As the term indicates, the curriculum was not 'discipline-based', as was the case in established faculties, but 'problem-based'. Education was not offered in individual subjects, but in an integrated form, with certain clinical problems being the starting point each time. This also meant that no separation was made between pre-clinical and clinical education. In addition, there was a preference for offering *student-based* (thus, demand-based) education at McMaster, rather than the usual teacher-based (thus, supply-based) education. At the heart of this was an explicit rejection of the master-apprentice model, which traditionally prevailed in the education of medical professionals. Rather than relying on the expertise of experienced masters, students had to learn to solve specific problems from clinical practice to the greatest

59. See for example: Bossuyt, 'Evidence-Based Medical Testing', p. 8.

60. Daly, *Evidence-Based Medicine*, pp. 50-3.

61. *Ibid.*, pp. 50-3; Klijn, *Verlangen naar Verbetering*, pp. 234-9; P. J. Knegtmans, *De Medische Faculteit Maastricht. Een Nieuwe Universiteit in een Herstructureringsgebied, 1969-1984* (Assen: Van Gorcum, 1992), pp. 52-5; Mooij, *Polsslag*, pp. 430-1.

extent possible by themselves. They were guided in this process in small workgroups supervised by a tutor.⁶²

Also with regard to research, founding dean Evans and his close associates wanted to put innovative ideas into practice. They explicitly opposed the dominant 'biomedical paradigm' of the laboratory and sought ways to carry out research that was relevant to the problems of clinical practice. This also fitted in well with the ideology that was at the core of the problem- and student-based curriculum. With an almost evangelical drive, the vision of McMaster on medical education and medical research was developed and propagated. Evans himself subsequently said about this: 'It became a bit like spreading religion'.⁶³

As aptly put by Jeanne Daly, for the preaching of this 'religion' it was important that McMaster had a 'prophet'. This prophet was found in the charismatic figure of David Sackett, the first head of the department of clinical epidemiology and biostatistics of the new medical faculty. Sackett is described by friend and foe as an impressive, charismatic and apostle-like figure. While his *modus operandi* was also met with resistance, it is not disputed that his personal characteristics and activities greatly contributed to the successful proclamation of the message of McMaster.⁶⁴ Something similar may also be argued for the department of clinical epidemiology and biostatistics as a whole. On the one hand, the people who worked there were sometimes thought of as being arrogant and boastful, yet on the other hand it is evident from many testimonies that it was hard not to be kindled by the enthusiasm and creativity of these 'crazy maverick, exciting people'.⁶⁵

With regard to this, Daly points to the 'careful planning that went into recruitment'.⁶⁶ She argues that Sackett and his followers were keen to recruit the right people in the right places. To start with, expertise in the field of methodology and biostatistics was acquired. Another priority was the acquisition of support of clinical departments by seeking collaboration with clinician-researchers affiliated to these departments or even appointing them in their own department for part of the time. It was also a policy that all clinical epidemiologists did clinical work for some of the time, thus working in a clinical department part-time. This way of working proved to be extraordinarily fertile. Due to the high quality delivered in the area of methodology development and (patient-related) research, McMaster and, in particular, the department of clinical epidemiology and biostatistics

62. See n. 61 above.

63. Quoted in: Daly, *Evidence-Based Medicine*, p. 53.

64. Interview with Büller; Bossuyt, 'Evidence-Based Medical Testing', p. 11; Daly, *Evidence-Based Medicine*, in particular p. 57.

65. A quote from Jack Hirsh, cited in: Daly, *Evidence-Based Medicine*, p. 59.

66. *Ibid.*, p. 57.

began to be held in high regard internationally.⁶⁷ Daly speaks of a department that grew quickly and generated a ‘multi-million-dollar research program.’⁶⁸

In addition, the policy of Sackett and his staff was characterised by openness to innovation and diversification. In the course of the 1970s, for example, health economists were recruited. Among them were George Torrance and Greg Stoddart, who eventually established the Centre for Health Economics for Policy Analysis in 1988.⁶⁹ Also, virtually right from the start, the department of clinical epidemiology at McMaster focused on both the micro-level of care for individual patients and at the macro level of healthcare management and policy. Besides clinicians, ‘administrators, hospital boards, the sort of folk that have to free up resources’⁷⁰ also belonged to the ‘audience’ Sackett and his staff wanted to reach.

There can be no question that Sackett and his staff managed to develop a special and vigorous department. However, the fact that, in the course of the 1980s, the department evolved from being a local success to an influential international centre should to a great extent be attributed to an external factor, i.e. a change of course on the part of the Rockefeller Foundation.

This change of course was induced by the publication of a report in 1981 entitled, *Health of Populations: Training for Measurement and Management in Medicine & Public Health*.⁷¹ The author, John Evans, was asked by the Rockefeller Foundation, through their chairman, Kerr White, to report on the healthcare challenges of the 1980s. Evans wrote in his report that the new decade would see a great need for ‘more effective management of health services at all levels’, both in rich countries and in developing countries. Yet those who ought to take the lead in this field lacked the knowledge and analytical skills necessary to properly respond to this challenge. The knowledge and skills required were admittedly taught at the so-called ‘schools of public health’, but the wrong people were trained in the wrong way there, according to Evans. These schools of public health had been set up from 1916 onwards, mainly in Anglo-Saxon countries, and kept running by virtue of large sums of money of the Rockefeller Foundation. It was therefore of essential

67. Ibid., pp. 58-60, 64, 73-4.

68. Ibid., p. 64.

69. Ibid., pp. 61-4. See also their highly influential book: M. F. Drummond, G. L. Stoddart & G. W. Torrance, *Methods for the Economic Evaluation of Health Care Programmes* (Oxford: Oxford University Press, 1987).

70. Daly, *Evidence-Based Medicine*, p. 60. See for an example of the strong link that was laid between clinical epidemiology and health economics: S. B. Halstead, P. Tugwell & K. Bennet, ‘The International Clinical Epidemiology Network (INCLIN): A Progress Report’, *Journal of Clinical Epidemiology* 44 (1991), pp. 579-89.

71. J. R. Evans, *Health of Populations: Training for Measurement and Management in Medicine & Public Health* (New York: The Rockefeller Foundation, [1981]).

importance to his client that Evans concluded that the ‘schools of public health’ and the ‘schools of medicine’ had become separate worlds to too great an extent, as a result of which the former institutes had become marginalised and irrelevant.

In order to remedy this, Evans basically pleaded for the introduction of the McMaster model. This is not surprising: in 1965 he was the ‘founding dean’ of the medical faculty at McMaster University (although he had meanwhile left for the University of Toronto). The client, Kerr White, probably realised exactly who he had brought in by recruiting Evans and what result he could expect. White himself – and he was by no means the only one⁷² – had long had concerns about the (alleged) gap between the schools of public health and the medical schools. It is therefore not surprising that the report he had asked for contained a plea for *clinical* epidemiology which was (to be) integrated into medical schools.⁷³

Evans’s report caused the money flows of the Rockefeller Foundation to go in a different direction. Public health was allocated considerably less money, and instead clinical epidemiology received a great deal of financial support. In 1982, the International Clinical Epidemiology Network (INCLLEN) was founded, with the objective of establishing ‘Clinical Epidemiology Units’ (CEUs) in countries across the world and above all in developing countries. These units were intended to encourage ‘rational decision-making’ and the application of quantitative measuring principles in healthcare (policies) in the countries of establishment. The development of CEUs was organised in two ways. Firstly, people from developing countries who were to man CEU’s there were trained in specially designated training centres. McMaster was the most important of these centres, and in addition people were trained at the universities of Toronto, Pennsylvania and North Carolina and at the University of Newcastle in Australia. Clinical epidemiology formed the heart of the offered training programmes. Secondly, a network was set up for continuous collaboration and mutual support between the various CEUs. At the tenth anniversary of the INCLLEN in 1991 it was reported that 27 CEUs had been set up by then, 7 in Asia, 6 in South America, 6 in India, 6 in Africa and 1 in France.⁷⁴

The INCLLEN was important to McMaster: it increased the funds, the intake and the reputation of the educational programme of the department of clinical epidemiology. Many people from outside the countries where a CEU was established also went to McMaster to attend training courses or workshops there. This position of the department of

72. See for example: Gordis, ‘Challenges to Epidemiology’; Terris, ‘Epidemiology as a Basic Science’.

73. See about Kerr White in this context: Daly, *Evidence-Based Medicine*, pp. 15, 40-6.

74. N. K. Arora & A. L. Dans, ‘The JCE-INCLLEN Collaboration: Knowledge Sharing in Action’, *Journal of Clinical Epidemiology* 60 (2007), pp. 537-9; ‘Clinical Epidemiology in the Third World’, *Lancet* 319 (1982), p. 1448; Daly, *Evidence-Based Medicine*, pp. 46-7, 50, 66-71; Halstead, Tugwell & Bennet, ‘International Clinical Epidemiology Network’, pp. 579-89; Holland, ‘Inappropriate Terminology’; Sackett, ‘Three Cheers’; Vandenbroucke, ‘Epidemiology in Transition’; Idem, ‘Overpeinzigen bij WEON-VIII’, *Tijdschrift Voor Sociale Gezondheidszorg* 61 (1983), p. 754.

clinical epidemiology and biostatistics at McMaster as an international training centre attracting people from far and near, probably greatly contributed to a situation in which the concept of evidence-based medicine, after it was ‘invented’ there, could spread like wildfire across the world.

From Critical Appraisal to Evidence-Based Health Care⁷⁵

Evidence-based medicine originated in this extraordinary department of clinical epidemiology and biostatistics at McMaster. Yet it is not possible to pinpoint one moment in time at which EBM was ‘born’ – although the term does appear to have been coined on a specific day and at a specific time in 1990 by Gordon Guyatt.⁷⁶ There tended to be a gradual process in which EBM developed and also changed (somewhat) in character and content over time. Following on from the clinical epidemiologist Patrick Bossuyt, three phases may be distinguished in this process. First of all, the idea of *critical appraisal* of the medical literature sprang from clinical epidemiology. Secondly, *evidence-based medicine* subsequently developed from critical appraisal; in this phase, the emphasis shifted from critical appraisal to systematic reviews and clinical guidelines. Finally, there was an

75. This section is based on the following literature: E. Barends, S. ten Have & F. Huisman, ‘Learning from Other Evidence-Based Practices: The Case of Medicine’, in: D. M. Rousseau (ed.), *The Oxford Handbook of Evidence-Based Management* (Oxford: Oxford University Press, 2012), pp. 25-42; Bosch, *Archie Cochrane*, pp. 242-53; Bossuyt, ‘Evidence-Based Medical Testing’, pp. 8-11; Chalmers, Hedges & Cooper, ‘A Brief History’; I. Chalmers, D. Sackett & C. Silagy, ‘The Cochrane Collaboration’, in A. Maynard & I. Chalmers (eds.), *Non-random Reflections on Health Services Research: On the 25th Anniversary of Archie Cochrane’s Effectiveness and Efficiency* (London: BMJ Publishing Group, 1997), p. 231-49; M. Clarke, ‘The Cochrane Collaboration: Providing and Obtaining the Best Evidence about the Effects of Health Care’, *Evaluation & the Health Professions* 25 (2002), pp. 8-11; Daly, *Evidence-Based Medicine*; D. M. Fox, ‘Systematic Reviews and Health Policy: The Influence of a Project on Perinatal Care since 1988’, *Milbank Quarterly* 89 (2011), pp. 425-49; Hanney and González-Block, ‘Evidence-Informed Health Policies’; Kristiansen and Mooney, ‘Evidence-Based Medicine’; K. N. Lohr, K. Eleazer, J. Mauskopf, ‘Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines’, *Health Policy* 46 (1998), pp. 1-19; Sackett, ‘Clinical Epidemiology: What, Who, and Whither’; D. L. Sackett & W. M. C. Rosenberg, ‘The Need for Evidence-Based Medicine’, *Journal of the Royal Society of Medicine* 88 (1995), pp. 620-4; Smith & Rennie, ‘Evidence-Based Medicine’; M. Starr et al., ‘The Origins, Evolution, and Future of the Cochrane Database of Systematic Reviews’, *International Journal of Technology Assessment in Health Care* 25, Supplement 1 (2009), pp. 182-95; Timmermans & Kolker, ‘Evidence-Based Medicine’; Weisz et al., ‘Emergence of Clinical Practice Guidelines’. See also the various interviews, biographies, and other sources of information on the websites of ‘Evidence-based medicine: an oral history’: <http://ebm.jamanetwork.com>, and of the James Lind Library: www.jameslindlibrary.org. There will be no further references in this section, except in the case of literal quotations or when specific additions to the references already given in this note are deemed necessary.

76. Daly, *Evidence-Based Medicine*, p. 89; Smith & Rennie, ‘Evidence-Based Medicine’, p. 366.

increasing focus on the 'macro-dimension' of EBM, which lead to the broadening of the concept to *evidence-based healthcare* (EBHC).⁷⁷

The *first phase*, that of *critical appraisal*, roughly coincided with the 1980s. Its roots, however, can already be found with the start of the medical school at McMaster at the end of the sixties. In fact, David Sackett's idea of critical appraisal of the medical literature fitted in seamlessly with problem-based learning, which was introduced there at the time. Students were expected to find the answers to questions and problems themselves as far as possible, for example by looking for relevant data in the literature. Yet this was far from straightforward. Already in the 1970s and 1980s, an extraordinary and increasing number of publications appeared in medical journals, including many articles of a questionable calibre.

Sackett and his followers therefore developed a number of tools with which one could relatively quickly and efficiently separate the wheat from the chaff in the medical literature. In the process of critical appraisal of medical research papers it was first determined what type of research was involved – diagnostic, prognostic, aetiological or therapeutic – and criteria with which sound research had to comply were then defined for each category. The 'hierarchies of evidence' used within evidence-based medicine (see general introduction) originated from these 'critical appraisal tools', which had already been developed around 1980.

Not only did critical appraisal fit in with the educational activities, but equally so with the research activities of the department of clinical epidemiology and biostatistics at McMaster. The tools and criteria which had been defined for the critical *evaluation* of the medical literature were also used as a 'mirror image': as a tool to be deployed when *setting up* scientific research. This is not surprising for (the methodological support of) clinical research was the main activity of the department.

Critical appraisal of the medical literature, as applied within McMaster, first drew international attention through the publication of a number of articles by Sackett and staff in the *Canadian Medical Association Journal* in 1981, with as overarching theme: 'How to Read Clinical Journals'. Also influential was the textbook *Clinical Epidemiology* from 1985, by the same authors, in which the principles and tools of critical appraisal were applied to both the evaluation and the design of clinical research.

The transition at the beginning of the 1990s from the 'critical appraisal phase' to the '*EBM-phase*' was fluent. The concept of 'evidence-based medicine' was launched internationally in 1992 in an article by the 'EBM working group' in the JAMA.⁷⁸ This article formed the

77. Bossuyt, 'Evidence-Based Medical Testing', pp. 8-11.

78. Evidence-Based Medicine Working Group, 'Evidence-Based Medicine'.

introduction to a long series of tens of articles, which appeared in the course of the 1990s and 2000s, under the umbrella title 'Users' Guides to the Medical Literature'.⁷⁹ This title indicates that the primary focus of this series of articles was still the critical appraisal of the medical literature.

Evidence-based practice was (and still is) depicted as a five-step process.⁸⁰ The first step was the (proper) formulation of a clinical question. The second was the search for relevant articles in the medical literature and the third the critical appraisal of these articles. The fourth step was the putting into practice of what the previous steps had produced. The fifth step was the evaluation of (all) this. In the 'EBM literature', however, the focus was primarily on the first three steps.⁸¹

Thus initially, EBM did not differ essentially from critical appraisal, which had existed for some time. However, this changed rapidly. For the 'users' of the medical literature, it often proved problematic in practice to apply critical appraisal. Such was the abundance of publications in medical journals that for a practising physician it was next to impossible to even keep up with the literature in their field, let alone critically appraise it. This was one of the reasons why a market for so-called *systematic reviews* originated, in which the massive supply of research articles was filtered and summarised. From 1991 onwards, for example, these were published by the *ACP Journal Club* – an initiative of the American College of Physicians (ACP). A team under the supervision of Brian Haynes of McMaster created these *systematic reviews*, which initially appeared as an appendix to the *Annals of internal medicine* and subsequently in a digital database. In an interview, Haynes described the followed procedure as follows:

'Instead of every clinician having to go through 170 different journals to keep up to date, we go through those journals by explicit criteria – the critical appraisal criteria that we try to teach people – and pick out the articles that are directly relevant to internal medicine and that meet the criteria for validity'.⁸²

79. See for example the 25th article in this series: G. H. Guyatt et al., 'Users' Guides to the Medical Literature XXV. Evidence-Based Medicine: Principles for Applying the Users' Guides to Patient Care', *Journal of the American Medical Association* 284 (2000), pp. 1290-6.

80. See a.o.: W. Rosenberg & A. Donald, 'Evidence Based Medicine: An Approach to Clinical Problem-Solving', *British Medical Journal* 310 (1995), pp. 1122-6; Sackett & Rosenberg, 'The Need for Evidence-Based Medicine'; D. L. Sackett et al., *Evidence-Based Medicine: How to Practice and Teach EBM* (New York: Churchill Livingstone, 1997). See also the website of the Centre for Evidence-Based Medicine in Oxford: <http://www.cebm.net>.

81. See for example: Guyatt et al., 'Users' Guides to the Medical Literature XXV'; Sackett et al., *Evidence-Based Medicine: How to Practice and Teach EBM*.

82. Quoted in: Daly, *Evidence-Based Medicine*, p. 84.

This quotation demonstrates the extent to which the systematic reviews were a continuation of the critical appraisal as applied within McMaster. In 1995, the link with EBM became more than clear due to the launch of the journal *Evidence-Based Medicine*, the content of which was completely focused on systematic reviews and was available digitally right from the very beginning.⁸³ The same team around Haynes was the driving force behind this journal and several other journals and databases which were created in subsequent years.

From the 1980s onwards, a special, quantitative form of systematic review was developed as well: the meta-analysis. In a meta-analysis, the data of several clinical trials on, for example, the efficacy of a certain therapy are compiled and analysed with the help of statistical methods. Put simply, the underlying idea is that the collected data of several trials, selected in a systematic review on the basis of their quality, give a better estimate of the studied effect than the data of a single trial. Moreover, the meta-analysis is regarded as an inexpensive way of reducing the inherent uncertainty of the results of (relatively) small-scale researches, while the alternative, the implementation of increasingly large 'mega trials', is very costly. It is therefore not surprising that, in the wake of the systematic reviews, the number of meta-analyses has greatly increased since the 1990s.

It is important to note that the production of systematic reviews and meta-analyses was not primarily a North American, but (initially) above all a British phenomenon. In Great Britain, from the 1970s onwards and inspired by the work of Archie Cochrane (that was addressed earlier in this chapter), various people, including the obstetrician, Iain Chalmers, undertook initiatives to develop the instrument of the systematic review methodologically and substantively. This led to the publication of a number of books in the course of the 1970s and 1980s in which all the critically filtered scientific research with respect to care in pregnancies and birth was systematically collected and summarised. In addition, a digital database became available as of 1989: the *Oxford Database of Perinatal Trials*.

This database served as a model for a much more ambitious initiative. In 1992, a small group of people in Oxford led by Iain Chalmers started work on the *Cochrane Collaboration* – named after Chalmers's great inspiration, Archie Cochrane, who had written in 1979:

'It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials.'⁸⁴

83. See a.o.: F. Davidoff et al., 'Evidence Based Medicine: A New Journal to Help Doctors Identify the Information they Need', *British Medical Journal* 310 (1995), pp. 1085-6.

84. See for this quote a.o.: Chalmers, 'Archie Cochrane'; see also the website of the Cochrane Collaboration: <http://www.cochrane.org/about-us/history/archie-cochrane>.

Within several years, the Cochrane Collaboration developed into a large international network in which medical professionals from across the world collaborated on the production of systematic reviews. In many countries 'Cochrane Centres' were established. Established in the Academic Medical Centre in Amsterdam in 1994, the 'Dutch Cochrane Centre' was one of the first. These days, the database of the Cochrane Collaboration is one of the most – or even *the* most – important sources of information for clinical guideline developers and (therefor) for practising physicians.

Moreover, the British systematic review movement has eventually had a tremendous influence on healthcare policy in many parts of the world. Recent developments in the United States are illustrative of this. In 2009, almost immediately after taking office, president Obama announced that he had allotted \$ 1,1 billion to a stimulation package for 'comparative effectiveness research.' In his view, this kind of research could contribute greatly to reducing healthcare spending and would therefore be a key factor in making his ambitious health care reform plans ('Obamacare') sustainable. Echoing (in a way) the ideas of Archie Cochrane, Obama maintained that 'we need to know what works and what doesn't work' in health care. Implicitly, his message was that only what worked could and should be reimbursed, in order to be able to achieve the goal of 'Obamacare': access to insured healthcare for a larger proportion of the American population (and eventually for all Americans). Despite severe criticism from republicans, Obama put through his plans for funding and promoting comparative effectiveness research. In 2010, the Patient-Centered Outcomes Research Institute (PCORI), a nonprofit, nongovernmental organization located in Washington D.C. was established in the famed Patient Protection and Affordable Care Act ('Obamacare'). The main work of the PCORI consists of producing systematic reviews.⁸⁵

The Cochrane Collaboration and everything that preceded it is considered to be a second pillar of evidence-based medicine – in addition to the ideas and methods developed by Sackett and others at McMaster University. The founders of the Cochrane Collaboration and of EBM themselves have always emphasised that they represented two different initiatives, which should be viewed independently of one another. Yet they were very soon equated to each other by the outside world and also by the epigones of said founders – and increasingly so over time. From the start, there has been a great deal of mutual contact and support and exchange of ideas between both movements. Furthermore, the similarities were great from an ideological perspective – for example with regard to the importance of randomised controlled trials. Moreover, as both initiatives developed and conquered the world from their Canadian and English origins respectively, the number

85. See a.o. the website of the PCORI: <http://www.pcori.org>. The story of Obama, Obamacare and 'comparative effectiveness research' can be found in all kinds of public sources (newspapers, news websites, etc.).

of people belonging to both the EBM movement and the Cochrane Collaboration increased. In the Netherlands, for example, it was the people of the Dutch Cochrane Centre who provided the main courses in evidence-based medicine and also published the very successful Dutch textbook on EBM.⁸⁶

In one respect there has always remained an important difference between EBM and the Cochrane Collaboration. Where Sackett and his followers had the ambition to transform medicine at the micro and macro level – they even claimed to introduce a ‘new paradigm’ for medicine – the Cochrane Collaboration served a more modest or, in any case, a more narrowly defined purpose. This organisation confined itself to summarising and making accessible and available the results of clinical research – and above all, randomised controlled trials. The *translation* of systematic reviews and meta-analyses to clinical practice (or healthcare policy) was left to others. Thus, unlike EBM, the Cochrane Collaboration did not have any clinical pretensions. Intentionally or unintentionally, however, the Cochrane Collaboration, as supplier of reliable ‘evidence’, did become an important link *within* evidence-based medicine and ‘evidence-based health policy’.

The step from systematic reviews to practical application, which was not part of the mission of the Cochrane Collaboration, was soon taken by others. This mainly occurred in the form of the preparation of clinical practice guidelines, in which the evidence was translated to specific guidance, criteria and decision trees which could assist physicians in making decisions regarding the diagnostics and treatment of a certain condition. Such protocols and guidelines for medical practice were not a new phenomenon, but previously these would often be drawn up on the basis of consensus, during so-called consensus conferences. In the 1990s, a significant production of guidelines was set in motion which, according to the makers, were not based on consensus but on evidence. This usually involved using the principles of the EBM movement and the data of systematic reviews from, among others, the Cochrane Collaboration.

Clinical practice guidelines were already on the rise in the 1980s, but this trend was given a boost by the introduction of EBM in the 1990s. According to Weisz et al., ‘the proliferation of collectively produced guidelines since the 1980s represents a growing effort to bring order and coherence to a rapidly expanding and heterogeneous medical domain.’⁸⁷ Soon evidence-based clinical practice guidelines were so ubiquitous in many countries, that they became to be regarded by many ‘average’ physicians and non-medical parties as the core or even the essence of EBM.

86. M. Offringa, W. J. J. Assendelft & R. J. P. M. Scholten (eds.), *Inleiding in Evidence-Based Medicine: Klinisch Handelen Gebaseerd op Bewijsmateriaal* (Houten: Bohn Stafleu van Loghum, 2000).

87. Weisz et al., ‘Emergence of Clinical Practice Guidelines’, p. 692.

Thus, very shortly after the introduction of this concept, the emphasis within EBM shifted from critical appraisal to systematic reviews and clinical guidelines. This development and the essential change of EBM it involved was also recognised by Gordon Guyatt, the inventor of the term ‘evidence-based medicine’:

‘When I started, I thought we were going to turn people into evidence-based practitioners, that they were really going to understand the methodology, that they were really going to critique the literature and apply the results to clinical practice. I no longer believe that. What I believe now is that there will be a minority of people who will be evidence-based practitioners, and that the other folk will be evidence-users who will gain a respect for the evidence and where it comes from and a readiness to identify evidence-based sources which summarize the evidence for them. But they are not actually expected to read and understand the articles and really be able to dissect the methodology.’⁸⁸

The fact that the majority of physicians could not operate so much as ‘evidence-based practitioner’ but more as ‘evidence user’, as formulated by Guyatt, had everything to do with the manner in which the evidence was made available to them in ‘manageable segments’ in systematic reviews and clinical guidelines. That these instruments could be produced on a large scale and that medical professionals had easy access them as well was, moreover, due to the spectacular recent developments in the field of information technology.

There is little doubt that medicine changed significantly under the influence of information and computer technology. Following on from the well-known article of Jewson on ‘bedside’, ‘hospital’ and ‘laboratory medicine’ (see chapter 1), the British sociologist Sarah Nettleton speaks of the emergence of an entirely new ‘medical cosmology’: ‘e-scaped medicine’ or ‘informational medicine’. She argues that networked computer systems not only serve as tool for editing and processing data, but also exert a great deal of influence on the way of thinking and acting of physicians, patients and other stakeholders in the field of illness and health. She bases this conceptually on the work of the philosopher De Mul. Inspired by the work of the historian Dijksterhuis on the ‘mechanisation of the world picture’ (during the sixteenth and the seventeenth centuries), De Mul argues that currently an *informatisation* of the world picture is taking place.⁸⁹

According to Nettleton (and many others) the rise of evidence-based medicine should be understood in this broader context of informatisation. She points to the explosion of medical knowledge, the organisation and dissemination of this medical knowledge

88. Quoted in: Daly, *Evidence-Based Medicine*, p. 91.

89. Nettleton, ‘Emergence’; see also: Idem., ‘Commentary’; S. Nettleton & R. Burrows, ‘E-scaped medicine? Information, Reflexivity and Health’, *Critical Social Policy* 23 (2003) pp. 165-85.

in databases with systematic reviews, the shift in emphasis from clinical experience to evidence and the associated erosion of the *art* of medicine. Quoting an article from the *British Medical Journal*, she states that the modern expert is no longer the person who has specialist knowledge, but 'someone who knows to access knowledge efficiently and judiciously and who can form conceptual links between related areas.'⁹⁰

The *third phase* in the development of EBM – that of broadening to *evidence-based health care (EBHC)* – largely overlapped with the second phase, which was characterised by the emergence of systematic reviews and 'evidence-based' clinical guidelines. These instruments were extraordinarily attractive to managers and policymakers in medicine, for they seemed to offer them opportunities to gain more of a grip on medical practice. Where critical appraisal was limited to skills that could be acquired by individual clinicians, systematic reviews and clinical guidelines could be interpreted as tools for determining the right diagnostic and therapeutic strategies at a more generic and collective level. In addition, more emphasis was placed on the health economics and political aspect of EBM. This was particularly in line with the British 'root' or 'pillar' of EBM, which had originated from the ideas of Cochrane on a more effective and efficient *National Health Service*.

Significantly, this broadening of the scope of EBM occurred most markedly after the centre of gravity of the movement shifted towards Great Britain. The Cochrane Collaboration was already (primarily) based in Oxford, but in 1994 David Sackett himself also moved to this university town. He became the first head of the Centre for Evidence-Based Medicine there, which is, incidentally, only a small, almost virtual institute at Oxford University. Sackett devoted large part of his time in England to giving lectures throughout the country (and outside it as well), spreading the 'gospel' of EBM. It does not seem a coincidence that precisely in the country of the National Health Service, the principles and instruments of EBM were used more than anywhere else in the design of healthcare *policy*, in which it was mainly about cost control by increasing the effectiveness and efficiency of healthcare.

This was reflected conceptually when Muir Gray coined the term 'Evidence-Based Health Care' in 1997 in his book *Evidence-Based Health Care. How to Make Health Policy and Management Decisions*. This seminal book was intended to offer policymakers the tools required to be able to address the challenges facing a modern healthcare system at a time of increasing scarcity of financial resources. The concept of Evidence-Based Health Care (EBHC) caught on, most of all in Great Britain. This became evident in 1999, for ex-

90. S.W. Fraser & T. Greenhalgh, 'Coping with Complexity: Educating for Capability' *British Medical Journal* 323 (2001) pp. 799-803, on p. 800. Also cited in: Nettleton, 'Emergence', p. 671. See also on all this: J. A. November, 'Early Biomedical Computing and the Roots of Evidence-Based Medicine', *IEE Annals of the History of Computing* (2011: April-June), pp. 9-23.

ample, when the National Institute for Health and Care (as of 2005: Clinical) Excellence (NICE) was established. As an independent government body, the activities of which include ‘technology appraisals’, ‘cost-effective analyses’ and the development of evidence-based clinical practice guidelines, NICE is now internationally renowned.

The broadening to EBHC meant that EBM became increasingly politicised. Although this did not happen out of nowhere – early on, there was already a focus on health economics and political aspects in the department of clinical epidemiology at McMaster – clinical epidemiology and critical appraisal were still mainly internal methodological matters that were primarily discussed among medical professionals. Yet as the importance of systematic reviews, clinical guidelines and application in healthcare policy on a macro-level increased, EBM, as a concept and as a movement, was also increasingly subject to the influence of political convictions, financial interests and lobby groups outside the medical profession.

Criticism and Self-reflection⁹¹

The increasing politicisation of EBM gave rise to a torrent of criticism. Many wondered what remained of the original principles and ideals of EBM, as soon as they were exposed to political and macro-economic forces. Some warned that, practised in this way, EBM would become a mere slogan, only used to legitimise cutbacks.

There were other reasons, too, for the considerable level of resistance to EBM/EBHC from the very beginning. For example, from the side of the philosophy and sociology of science as well as in the medical world itself, there were accusations that Sackett and

91. It is impossible to provide a comprehensive overview of the criticism of and the (internal) debate on EBM. This paragraph only offers a broad overview based on extensive research of the literature. As it is equally impossible to provide a list of all the studied articles, comments, letters to the editor, etc., references to a number of articles and (sections of) books in which the debate on EBM is described and explained on a ‘meta-level’ must suffice here: Barends, Have & Huisman, ‘Learning from Other Evidence-Based Practices’; K. Borgerson, ‘Bias and the Evidence Hierarchy of Evidence-Based Medicine’, *Perspectives in Biology and Medicine* 52 (2009), pp. 218-33; Cohen, Stavri & Hersh, ‘Categorization’; Darlenski et al., ‘Evidence-Based Medicine’; Dehue, ‘Dutch Treat’; K. Hannes et al., ‘Evidence-Based Medicine: een Bespreking van de Meest Voorkomende Kritiek’, *Nederlands Tijdschrift Voor Geneeskunde* 149 (2005), pp. 1983-8; Ho, ‘Medicine, Methodology, and Values’; Howick, *Philosophy of Evidence-Based Medicine*; M. P. Kelly & T. A. Moore, ‘The Judgement Process in Evidence-Based Medicine and Health Technology Assessment’, *Social Theory & Health* 10 (2012), pp. 1-19; Kristiansen & Mooney, ‘Evidence-Based Medicine’; J. M. Satterfield, et al., ‘Toward a Transdisciplinary Model of Evidence-Based Practice’, *Milbank Quarterly* 87 (2009), pp. 368-90; Sehon & Stanley, ‘Philosophical Analysis’; Timmermans & Kolker, ‘Evidence-Based Medicine’; M. R. Tonelli, ‘The Limits of Evidence-Based Medicine’, *Respiratory Care* 46 (2001), pp. 1435-40; Upshur, ‘Looking for Rules’; M. H. Waymack, ‘Yearning for Certainty and the Critique of Medicine as a “Science”’, *Theoretical Medicine and Bioethics* 30 (2009), pp. 215-29; Weisz, ‘From Clinical Counting’. See also the ‘theme issue’ on EBM of the *British Medical Journal* of 30 October 2004 (vol. 329).

his associates used a unilateral and naive positivist definition of scientific knowledge. In this respect, the main stumbling block was the privileged position allocated to the randomised controlled trial within EBM. Frequent mention was made of the Achilles' heel of the RCT: its external validity or capacity for generalisation was often very limited. The findings on a treatment method obtained in an artificial experimental situation with strictly selected subjects could not simply be translated into the uncontrolled circumstances of clinical reality.

In addition, it was argued that RCTs could only fulfil a very limited role. As a research design, it could actually only be applied for determining the efficacy of therapies with marginally positive treatment effects. For treatments with major effects the performance of an RCT was not actually needed and, moreover, would be considered unethical. The research design was also not very suitable for establishing the presence of side-effects. In addition, there were countless important clinical questions, mainly in the field of diagnostics and prognostics, which could not be answered with an RCT. Entirely different, more innovative forms of research were required for the acquisition of genuinely new medical knowledge and insights, both in the clinic and in the laboratory. Due to the unilateral emphasis on the RCT within EBM, critics feared that not enough attention, manpower and resources would be devoted to other (perhaps) much more important forms of medical scientific research.

Some commentators also argued that the EBM movement played into the hands of the pharmaceutical industry. The main area of application of RCTs was establishing the efficacy of new medicines as a condition for admission to the market. As RCTs were particularly suitable for detecting *minor* treatment effects, critics thought they formed an ideal vehicle for manufacturers for the marketing of 'me-too drugs', *lifestyle* medicines and other medication which contributed little or nothing to improving (public) health. Alarming reports were regularly published on the poor quality of industry-sponsored trials or on the low quality of the manner of reporting on these trials. An example is an article from 2008 by Greek methodologist Ioannidis, on the more than thousand trials performed with so-called 'SSRIs' – the group of antidepressants to which, among others, Prozac belongs. With the help of two meta-analyses, Ioannidis painted an alarming picture of 'many small randomized trials with clinically non-relevant outcomes, improper interpretation of statistical significance, manipulated study design, biased selection of study populations, short follow-up, and selective and distorted reporting of results'. According to Ioannidis, an 'evidence-based myth on antidepressant effectiveness' had been construed this way.⁹²

92. J. P. A. Ioannidis, 'Effectiveness of Antidepressants: An Evidence Myth Constructed from a Thousand Randomized Trials', *Philosophy, Ethics, and Humanities in Medicine* 3:14 (2008).

The methodological shortcomings identified by Ioannides and many others⁹³ were not unique to industry-sponsored RCTs. In independent trials they occurred too, albeit to a slightly lesser extent. The same was true for non-experimental observational studies for that matter.⁹⁴ EBM proponents could therefore maintain that RCTs were still superior to, for example, non-experimental cohort studies, partly because, with randomisation, more sources of bias could be eliminated than without randomisation.⁹⁵

It was nevertheless clear that an RCT did not necessarily guarantee scientific rigor. In their implementation, all manner of more or less subjective choices had to be made – for example, with respect to inclusion and exclusion criteria for test subjects, outcome measures and criteria and the duration of experimental treatment and follow-up – where all sorts of things could go ‘wrong’. In addition, in practice, all manner of difficulties occurred with placebo-controlled and (sustained) double-blind trials. Moreover, there was the issue of ‘publication bias’: the fact that studies yielding negative, non-significant results remained unpublished much more often than studies yielding positive, significant results. As a result, the total number of publications on a certain therapy often creates a biased, too positive view of its efficacy. This was widely – also within the EBM movement itself – regarded as perhaps the biggest threat to obtaining a reliable ‘evidence base’ for medical practice.⁹⁶

In the hierarchy of evidence of EBM, systematic reviews or meta-analyses of RCTs were ranked even higher than a single RCT. The results of several trials were logically considered to constitute more powerful evidence than those of a single trial. However, many methodologists warned that the results of various studies could not simply be taken together, let alone be ‘added’ together in order to obtain greater statistical ‘power’. Feinstein,

93. See a.o.: H. Melander, J. Ahlqvist-Rastad, G. Meijer, & B. Beerman, ‘Evidence B(i)ased Medicine – Selective Reporting from Studies Sponsored by Pharmaceutical Industry: Review of Studies of New Drug Applications’, *British Medical Journal* 326:1171 (2003); E. H. Turner, A. M. Matthews, E. Linardatos, R. A. Tell, & R. Rosenthal, ‘Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy’, *New England Journal of Medicine* 358:3 (2008), pp. 252-60.

94. D. G. Altman, ‘The Scandal of Poor Medical Research’, *British Medical Journal* 308 (1994), pp. 283-4; S. Every-Palmer & J. Howick, ‘How Evidence-Based Medicine Is Failing Due to Biased Trials and Selective Publication’, *Journal of Evaluation in Clinical Practice* (2014), doi:10.1111/jep.12147; J. P. A. Ioannidis, ‘Why Most Published Research Findings Are False’, *PLoS Medicine* 2: 8 (2005), e124, doi:10.1371/journal.pmed.0020124. See also the *Lancet*-series ‘Research: Increasing Value, Reducing Waste’, published January 8, 2014, available from: <http://www.thelancet.com/series/research>.

95. This was the tenor in the discussions during the summer course ‘History and Philosophy of Evidence-Based Healthcare’ of the Centre of Evidence Based Medicine at Oxford University, in which TB participated in July 2012. See the website of the course: <http://www.conted.ox.ac.uk/B900-77>.

The same tenor is, for example, present in: Howick, *Philosophy of Evidence-Based Medicine*.

96. See n. 94 above.

for example, called the meta-analysis ‘statistical alchemy for the 21st century’.⁹⁷ Systematic reviewers and, in particular, the Cochrane Collaboration were also regularly described as rigid and unilaterally dogmatic in their preference for (meta-analyses of) the RCT.

Walter Spitzer, for example, the then coeditor of the *Journal of Clinical Epidemiology*, wrote that during his visit to the annual international conference of the Cochrane Collaboration in 1996 he had been annoyed by the prevalent ‘doctrinaire unthinking rigidity’. According to him, there was no room whatsoever for ideas that did not fit seamlessly within the dominant ‘theology of meta-analysis’. Every proposal to also pay attention to (methods for the) development of systematic reviews of *observational* studies was immediately cast aside with the argument that: ‘meta-analysis is for randomized trials only. Discussion of aggregating observational studies is irrelevant’.⁹⁸

The picture Spitzer sketches of the atmosphere during these annual conferences in the early days of the Cochrane Collaboration is confirmed by Pim Assendelft, the (former) managing director of the Dutch Cochrane Centre:

‘Those annual colloquia at the beginning, when the Cochrane Collaboration was still very small, were attended by a real inner crowd. They were all people for whom it was an additional calling and who strongly believed in it [...]. I was at a conference once and we all wore a badge with the logo of the Cochrane Collaboration on it. You could see the other hotel guests looking at us in the lift: who *are* these people? They thought that a religious sect was staying at their hotel! The Cochrane Collaboration *did* certainly have sectarian tendencies. At that point we really thought – I myself thought it as well – that this was it! You had to put everything in a trial and only then could you tell if something really worked. And if it had not been researched in a trial, well then it was no good, by definition.’⁹⁹

Both Assendelft and Spitzer sketch *two* sides of the same coin for that matter. On the one hand, they praise the enthusiasm and drive of the relatively young people who found each other in the Cochrane Collaboration and their ‘adherence to the philosophy of the pre-eminence of evidence’, on the other hand they point to the downside of rigidity and ‘sectarian tendencies’.

Broadly speaking, the EBM movement of the (early) 1990s (which partly consisted of the same people) may be typified in a similar way. On the one hand, the charismatic leadership of Sackett and the ideological fire of his ‘followers’ contributed to the appeal of

97. A. R. Feinstein, ‘Meta-Analysis: Statistical Alchemy for the 21st Century’, *Journal of Clinical Epidemiology* 48, no. 1 (1995), pp. 71-9. See also, for example: W. O. Spitzer, ‘The Challenge of Meta-Analysis’, *Journal of Clinical Epidemiology* 48 (1995), pp. 1-4.

98. Spitzer, ‘The Future of Epidemiology’, p. 708.

99. Interview with Assendelft.

the movement. On the other hand, there was strong resistance, precisely for this reason. Among others, the claim that EBM was no less than a new paradigm for medicine and the almost religious, evangelical manner in which the notion of ‘levels of evidence’ was expressed, went too far for many critics.

Against this background, some of them warned that EBM was nowhere near as ‘democratic’ as Sackett and his followers argued. It was true that the rise of EBM had been at the expense of traditional ‘authority-based’ medicine, in which the opinions of ‘eminent’, experienced physicians prevailed. According to these critics, however, a new form of ‘authority-based’ medicine had come in its place, namely a dictatorship of the ‘hierarchy of evidence’, of the underlying statistical principles and of those who use these principles to create systematic reviews and clinical guidelines. In this context, it was noted that evidence in systematic reviews is not necessarily objective or value-free, but is presented in a ‘pre-sorted, formatted and highlighted’ form.¹⁰⁰ As a result, the Cochrane Collaboration and other systematic reviewers enjoyed a position of considerable power.

This debate was stepped up further by the extensive production and application of evidence-based clinical guidelines, which began in the 1990s. Guidelines potentially had an even greater impact on the actual practice of physicians than systematic reviews. Many saw them as a threat to the professional autonomy of physicians. It was believed that, due to the unilateral focus on ‘hard’, quantitative evidence from RCTs, there would be increasingly less space for ‘softer’ but, to medical practice, equally essential matters such as the *art* of medicine, clinical expertise, pathophysiological reasoning and attention for psychosocial aspects. Some physicians feared legal consequences as well: would physicians, when deviating from guidelines, be immediately held to account for this in disciplinary proceedings? Yet the principal and recurring criticism of evidence-based clinical guidelines was that they would lead to ‘cookbook medicine’. The individuality of the physician and above all that of the patient would be completely overlooked, for everyone had to be treated in accordance with the fixed ‘recipe’, the clinical guideline.

David Sackett and other proponents of EBM defended themselves fiercely against all this criticism. They were offered a platform for this in the *BMJ* and the *JAMA*, among others, while criticism of EBM tended to appear in *the Lancet* and the *New England Journal of Medicine*, whereby the editors-in-chief themselves also adopted a somewhat sceptical stance towards the new movement.¹⁰¹ In addition, there was the *Journal of Evaluation in Clinical Practice*, which seemed entirely devoted to combating EBM.

100. This is a quote from: Daly, *Evidence-Based Medicine*, p. 212.

101. Illustrative is, for example, a *Lancet*-editorial from 1995: ‘Evidence-Based Medicine, in its Place’, *Lancet* 346 (1995), p. 785. See also the book of (the then) *Lancet*-editor Richard Horton: R. Horton, *Second Opinion: Doctors, Diseases and Decisions in Modern Medicine* (London: Granta, 2003).

In the EBM-debate two striking trends became visible over time. Firstly, Sackett and his followers soon softened the sometimes far-reaching claims that they had made when they wanted to put EBM on the map in the early 1990s. The most influential example of such a qualification of previous statements was the article published by Sackett and several co-authors in 1996 in the *BMJ* entitled: 'Evidence-based Medicine: What it Is and What it Isn't'. Ever since then, it has almost become the standard response of EBM proponents to criticisms to refer to this article, in which Sackett and associates argued:

'Evidence-based medicine is not "cookbook" medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. *External clinical evidence can inform, but never replace, individual clinical expertise* [...]. Some fear that evidence based medicine will be hijacked by purchasers and managers to cut the costs of health care [...]. Doctors practicing evidence-based medicine will identify and apply the most efficacious interventions to maximise the quality and quantity of life for individual patients; this *may raise rather than lower the cost* of their care.'¹⁰²

A second change in the debate on EBM was that, in the course of time, particularly after approximately the year 2000, criticism of EBM came more and more from *within*. Partly because external criticism appears to have decreased as EBM gained mainstream acceptance, the focus increasingly shifted to the internal discussions within the movement. This led to specific initiatives aimed at refining and improving EBM. In 2000, for example, Gordon Guyatt and others founded the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group, with the aim of doing something about 'the shortcomings of present grading systems in health care'. The GRADE approach may be viewed as an attempt to refine the instrument of a 'hierarchy of evidence', which is used within EBM. Evidence from RCTs may, for example, be 'downgraded' if the treatment effects detected are minor or if methodological shortcomings are established, while evidence from observational studies may be 'upgraded' in the event of considerable treatment effects and careful methodological implementation of the research.¹⁰³

Within the Centre for Evidence-Based Medicine in Oxford too, doubts were raised about the way in which 'levels of evidence' were initially dealt with for EBM. According to

102. Sackett et al., 'Evidence Based Medicine: What it Is.' TB's italics. See also, for example: G. Guyatt, D. Cook & B. Haynes, 'Evidence-Based Medicine Has Come a Long Way', *British Medical Journal* 329 (2004), pp. 990-1.

103. See a.o. the website of GRADE (which also includes the series of articles published by the GRADE Working Group in the *BMJ* in 2008 and in the *JAMA* in 2011): <http://www.gradeworkinggroup.org>

some staff members, this had done ‘more harm than good’.¹⁰⁴ This resulted, among others, in the proposal by staff members of the centre to replace the ‘pyramid approach’ with an approach in which various forms of evidence are regarded as being more complementary.¹⁰⁵

In addition, right from the start, leading figures within the Cochrane Collaboration have been committed to improving the ‘evidence base’ of EBM, repeatedly addressing the shortcomings in the implementation and manner of reporting. They did not shy away from speaking of ‘the scandal of poor medical research’¹⁰⁶ and the ‘waste’¹⁰⁷ of a large part of the billions invested in medical research. They also made specific recommendations for improvement and were particularly committed to solving the problem of publication bias with, for example, central registration of *all* (therefore also unpublished) RCTs.¹⁰⁸ Also, within the Cochrane Collaboration there was gradually more attention paid to and appreciation of (systematic reviews of) observational research.¹⁰⁹

With respect to the *application* of evidence, there was an increasing focus on the difficulties surrounding the (lagging) implementation of evidence in clinical practice. There seems to have been a shift here towards an approach reminiscent of that of clinical decision analysis. Besides, with the evidence, there was an increasing focus on the decision to be subsequently taken – which not automatically follows from the evidence. Some exponents of the EBM movement therefore started preferring the term ‘evidence-informed medicine’ to ‘evidence-based medicine’. Part of this trend was a gradually increasing interest in values, in particular patient values, and how to integrate them into an evidence-based clinical practice.¹¹⁰

104. This was explicitly mentioned, and also the ‘general mood’ among the participants and tutors during the course ‘History and Philosophy of Evidence-Based Health’ care, organized by the Centre for Evidence-Based Medicine in July 2012. See the website: <http://www.conted.ox.ac.uk/B900-77>

105. J. Howick, P. Glasziou & J. K. Aronson, ‘The Evolution of Evidence Hierarchies: What can Bradford Hill’s “Guidelines for Causation” Contribute?’, *Journal of the Royal Society of Medicine* 102 (2009), pp. 186-194. See also: T. Greenhalgh, J. Howick & N. Maskrey, ‘Evidence-Based Medicine: A Movement in Crisis?’, *British Medical Journal* 358 (2014), g3725; Howick, *Philosophy of Evidence-Based Medicine*.

106. Altman, ‘Scandal’.

107. *Lancet*-series ‘Research: Increasing Value, Reducing Waste’.

108. *Ibid.*

109. See a.o. the website of the Cochrane Collaboration: <http://www.cochrane.org>. See also the letter in the *BMJ* of 2014 of two representatives of the Cochrane Collaboration: D. Tovey & R. Churchill, ‘Evidence Based Medicine: Looking Forward and Building on What We Have Learnt’, *British Medical Journal* 349 (2014), g4508.

110. See a.o. Guyatt, Cook & Haynes, ‘Evidence-Based Medicine Has Come a Long Way’. Illustrative examples of the trends described in this paragraph are: (1) the so-called ‘Sicily Statement’, a consensus (!) statement that resulted from an international conference of EBHC teachers and developers in 2003; (2) the project on ‘Values-Based Practice’ of people from Warwick University. See respectively: M. Dawes et al., ‘Sicily Statement on Evidence-Based Practice’, *BMC Medical Education* 5: 1 (2005); K. W. M. Fulford, E. Peile & H. Carroll, *Essential Values-Based Practice: Clinical Stories Linking Science with People* (Cambridge: Cambridge University Press, 2012).

The trend of increasing self-reflection and self-criticism resulted in an article published in the *British Medical Journal* in 2014: 'Evidence-Based Medicine: a Movement in Crisis?'¹¹¹ Strong exponents of the EBM movement, the authors argued that 'although evidence-based medicine has had many benefits, it has also had some negative unintended consequences.' These 'negative unintended consequences' included: misuse of the 'brand' of EBM through 'vested interests' and a volume of evidence and clinical guidelines that 'has become unmanageable'. It had also become clear over time that 'statistically significant benefits may be marginal in clinical practice', 'inflexible rules and technology-driven prompts may produce care that is management-driven rather than patient-centred' and 'evidence-based guidelines often map poorly to complex multi-morbidity'. The authors subsequently presented 'a preliminary agenda for the movement's renaissance, refocusing on providing useable evidence that can be combined with context and professional expertise so that individual patients obtain optimal treatment'.

Despite all these nuances and changes applied within EBM, the essence of the ideas of Sackett and his followers remained unchanged. The authors who spoke of 'a movement in crisis' too, did not so much plead for less EBM or for it to end, as for a *renaissance* under the name of 'real EBM'.¹¹² The purpose and ideal continued to be a form of medicine based, as far as possible, on numerical, statistical-epidemiological knowledge. In addition, the key role of the RCT, not only as producer of reliable evidence, but also as paradigmatic example for the way in which bias could be eliminated as much as possible, remained one of the most distinctive features of EBM.¹¹³

Conclusion

Thus, the question as to whether EBM truly offered something new or is only old wine in new bottles seems to have been answered. Although it would probably be going too far to regard EBM as a new paradigm, a strong case may be made for saying that this movement went hand in hand with a distinctive increase in the importance of 'trust in numbers' in medicine. This does not just concern further development of the process of objectification and quantification which was set in motion as early as the nineteenth century. (Partly) under the influence of clinical epidemiology, the systematic review movement and the rise of evidence-based clinical guidelines, a specific form of quantification – namely statistical-epidemiological, probabilistic reasoning – penetrated medical practice more than ever before. The connection between EBM and healthcare policy, moreover, is also 'something new' compared to, for example, Pierre Louis's numerical method from the

111. Greenhalgh, Howick & Maskrey, 'Evidence-Based Medicine: A Movement in Crisis?'

112. Ibid.

113. See on this, for example: Howick, *Philosophy of Evidence-Based Medicine*.

nineteenth century which hardly had this political and macro-economic dimension. As a third new element, the intricate relations between information technology and evidence-based medicine might be added, following on from the work of the sociologist Nettleton on 'E-scaped' or 'informational medicine'.

This chapter outlined how and in what context this (relatively) new movement of clinical epidemiology, systematic reviews and EBM/EBHC emerged. Of great importance was the vision of founders such as Feinstein, Sackett, Wulff, Cochrane and Chalmers who, in the 1960s or 1970s, started opposing the dominance of the basic laboratory sciences and strived for a 'basic' *clinical* science for medicine and a more scientific medical practice. They did this at a time when medicine was faced with a large number of internal and external challenges, which may partly be understood as the downside of the successes of the 'golden age' of medicine in the 1940s, 1950s and 1960s. Scientific and technological progress had made everyday clinical practice more complex. Physicians were confronted with an increasing number of options and uncertainties, while they were not, or barely, able to keep up with all the developments in their profession. Furthermore, particularly from the 1970s onwards, there was severe external pressure on medicine because patients were empowered more, a strongly polarised debate was triggered on medicalisation and iatrogenesis, and because there was increasing government intervention in healthcare due to the burgeoning costs.

Clinical epidemiology was only one of the many new frameworks that were introduced in medicine against this background. Save for some local successes in the United States and Canada, impact and visibility of the new discipline was still very limited in the 1970s. This changed in the 1980s, when clinical epidemiology experienced a remarkable breakthrough in a number of countries. This can partly be attributed to the (relative) success enjoyed by clinical epidemiologists in both education and research. The department of clinical epidemiology and biostatistics at McMaster, in particular, proved its worth under the supervision of David Sackett. It was a special department in many ways, but Sackett and his followers were also helped by a change of course of the Rockefeller Foundation, which, at the beginning 1980s, decided to focus less on public health and more on clinical epidemiology.

In said department of clinical epidemiology at McMaster the EBM concept subsequently saw the light of day. EBM changed character over time: the initial emphasis on critical appraisal by *individual* clinicians shifted to systematic reviews and clinical guidelines, which served physicians *collectively* and aimed to 'bring order, predictability, and commensurability in an increasingly vast and heterogeneous domain'.¹¹⁴ To a considerable extent, this development was due to the growing influence of the British 'root' of EBM – the systematic review movement, that took-off in the 1970s inspired by the work

114. Weisz et al, 'Emergence of Clinical Practice Guidelines', p. 716.

of Cochrane and resulted in the Cochrane Collaboration in the 1990s. In addition, particularly in Great Britain, the country of the NHS, the principles of EBM were increasingly emphatically applied as an instrument for public health policy. This manifested itself in the concept of Evidence-Based Health Care. The external criticism of EBM which erupted contributed to the further refinements and nuances of the ideas of the movement, among others by Sackett himself. Yet the core of these ideas remained intact.

This historical overview 'from clinical epidemiology to EBHC' is broadly in line with what was written in the previous chapters on the processes of objectification and quantification in medicine and the accompanying shift from disciplinary to mechanical objectivity. Yet it is important to note that only a very rough sketch has been presented here, which merely provides a global impression of which factors played a role in the rise of clinical epidemiology, EBM, the Cochrane Collaboration and EBHC. It has been mentioned that the level of success and the manner of introduction of clinical epidemiology differed from country to country, and can only be truly understood when the specific local and national contexts are taken into account. This may be particularly true for the introduction of EBM/EBHC as there are major differences in terms of health culture and healthcare system between countries. It is therefore sensible to examine in more detail the introduction of clinical epidemiology and EBM in one country.

Moreover, such a 'case study' may help to provide more insight into the *effects* of quantitative methods and the statistical-epidemiological style of reasoning in medicine and healthcare policy. In this context, the historian Weisz raises the question of whether EBM is actually that significant. He argues that the softening of previous claims by Sackett and other EBM proponents have made for 'such a protean concept that anyone can appropriate it'.¹¹⁵ He therefore predicts: 'Available to everyone, and *meaning relatively little*, EBM will probably remain a popular catchphrase, at least until something better comes along'.¹¹⁶

In the next two parts, the Netherlands will be taken as a 'case study'. The main objective is to analyse the emergence of clinical epidemiology and EBM in more depth and detail. Secondly, an attempt will be made to demonstrate the significance and impact this has had.

115. Weisz, 'From Clinical Counting', p. 388.

116. *Ibid.*, p. 389.



Part II.

**The 'Evidence Base' of EBM:
a History of Clinical Epidemiology
in the Netherlands**

Introduction to Part II

When he retired as co-editor of the *Journal of Clinical Epidemiology* in 1996, Walter Spitzer reflected on the origin and rise of clinical epidemiology in the preceding quarter of a century. According to Spitzer, this 'bridge discipline'¹ did not have one but several founders: 'I am inclined to say that the combined efforts of Alvan R. Feinstein at Yale, David L. Sackett at McMaster, Sir Donald Acheson at Southampton, *and what I call the "Dutch School" of epidemiology*, deserve the lion's share of credit for the vigorous existence and advancement of clinical epidemiology.'²

There are more indications in the literature that the Netherlands occupies a special place in the history of clinical epidemiology. For example, in 2002, at the end of his career, David Sackett wrote in an article entitled 'Clinical Epidemiology: What, Who, and Whither': 'The dissemination of clinical epidemiology to other high-income countries proceeded at different paces and with varying enthusiasm. *It was quickly adopted in The Netherlands [...]*'³ It is striking that, in his summary of countries in which the 'dissemination' of clinical epidemiology was successful, Sackett mentioned the Netherlands first.

Following on from clinical epidemiology, evidence-based medicine too was accepted relatively quickly in the Netherlands, judging by the literature and interviews with Dutch stakeholders. The Dutch Cochrane Centre (DCC), for example, was established as early as 1994 – it was one of the first to be set up after the establishment of the 'mother centre' in Oxford, which officially launched in 1993 – and it has always been one of the most productive centres within the Cochrane Collaboration.⁴ The image of the Netherlands as one of the 'vanguard countries', when it comes to both clinical epidemiology and EBM, is further reinforced by the (alleged) contrast with surrounding countries. Sackett wrote in the aforementioned article that countries such as Germany and Spain were still dominated by "clinical authorities"⁵ Others argued that nations such as France and Belgium also 'lag behind' to a great extent. In this respect, Bossuyt mentioned the remarkable fact that Belgium did not boast any professor of clinical epidemiology, while in the Netherlands two Belgians – Bossuyt and Jan Vandenbroucke – have landed a chair of clinical epidemiology. On the situation in his country of origin, Bossuyt furthermore stated: 'Striking, isn't it [...]: when you travel 100 kilometres to the south, EBM is far less prominent'. He thought that the same was true for Germany, France and the countries in Southern Europe for that matter. Even in the United States, clinical epidemiology and EBM were never that significant – and in Canada and the Scandinavian countries only

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1. Spitzer, 'Clinical Epidemiology'.
 2. Spitzer, 'Future of Epidemiology', p. 706. TB's italics.
 3. Sackett, 'Clinical Epidemiology: What, Who, and Whither', p. 1163. TB's italics.
 4. See a.o. the website of the DCC: <http://dcc.cochrane.org/dutch-cochrane-centre>.
 5. Sackett, 'Clinical Epidemiology: What, Who, and Whither', p. 1163.

partially so. Only in Great Britain, Australia and the Netherlands, Bossuyt argued, did the EBM movement really manage to 'gain a foothold' early on. In this regard, the Netherlands was 'really special'.⁶

This begs the question of whether the Netherlands was indeed that 'special' – in terms of the manner in which, and the pace at which, clinical epidemiology and EBM were embraced. And if this is the case, what explanations could be given for this? In order to answer these questions properly, a thorough, international comparative study would have to be conducted. However, this falls outside the scope of the present research. It is nevertheless possible to shed more light on this issue, first of all by providing a description – in this second part of this dissertation – of how the introduction of clinical epidemiology within academic medicine in the Netherlands occurred. The persons or institutions that took the initiative, when and in what manner they did this and what forces or factors encouraged or rather delayed this, will be detailed. This way, the dominant image of a successful introduction of clinical epidemiology (and subsequently of EBM) in the Netherlands may be subjected to a critical analysis. In addition, there will be an attempt to present a further historical interpretation and explanation of the (relative) 'success' of this discipline in the Netherlands.

This part contains three chapters that will outline a history of clinical epidemiology in the Netherlands. Chapter 4 will begin with a description of how general or 'population' epidemiology in the Netherlands developed into an independent academic discipline in the 1970s and 1980s. The reason being that the rise of clinical epidemiology (and thus of EBM) in the Netherlands cannot be properly understood without having an insight into the developments in the 'mother discipline' (e.g. 'population epidemiology' or 'public health epidemiology'), which by and large preceded it. The increasing independence of epidemiology occurred in the context of a significant transformation of academic scientific research in the Netherlands during the course of the 1980s. Chapter 5 will sketch how, in the same decade and in the same context of a changing scientific climate, a remarkable 'movement' for the promotion of patient-related research originated. It will be argued that the academic establishment of clinical epidemiology in the Netherlands was largely related to this movement. There will also be an exploration here regarding the extent to which the introduction of clinical epidemiology in the Netherlands occurred in parallel to international developments, and to what degree 'typically Dutch' elements were present. In chapter 6, the main conclusions of chapter 5 will be refined with the help of four historical case studies of specific academic departments of clinical epidemiology in the Netherlands.

6. Interview with Bossuyt. Knottnerus and Vandenbroucke made similar statements in the interviews conducted by TB. See also: Hofman, *Veertig Jaar Epidemiologie*, p. 29; Jöckel & Stang, 'Perspectives of Clinical Epidemiology', pp. 375-8.

Thus, this second part contains a description and analysis of how both the 'evidence-base' and the institutional academic foundation were created for the introduction of evidence-based medicine in the Netherlands. At the same time, it will, however, become clear that the developments within medical (and in particular: clinical) scientific research largely have their own dynamics, which exist independently from trends and requirements in medical practice. This history of clinical epidemiology in the Netherlands will therefore, at the end of chapter 6, result in a number of pressing questions on EBM as a bridge between science and practice.

Chapter 4.

Epidemiology in the Netherlands

Contrary to what seems to be the case for clinical epidemiology, the Netherlands was nowhere near a 'pioneer' in the field of general or population epidemiology. Only during the 1970s and 1980s did general epidemiology acquire an independent status in the Netherlands. Nevertheless, this partly paved the way for the successful introduction of clinical epidemiology in the Netherlands. It is therefore necessary to elaborate on a number of developments within the 'mother discipline', in order to be able to understand and interpret the rise of the clinical variant.

This chapter first describes how general epidemiology in the Netherlands evolved from an auxiliary discipline to social medicine into an independent academic discipline. This development will subsequently be related to a number of radical changes that occurred in university scientific research from approximately 1980 onwards. This will provide a broader context in which, not only the evolution of general epidemiology in The Netherlands is to be expressly placed, but also – as will be discussed in chapters 5 and 6 – the emergence of *clinical* epidemiology.

As it is impossible to provide a complete overview of the history of epidemiology in the Netherlands in one chapter, the following paragraphs will mainly focus on the department of epidemiology at Erasmus University in Rotterdam. This department is very suitable for a case study, for a relatively large amount of information on its history is available.¹ Moreover, it was one of the most influential departments of epidemiology in the Netherlands. In addition, people from Rotterdam played a key role in the rise of clinical epidemiology in this country. Still, it must be noted that this single case-study can do no full justice to other departments of epidemiology.

The First Independent Chair; the Role of Querido

In 1969, the first 'ordinary' chair of epidemiology in the Netherlands was established in Rotterdam. This happened at the instigation of Andries Querido, who, from 1966 until

1. This is partly due to the active contribution to the writing of the history of the department by the epidemiologists from Rotterdam themselves. See a.o.: Hofman, *Veertig Jaar Epidemiologie*; Valkenburg & Hofman, *Kwart Eeuw*.

1969, was the founding dean of the medical faculty in the port city. The newly founded faculty was to contribute to a rapid increase in the number of training places for future physicians in the Netherlands, so that a threatening serious shortage of physicians could be averted. By mentioning the personal initiative of Querido and the fact that it concerned a new faculty, so that vested interests and historically developed organisational forms did not play a role, the main reasons are already identified as to why the first chair of epidemiology could be established.²

Querido had been professor of internal medicine at Leiden since 1948 and would, except for the short Rotterdam period, continue to fulfil this role until his retirement in 1983. Under his supervision, the clinical research carried out in the field of endocrinology flourished in Leiden. His foreign experiences were guiding here. During his studies in the 1930s, he had spent some time in Baltimore, at the department of biochemistry of the Johns Hopkins University, and he had visited laboratories in London and Cambridge. He subsequently worked for eight months in the laboratory for Microbial Physiology at the Institut Pasteur in Paris. A decade later, shortly after his appointment as professor in 1948, he spent six months as 'Rockefeller research fellow' in Massachusetts General Hospital in Boston. Apart from the fact that these foreign episodes formed Querido as a scientist, they strongly contributed to the development of his views on the proper manner of organisation for academic departments. In Leiden, he managed to successfully implement these ideas in his own department. Yet this did not satisfy him entirely as, over time, he had come to realise that clinical departments, university hospitals and medical faculties in the Netherlands could only (continue to) flourish if, by example from abroad, structural changes were implemented at a national level. During the 1950s and early 1960s, he made vigorous efforts to help realise these reforms.³ At the exact moment when, in 1965, Querido had to conclude, with great disappointment, that these efforts had yielded little, he was asked to establish a new medical faculty in Rotterdam.⁴

In his autobiography from 1990 he described his motives for saying 'yes' to this request as follows:

'Now the national activities had failed, the faculty level seemed to me the only area where change stood a chance. The existing faculties lacked shared objectives because they had

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2. See a.o. M. J. van Lieburg, *Vijf Eeuwen Medisch Onderwijs, Onderzoek en Patiëntenzorg in Rotterdam. Het Erasmus MC in Historisch Perspectief* (Rotterdam: Erasmus Publishing, 2003), pp. 98-112, 125-6, 128; A. Querido, *De Binnenkant van de Geneeskunde* (Amsterdam: Meulenhoff, 1990), pp. 191-2, 197; Valkenburg & Hofman, *Kwart Eeuw*, p. 50.
 3. Querido did this a.o. as chairman of the Committee of Scientific Personnel Medical Faculties that was established by the Ministry of Education and Science.
 4. Querido, *De Binnenkant*. See also: H. Benneker, J. C. van Es & E. Mandema, 'In Memoriam Prof. Dr. A. Querido', *Nederlands Tijdschrift voor Geneeskunde* 145 (2001), pp. 651-2; Van Lieburg, *Vijf Eeuwen*, pp. 99-100.

splintered into little kingdoms. Perhaps a new faculty could be set up in a more cohesive manner. Perhaps an efficient internal organisation would even be possible this way, so that from the total budget that was set by the government money could remain for new objectives of our own. Rotterdam opened a new door.⁵

The most distinctive and innovative aspect of Querido's role as dean was his drive to assign scientific research a much more central and substantial role than was usual at Dutch medical faculties.⁶ Querido's thoughts, however, were not primarily focused on epidemiology. The Rotterdam faculty launched in 1966 with two main areas of research – laboratory research in basic biomedical sciences and clinical research – within which no place was reserved for epidemiology.

This situation changed because Querido became inspired by the, in the course of his deanery also newly founded, medical faculty of Nottingham. Under the name of 'community medicine', a new field of education and research was introduced there, in which particular attention was paid to the issues of health and healthcare *outside* the hospitals. Typical here was that the 'community' functioned as 'patient' or object of investigation, as 'the health characteristics of a defined section of the population' were mapped out and studied.⁷ Querido wrote about this in his autobiography: 'It seemed to me that this new branch of medicine would help to make visible the real need for healthcare in society, as a result of which a more realistic design of this care would be possible.'⁸ He saw a possibility to give real substance to his determination to build a faculty that could 'respond to developments in research as well as to societal demand'.⁹

Querido decided to establish 'community medicine' as a research area in Rotterdam in the form of an 'extramural healthcare' partnership of which several institutes would form part: general practice (e.g. family medicine), 'social healthcare' (e.g. health services research), preventive and social psychiatry and medical psychology and sociology. Within and alongside this partnership, a large research institute for epidemiology and biostatistics would be created, one of the ideas behind it being that the institutes involved could receive advice and support in their research activities from this new research institute. However, the envisaged partnership did not get off the ground, yet the abovementioned (individual) institutes did originate, including an institute for epidemiology and biostatistics.¹⁰

5. Querido, *De Binnenkant*, p. 194.

6. See n. 2 above.

7. This definition of 'community medicine' is (a.o.) derived from Querido himself. See: *Ibid.*, p. 210.

8. *Ibid.*

9. *Ibid.*

10. Van Lieburg, *Vijf Eeuwen*, pp. 122, 127; Hofman, *Veertig Jaar Epidemiologie*, pp. 12-14; Querido, *De Binnenkant*, pp. 199, 210-11; Valkenburg & Hofman, *Kwart Eeuw*, pp. 42-4.

Thus, the establishment of the first independent department of epidemiology in the Netherlands was, 'irreverently put, part of a failed project.'¹¹ The appointment of Hans Valkenburg as professor of epidemiology, an internist from Leiden who had become an epidemiologist, did not come about smoothly either. The board of professors and lecturers in Rotterdam, which decided on professorship appointments, was not particularly convinced of the desirability of a chair of Epidemiology. Querido had to use all his powers of persuasion to push Valkenburg's nomination through. His main argument was that the input of a strong, independent department of epidemiology was required urgently, if extramural scientific research was to take off in Rotterdam. He argued that none of the other institutes that were supposed to venture into this field had a solid research tradition, nor did they have the right research methods at their disposal.¹²

Epidemiology and Social Medicine

The difficulties encountered with Valkenburg's appointment were typical for the marginal position of epidemiology in the Netherlands at that time. Valkenburg himself wrote that, in the years leading up to his appointment in Rotterdam, he had experienced 'that epidemiological research was still persistently considered to belong to the field of infectious diseases, and that it was not understood that epidemiology was an independent discipline, which carried out research in several areas and was not only concerned with combating epidemics.'¹³

Yet already in the 1940s and 1950s, people in the Netherlands were active in the field of the epidemiology of *chronic* diseases. Some of them carried out research into the relationship between smoking and lung cancer, similar to the famous English and American studies on this subject. From the 1950s onwards, the Netherlands was even an international leader in the field of tuberculosis epidemiology. In the 1960s and 1970s, the epidemiology of chronic diseases increasingly took shape within various medical faculties in the Netherlands. Valkenburg himself was an exponent of this trend. At the beginning of the 1960s, he very consciously shifted his focus from the epidemiology of infectious diseases to that of chronic diseases. Under the inspiring leadership of the Goslings brothers in Leiden, he subsequently started conducting research in the field of rheumatoid arthritis, a subject that has always remained of special interest to him. In his farewell oration from 1989, Valkenburg described himself as a typical representative of a generation of epidemiologists originating from the clinic. In their clinical work, they had run

11. This quote is from Esther van Osselen, who was one of the main authors of: Hofman, *Veertig Jaar Epidemiologie*. See p. 13.

12. *Ibid.*, pp. 11-14; Valkenburg & Hofman, *Kwart Eeuw*, pp. 44-5.

13. Valkenburg & Hofman, *Kwart Eeuw*, p. 44.

up against the fact that they only had the opportunity to investigate disease ‘independently of the environment in which it had originated’ and usually in an advanced stage as well. ‘So some of them took off their white coat, shut the hospital door behind them and started examining patients in their own environment’, Valkenburg recalled.¹⁴

According to experts, this generation of ‘old epidemiologists’ conducted research of high quality,¹⁵ yet its visibility and appeal within the academic world as a whole were limited. It was probably not conducive that epidemiology was generally considered to be part of social medicine at the time. Social medicine¹⁶ gained momentum in the Netherlands in the first decades after the Second World War. In the period between 1955 and 1970, nearly every university had a full professor of social medicine, who supervised an independently operating scientific institute. Over time, differentiation occurred in five separate branches of social medicine, namely: occupational medicine, insurance medicine, general healthcare, youth healthcare and a ‘fifth branch’ consisting of ‘special forms of social medicine’. The flowering of social medicine proved to be relative, however, and was short-lived moreover. Particularly from the 1970s onwards, there was an internal ‘branch debate’, which was characterised by concerns about the fragmentation into the aforementioned branches of the discipline and disagreement on its proper definition. Furthermore, both friend and foe had second thoughts about the scientific basis of social medicine. Research in this field would hardly materialise because the emphasis was mainly on educational activities. Yet education in social medicine did not meet expectations either. It was argued that it was not sufficiently in-depth and that sometimes it did not exceed the level of vocational training. Perhaps the main problem of social medicine, as also repeatedly argued by social physicians themselves, was its lack of appeal to medical students. For the majority of students, a career as a medical specialist or a general practitioner represented a much more attractive perspective than a career as a social physician. Social medicine was ‘an area you did not want to end up in at all; it was something you did only if you couldn’t do anything else.’¹⁷ In other words, social medicine never had the ‘glamour’ of

14. Valkenburg & Hofman, *Kwart Eeuw*, p. 21, see also pp. 4, 9, 19-20, 52. See also: Hofman, *Veertig Jaar Epidemiologie*, p. 15; Vandenbroucke, ‘Opkomst van de Medische Statistiek’, p. 2627.

15. See in particular: Vandenbroucke, ‘Opkomst van de Medische Statistiek’, p. 2627.

16. The most frequently used definition (from 1966 by professor Muntendam) for the discipline was: ‘Social medicine is the part of medicine which studies the interaction in relation to health and disease between man and the environment in both the material and immaterial sense, as well as the means to influence this interaction for preservation, improvement and recovery of health, and for prevention and spread of disease.’ Quoted in: J. B. Ringoir, ‘Nieuwe Bloei voor Sociale Geneeskunde? Ontwikkelingen in Kaart Gebracht’, *Medisch Contact* 48:2 (1993), pp. 55-7, on p. 55. Also see, for example: F. Sturmans, *Asklepios en Hygieia* (Nijmegen: Dekker & van de Vegt, 1979), p. 9.

17. Interview with Rick Grobbee, d.d. 23 januari 2012.

curative medicine – and population-oriented health care never received the same status as individual-oriented health care – to begin with.¹⁸

Querido, too, did not hold social medicine in high regard. In his view, 'precious little good and relevant research' had evolved from that corner.¹⁹ In the 'philosophy' he applied as founding dean, there was a strong focus precisely on research. In this respect, he saw much more potential in epidemiology, given the strong methodological and scientific developments this discipline had experienced since the Second World War, particularly in Anglo-Saxon countries, after some epidemiologists had started concentrating on the study of chronic conditions. Querido therefore decided to give epidemiology in Rotterdam an independent status, with a chair and department of its own, rather than placing it within an Institute for Social Medicine, as was the case with other medical faculties in the Netherlands.

According to Albert Hofman, who succeeded Valkenburg as professor of Epidemiology in Rotterdam in 1988, this decision had a major significance: 'With the appointment of Valkenburg, epidemiology acquired a distinct identity of its own. Its own "residence". And the opportunity to map out its own future.'²⁰ Hofman suggests that the establishment of an independent department of epidemiology enabled epidemiology to break free from social medicine in the course of the 1970s and especially in the 1980s, allowing it to develop into one of the most flourishing branches of science in the Netherlands.

It is too much of a stretch to only give the Rotterdam group credit for the eventual independence and flowering of epidemiology in the Netherlands. In, among others, Utrecht, Nijmegen, Groningen and subsequently Maastricht too, epidemiologists were active who contributed to this. This eventually led to a situation where, particularly in the 1980s, institutes for social medicine were partly or entirely transformed into or replaced by departments of general or clinical epidemiology.²¹ As Vandenbroucke had pointed out, epidemiology behaved like a 'young cuckoo' towards social medicine.²²

18. See on the problems of/in social medicine as addressed by representatives of the discipline themselves: 'Dr. H. Rengelink, Voorzitter College Voor Sociale Geneeskunde', *Medisch Contact* 45:49 (1990), pp. 1463-4; J. Bosman & J. W. H. Garvelink, 'Sociale Geneeskunde Moet Zich Sterker Profileren', *Medisch Contact* 39: 22 (1984), p. 680; Ringoir, 'Nieuwe Bloei'; J. K. van Wijngaarden & P. Schnabel, 'School of Public Health: een Nieuwe Opleiding in Nederland', *Medisch Contact* 46: 38 (1991), pp. 1107-10.

19. These are not Querido's own words, but this is what Valkenburg said in his farewell oration (many years later) about Querido's views on social medicine. See: Valkenburg & Hofman, *Kwart Eeuw*, p. 16.

20. Geciteerd in: Hofman, *Veertig Jaar Epidemiologie*, p. 15.

21. 'Dr. H. Rengelink'; Ringoir, 'Nieuwe Bloei'; Valkenburg and Hofman, *Kwart Eeuw*, p. 24; Vandenbroucke, 'Opkomst van de Medische Statistiek', pp. 2627-8. See also the way Dutch epidemiologists reflected, in the early 1980s, on the 'growth and flowering' of their discipline and their observation that this increasingly took place 'outside of social medicine': A. Hofman, 'Epidemiologie, waarheen?', *Tijdschrift voor Sociale Geneeskunde* 60 (1982), pp. 815-16; Vandenbroucke, 'Overpeinzingen'.

22. Vandenbroucke, 'Opkomst van de Medische Statistiek', p. 2627.

A striking example of this is the inaugural speech delivered by Ferd Sturmans in 1979 during the acceptance of his appointment of professor of Social Medicine at the Catholic University of Nijmegen. Although he was appointed professor of social medicine, his speech was mainly about epidemiology. At the end of his oration, Sturmans explicitly spoke of ‘the emphasis I feel I should be putting on Epidemiology within Social Medicine’. To his mind, social medicine, as designed in 1943 by its founder, Ryle, from Oxford, could be continued within the institutes for general practice, which had by then originated at all medical faculties.²³ Three years later, as it happens, Sturmans also officially became professor of epidemiology (rather than of social medicine), at Limburg University in Maastricht this time.

So it happened that social medicine was overpowered by the former ‘auxiliary discipline’ of epidemiology at virtually all Dutch faculties in the course of the 1970s and 1980s. Although this is not exclusively due to the Rotterdam department, it did play a key role in this process. Even when there were new developments which did not directly originate from this department, there would, as a rule, be a ‘Rotterdam’ connection of sorts. Sturmans, for example, before he was appointed in Nijmegen as professor of social medicine, was head of the Health Information Department of the Municipal Medical and Health Service (Dutch abbreviation: GG & GD) in Rotterdam, in which capacity he regularly worked with Valkenburg.²⁴

The Rotterdam Department

The Rotterdam department was not a great success from the start. Both education and research were very slow to get off the ground. In the design of the curriculum at the new Rotterdam medical faculty, the advent of new subjects such as epidemiology had not been taken into account. All lecture hours had already been allocated and, as was to be expected, other departments were reluctant to part with hours they had already acquired. Throughout Valkenburg’s professorship, available courses in epidemiology remained limited to six lectures for fourth-year medical students and a number of ‘practical’ courses.

During the first years, research within the department was minimal as well, partly because it proved extraordinarily difficult to recruit the right people for this. Valkenburg noted about this: ‘In the early days of the department, it was virtually impossible to find academics who were interested in epidemiology. Either no-one responded to repeated

23. Sturmans, *Asklepios En Hygieia*, the quote is on p. 23.

24. Valkenburg & Hofman, *Kwart Eeuw*, p. 24. See also on the Department of Epidemiology of the Medical Faculty in Rotterdam: Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan Onderzoek van het Disciplineplan Geneeskunde* (Den Haag, 1985), p. 73.

ads or the applicants were medical professionals who could not enter into another medical profession, and therefore considered an epidemiological role instead.²⁵

In the Netherlands there was a 'total unfamiliarity with the discipline'²⁶, according to Valkenburg. He felt compelled to participate in countless committees and consultative bodies, more than he would wish to, in order to establish a position for his department within the faculty and raise the profile of epidemiology.²⁷ Together with Sturmans, he also published two articles on epidemiology in *Medisch Contact* in 1976. From the tone and content of these articles, it becomes clear that the authors targeted an audience – namely the medical profession in the Netherlands – which was still in the dark about epidemiology and the most recent trends in this discipline. They deemed it necessary, for example, to reiterate that an epidemiologist also worked with 'diseases other than infectious ones'.²⁸

Other sources also show that the developments in the field of the epidemiology of chronic diseases, particularly in Anglo-Saxon countries, were barely registered in the Netherlands until well in the 1970s.²⁹ Sturmans, for example, published an article in 1977, once again in *Medisch Contact*, in which he described the transition from a mono-causal to a multi-causal disease model as if this was an entirely new phenomenon to the readers.³⁰ Even within the field of cardiology, it took a long time before multifactorial thinking in terms of risk factors was really accepted, although the 'new' epidemiology of chronic diseases had made headway, above all, in the cardiovascular field.³¹

The situation changed for the Rotterdam department of epidemiology in 1975 when Valkenburg had finally scraped together enough money for the launch of a research programme: the Epidemiological Preventive Research Zoetermeer (EPOZ), a prospective

25. Valkenburg & Hofman, *Kwart Eeuw*, p. 51.

26. *Ibid.*

27. See on the difficult early years of the Rotterdam department of epidemiology: *Ibid.*, pp. 45-6, 50-1, 54.

28. F. Sturmans & H. A. Valkenburg, 'Epidemiologie (I): Begripsomschrijving en Plaatsbepaling', *Medisch Contact* 31: 35 (1976), pp. 1111-7, the quote is on p. 1112; F. Sturmans & H. A. Valkenburg, 'Epidemiologie (II): Terreinen waarop Epidemiologische Benadering en Gegevens van Nut Kunnen Zijn', *Medisch Contact* 31: 36 (1976), pp. 1147-53.

29. In 1978, for example, the Dutch Health Care Inspectorate reported that the Netherlands lagged behind in the field of epidemiology. Combined with the articles on epidemiology in *Medisch Contact*, this also exemplifies that interest in epidemiology did increase from the latter half of the seventies onwards, and a fertile ground was originating for its blossoming. See: 'Jaarverslag 1976 Geneeskundige Hoofdinspecteur van de Volksgezondheid: Achterstand Gezondheidszorg op Gebied van Management en Epidemiologie', *Medisch Contact* 33: 5 (1978), pp. 137-41.

30. Sturmans, 'Epidemiologie en Ziekte-Oorzaken'.

31. This was, for example, explicitly and extensively stressed by Bart Dekker, the medical director of the Dutch Heart Foundation between 1971 en 1987, in the interview with TB. See also notes 27 and 28 above.

cohort study in which, eventually, 10,000 residents of Zoetermeer were followed.³² Important results and international publications would eventually result from the Zoetermeer study. In addition, this programme offered Valkenburg the opportunity to recruit PhD students. As a rule, these were young physicians who could not yet immediately embark on their specialised training and had therefore decided to carry out (epidemiological) PhD research to bridge this waiting period. For some of them this signified, usually unintentionally, the onset of a career in epidemiology. Examples include Hofman, who succeeded Valkenburg in 1988; Jan Vandenbroucke, who was appointed as professor of clinical epidemiology in Leiden in 1987; and Rick Grobbee, who became professor of clinical epidemiology in Rotterdam (1993) and in Utrecht (1996). They were taught the ‘craft’ of doing epidemiological research in the EPOZ at the beginning of the 1980s.³³

The Rotterdam department was still small at that time. About 20 people were employed, and this included support staff. It was, according to Grobbee, ‘one of these departments where accounting was done by Valkenburg on Sunday afternoons’. There was no structure or training for the handful of PhD students. ‘My training consisted of talking to Jan Vandenbroucke and Bert Hofman’, Grobbee recalls. Despite or perhaps due to the small scale and the lack of structure, it was, in his view, ‘one of the most innovative and

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32. Financial support from the Prevention Fund (in Dutch: Praeventiefonds) in particular was important to the EPOZ in the first years (the Dutch Heart Foundation and other funds would subsequently also contribute to the research). The Prevention Fund was founded in 1950 as the successor of the Prophylaxis Fund with the aim of promoting measures focused on the prevention of disease and/or the improvement of health. Where the Prophylaxis Fund had received monies from the Health Insurance Fund, the Prevention Fund drew on means from the Health Insurance Fund treasury. The fund was also managed by the Health Insurance Council (in Dutch: Ziekenfondsraad). In 1950, 4 million guilders were paid into this fund and 6 million guilders in subsequent years. From the coming into force of the General Act on Exceptional Medical Expenses (Dutch abbreviation: AWBZ) as of 1 January 1968 onwards, the revenue of the Prevention Fund was derived from the General Fund for Exceptional Medical Expenses, which was managed by the Health Insurance Council. The act stipulated that an amount of 10 million guilders be paid into the Prevention Fund annually, and that this amount be increased or decreased in accordance with the fluctuations of the index figure for wages in the Netherlands. This led to a considerable increase of the amounts to be spent by the Prevention Fund. In 1975, the fund could already spend twice as much, namely 20.7 million euros, as the 10 million from 1968. In the 1970s, it was the trend, moreover, that the greater part of the available monies was spent on research. Recommendations were made by a scientific advisory council, in which Andries Querido, particularly in 1973, held a prominent role. Coincidence or not: in this year Valkenburg received 1,392,000 guilders from the Prevention Fund. In 1975, another amount of 226,500 guilders followed. See on all this: C. Th. Bakker, *Geld voor GGZ. De Financiering van de Geestelijke Gezondheidszorg en de Invloed van Geld op de Zorgpraktijk (1884-1984)* (Amsterdam: Vosiuspers UvA, 2009), pp. 304-5; M. van Bottenburg, G. de Vries & A. Mooij, *Zorg tussen Staat en Markt: De Maatschappelijke Betekenis van de Ziekenfondsraad, 1949-1999* (Zutphen: Walburg Pers, 1999), pp. 77-8; Praeventiefonds, *Verslag over de Werkzaamheden van het Bestuur van het Praeventiefonds over het Jaar 1973* (’s Gravenhage, [1974]); Praeventiefonds, *Verslag over de Werkzaamheden van het Bestuur van het Praeventiefonds over het Jaar 1975* (’s Gravenhage, [1976]).
33. Hofman, *Veertig Jaar Epidemiologie*, pp. 17, 19-20, 27, 32, 203 et seq.; Van Lieburg, *Vijf Eeuwen*, p. 122; Valkenburg & Hofman, *Kwart Eeuw*, pp. 51-2, 57-61, 65, 70 et seq.

inspiring departments' and a 'hotbed of critical minds'.³⁴ Vandenbroucke subsequently wrote about this: "The greatest successes of Dutch epidemiology in recent years originated in places where small groups of researchers spontaneously found each other "on the workflow" [...]."³⁵ This image of a small yet special department emerges in virtually all available sources – including sources from *outside* this department.³⁶

In addition to the synergy between members of the 'small group' of Rotterdam epidemiologists, Anglo-Saxon examples and influences were also of key importance to the research programmes of the department. Between 1961 and 1963, Valkenburg had been research fellow at the School of Public Health of the University of Michigan where he had encountered a number of large cohort studies that had been set up in the United States based on the model of the Framingham Study (see chapter 2). His American experiences strongly impacted the manner in which the EPOZ as well as other research programmes took shape in Rotterdam.

This was not unique to Rotterdam. The epidemiologists Frits de Waard in Utrecht and Roelof van der Lende in Groningen, for example, were also strongly influenced by American and British examples in the design of their epidemiological research in the 1970s and 1980s. This greatly benefited the quality of Dutch epidemiological research, led to international publications and eventually contributed considerably to the development of the discipline in the Netherlands.³⁷ Thus, epidemiology was an important representative of a broader trend within Dutch (medical) science, in which, ever since the end of the Second World War, but increasingly so over time, a shift from a German to an Anglo-Saxon orientation had been manifest.³⁸

Dutch epidemiologists mainly looked at the developments in their discipline at the School of Hygiene and Tropical Medicine in London and at the Schools of Public Health of Harvard University in Boston, of the Johns Hopkins University in Baltimore and of several other North-American universities. The most influential figures in the field of research and methodology in epidemiology in the Netherlands included, among others, the Englishman, Geoffrey Rose; the American, Ken Rothman and the Finn, Olli Miet-

34. Interview with Grobbee.

35. Vandenbroucke, 'Opkomst van de Medische Statistiek', p. 2628.

36. See a.o.: Interviews with Büller, Dekker, Thomas and Vandenbroucke; Hofman, *Veertig Jaar Epidemiologie*; Valkenburg and Hofman, *Kwart Eeuw*.

37. See a.o.: Hofman, *Veertig Jaar Epidemiologie*, pp. 16-20, 30-31; Valkenburg & Hofman, *Kwart Eeuw*, pp. 1, 45, 51, 53, 64-5. Both books contain lists with dissertations and ('top') publications from people of the department. See also PubMed and other databases or search engines. See for the commentaries on all this from the early 1980s itself: Hofman, 'Epidemiologie, waarheen?'; Vandenbroucke, 'Overpeinzingen'.

38. This shift is (a.o.) mentioned in: H. de Waardt, *Mending Minds. A Cultural History of Dutch Academic Psychiatry* (Rotterdam: Erasmus, 2005), pp. 241-3; A. Mooij, *Polsslag*, pp. 437-42. Somewhat more implicitly this trend is also addressed in: L. J. Dorsman & P. J. Knegtman (eds.), *Universitaire Vormingsidealen: De Nederlandse Universiteiten sedert 1876* (Hilversum: Verloren, 2006), see in particular pp. 14-15, 97. Harry Büller too explicitly mentioned this shift in the interview conducted by TB.

tinien, who worked in the United States and later in Canada. Dutch epidemiology in the 1970s and 1980s was a niche environment, in which everybody knew each other well at a personal level. As a result, there was a great deal of exchange of ideas, and foreign examples were dealt with fairly eclectically. Yet various ‘schools’ of epidemiology emerged in the Netherlands to some degree, each with their own focus and their own foreign ‘heroes’.³⁹

The ‘Genius’ Miettinen

Within the Rotterdam ‘school’, Miettinen was, without a doubt, the great man. Valkenburg and his department got in touch with the Finn through Paul Hugenholtz, professor of cardiology and head of the prestigious Thorax Centre at the medical faculty in Rotterdam. Hugenholtz had left the Netherlands for the United States shortly after the Second World War, where he eventually ended up working as a paediatric cardiologist at the Children’s Hospital at Harvard Medical School. In 1965, he was visited by Querido in Boston, who offered him the professorship in Rotterdam. Querido had started looking for suitable people in the United States, that he had apparently been unable to find in the Netherlands, and with whom he could fulfil his ambition to give research a central place within the new Rotterdam faculty. Hugenholtz himself experienced a ‘dramatic’ difference between the Dutch situation of 1965 in which ‘clinical research as part of medical profession was barely heard of’ and the ‘Boston-American model where research was part of the clinic as a prerequisite’. In his perception it took many years – until approximately the mid-1980s – before the ‘American attitude’ was accepted by other Dutch academics in his profession.⁴⁰

Hugenholtz knew Miettinen from Boston and introduced him in Rotterdam. On the face of it, it might not be obvious for a professor of cardiology to come up with the idea of bringing his colleagues at the Rotterdam faculty into contact with a theorist in the field of epidemiology. Hugenholtz, however, took a personal interest in epidemiology, which had been triggered during his American period by the various developments in the field of cardiovascular epidemiological research occurring precisely in the United States. Furthermore, when he came to Rotterdam, it was brought to his attention by Querido that, in a sense, he had a moral obligation to ‘give something back’ to the citizens of Rotterdam. The dean suggested that something be done for the community of the town and its immediate surroundings: ‘Querido wanted for us, as a Thorax Centre, to stimulate and support community cardiovascular care provided by general practitioners’, Hugenholtz

39. Interviews with Bossuyt, Van der Graaf, Grobbee, Knottnerus and Vandenbroucke. See also: Hofman, *Veertig Jaar Epidemiologie*, pp. 20-1; Vandenbroucke, ‘De Vele Gezichten’.

40. Interview with Hugenholtz. See also: Van Lieburg, *Vijf Eeuwen*, pp. 102-3; Querido, *De Binnenkant*, 194.

explained. This resulted in the launch of a typical epidemiological study in the 1970s as one of the first research projects at the Thorax Centre, in collaboration with local general practices: the IMIR research (Imminent Myocardial Infarction Rotterdam research) in which the characteristics of patients with myocardial infarction as admission diagnosis were studied.⁴¹

Querido's autobiography casts some light on his motives for thus encouraging Hugenholtz to offer room for epidemiological research in the local community within the large clinical department that was the Thorax Centre. Querido wrote that he and his fellow board members were concerned as to whether staff members felt connected enough to the new faculty and would perhaps be recruited all too soon by other universities or succumb to the financial temptations of non-academic practice. It was therefore crucial in their view that staff members be proud of the fact they worked in Rotterdam. The faculty therefore had to acquire a 'distinct identity and reputation of its own, both for its peers and for the urban population'.⁴² At the Thorax Centre that Hugenholtz intended to set up, Querido recognised the ideal vehicle to focus the attention of both the Rotterdam people and medical professionals on the new faculty. Rotterdam still had few facilities in the field of thoracic cavity disorders, and the newly emerging cardiac surgery moreover appealed to the imagination. The Thorax Centre was also perfectly in line with Querido's ideas on the social role to be fulfilled by university hospitals:

'Ever since the Second World War, university hospitals had developed into the most specialised hospitals [...]. The way I saw it, university hospitals had therefore also been assigned a distinct regional role, independently from education. In addition to less specialised hospitals and other healthcare facilities, every region had to have such a highly specialised centre including staff and equipment.'⁴³

The Thorax Centre had to (and would) become an outstanding example of a specialised top department with a strong regional role. Not without pride, Querido mentioned in his autobiography that, already by the mid-seventies, Hugenholtz's department served a residential area with approximately two and a half million people in the South-West of the Netherlands.⁴⁴ Referring to the IMIR research, he added that the Thorax Centre 'also [acquired] a place with the people of Rotterdam themselves, first of all through large-

41. This study resulted in, among others, the so-called AMIRO meter (Acute Myocardial Infarction Rotterdam meter). On the basis of an 'AMIRO score' GPs could make an estimation of the probability that patients who reported chest pain had an acute myocardial infarction.

42. Querido, *De Binnenkant*, p. 206. See also: Van Lieburg, *Vijf Eeuwen*, p. 121.

43. Querido, *De Binnenkant*, p. 211.

44. *Ibid.*, pp. 206-7.

scale research in the town into the distribution of people with a threatening myocardial infarction.⁴⁵

Thus, a combination of motives – Querido's interest in community medicine, his desire to draw the attention of the local community to the new faculty and his efforts to flesh out the regional role of academic hospitals that he advocated – induced him to urge Hugenholtz to 'give something back' to the town of Rotterdam. This ultimately resulted in the IMIR research that was launched from the Thorax Centre. This created the remarkable situation in Rotterdam where there were not one but actually two departments conducting epidemiological research. Hugenholtz found that Valkenburg was to be applauded for allowing – and even supporting – the IMIR research by the Thorax Centre, which was essentially carried out in 'his' field. The cooperation of Sturmans, who worked for the Municipal Medical and Health Service in Rotterdam during the 1970s, was also of great importance according to Hugenholtz: 'He made the town receptive to epidemiological thinking.'⁴⁶

In order to get the IMIR research and, over time, other epidemiological research off the ground methodologically, Hugenholtz had Miettinen 'flown in' from Boston as an advisor. He left the further development of the epidemiological activities within the Thorax Centre largely to his *protégé* Koos Lubsen. In 1978, Lubsen, along with the future professor of general practice, Emiel van der Does, obtained a PhD with the IMIR research. Hugenholtz was supervisor, Miettinen one of the co-supervisors.⁴⁷ Lubsen was highly impressed by Miettinen, and continued to follow the Finn throughout his career, once describing him as 'one of the most important theorists and perhaps the 'Leibniz' of modern epidemiology'⁴⁸, among others, because he is believed to be the one who 'turned medicine into an exact science.'⁴⁹

Miettinen did not just influence Lubsen and the small epidemiological sub-department within the Thorax Centre. The researchers of Valkenburg's department also frequently collaborated with Miettinen and soon incorporated his ideas.⁵⁰ It did not take long, moreover, before Miettinen was also discovered by epidemiologically interested

45. Ibid. p. 207.

46. Interview with Hugenholtz. See also on all this: M. L. Geleijnse, J. W. de Jong & M. L. Simoons (eds.), *1968 Thoraxcentrum 2008* (Rotterdam: Erasmus MC, 2008), pp. 12-13, 124; Hofman, *Veertig Jaar Epidemiologie*, p. 19; Van Lieburg, *Vijf Eeuwen*, pp. 121-2, 130; The remark that there were 'actually two departments of epidemiology' is a paraphrase from the interview with Grobbee.

47. E. van der Does & J. Lubsen, *Acute Coronary Events in General Practice: The Imminent Myocardial Infarction Rotterdam Study* (Rotterdam, 1978); Hofman, *Veertig Jaar Epidemiologie*, pp. 19, 23; Van Lieburg, *Vijf Eeuwen*, p. 122.

48. J. Lubsen, *Epidemiologie als Wegwijzer bij Medisch Handelen* (Rotterdam, 1986), p. 6.

49. Cited in: Hofman, *Veertig Jaar Epidemiologie*, p. 20.

50. Ibid., p. 19.

scientists elsewhere in the Netherlands. The Dutch Heart Foundation played an important role as a mediator here. Early in the 1970s, Hugenholtz, who, after his arrival in Rotterdam, became involved with the Heart Foundation, had already brought Miettinen into contact with the then medical director of the foundation, Bart Dekker. He regarded Miettinen as 'a genius, one of the few true geniuses I know'⁵¹ and managed to recruit him as advisor to the Heart Foundation. Added to his contacts in Rotterdam, this meant that Miettinen was able to come to the Netherlands several times a year for a longer period of time. He used the opportunity to give a number of his famous courses and workshops on the theory and methodology of epidemiology in the Netherlands. Furthermore, with funding from the Heart Foundation, Dekker arranged for a number of people to be posted to Harvard for a year to follow the Master's programme in epidemiology there with Miettinen. These people included, among others, Dekker himself, Koos Lubsen and Frans Kok, who would become professor at the Agricultural University of Wageningen.⁵² Independently of this, Vandenbroucke had studied with Miettinen for a year in Boston at the end of the seventies, before he moved to the Netherlands.

When they had returned from Boston, these people, in turn, also gave courses in the spirit of their Finnish master, mostly with the aid of the Heart Foundation.⁵³ Lubsen later remembered the two-week courses that he supervised as follows:

'They were perceived to be tough and difficult by the participants. You would be taken up with it from nine in the morning until eleven at night. In the weekend between the first and the second week I organised a sailing trip on Lake IJssel (Dutch: IJsselmeer). It is called teambuilding these days. At any given time during this weekend there would be a number of people I had to convince not to give up. Yet after three years, 75 people had participated.'⁵⁴

51. Interview with Dekker.

52. Ale Algra, the latter professor of clinical epidemiology in Utrecht and Leiden, too, for example, was posted to Boston by the Heart Foundation, where he pursued the Master of Science in Epidemiology at the Harvard School of Public Health in the academic year 1984-1985. Miettinen had just left for McGill University in Montreal then, but his impact was still noticeable in Boston according to Algra. In addition, Miettinen twice returned to Boston for a week to give his 'famous course' (Interview with Algra). The Rotterdam department of epidemiology continued to cooperate with Harvard, where, after Miettinen's departure to McGill University, Ken Rothman was the big man in the field of epidemiology. Rick Grobbee stayed at Harvard for six months at the end of the eighties, for example, but he also followed a summer programme at McGill, so with Miettinen (interview with Grobbee). See also, on Miettinen's 'famous courses': A. Algra, *Hoofdzaken* (Leiden: Universiteit Leiden 2006), p. 14.

53. Interviews with Dekker, Grobbee, and Vandenbroucke; Hofman, *Veertig Jaar Epidemiologie*, p. 21. According to Vandenbroucke another 'collection box fund', the Queen Wilhelmina Cancer Fund, played a similar role in promoting epidemiology as the Heart Foundation in The Netherlands.

54. Cited in: Hofman, *Veertig Jaar Epidemiologie*, p. 21.

The number of this type of epidemiological courses, which were most often taught by either Miettinen himself or by followers of his, rose swiftly in the Netherlands in the early 1980s. This was partly due to the lack of formal training programmes and courses in epidemiology. When, for example, Yolanda van der Graaf, who later became a professor of clinical epidemiology in Utrecht, became involved in epidemiological PhD research in the mid-1980s, she found that regular training opportunities in this area simply did not exist. Instead she followed several of the aforementioned ‘informal’ courses, including one with Miettinen,⁵⁵ ‘as anyone in the Netherlands with any interest in epidemiology did.’⁵⁶ From the courses and the resulting follow-up days and discussion groups ‘the nucleus for epidemiology in the Netherlands eventually originated’, according to Lubsen.⁵⁷ Vandenbroucke speaks in this regard of ‘young people, who were gripped by epidemiology.’⁵⁸

A striking number of these ‘young people’, of whom a considerable number considered themselves followers of Miettinen, subsequently ended up in important and strategic places within epidemiology, clinical epidemiology, evidence-based medicine and health-care policy. The most explicit exponents of the ‘school’ of Miettinen in the Netherlands included the previously mentioned Hofman, Lubsen, Grobbee, Vandenbroucke, and Kok, who all took their first steps in the field of epidemiology in Rotterdam, and subsequently became professors of (general or clinical) epidemiology in Rotterdam or elsewhere. Under this category of Miettinen followers with Rotterdam ‘roots’, the names of several other professors may be filed, such as that of Jan Tijssen, who, after having worked at the Thorax Centre in Rotterdam for a long period of time, was appointed as professor of the clinical epidemiology of cardiovascular diseases at the University of Amsterdam; Arno Hoes, who obtained his PhD under the supervision of Hofman at the Rotterdam department of epidemiology, subsequently becoming professor of clinical epidemiology and general practice in Utrecht; and Martin Offringa, whose career also took off in Rotterdam, and who subsequently became head of the Dutch Cochrane Centre in Amsterdam, was one of the authors of the first Dutch textbook on evidence-based medicine, and later also became professor of clinical epidemiology in paediatrics at the University of Amsterdam.⁵⁹ In addition to these explicit ‘disciples’ of Miettinen, there were many others as well, including some from ‘outside’ Rotterdam, on whom the Finnish epidemiologist had some impact at the very least. This applies, for example, to the previously mentioned Van der

55. Interview with Van der Graaf. See also: Algra, *Hoofdzaken*, p. 14.

56. Interview with Vandenbroucke.

57. Cited in: Hofman, *Veertig Jaar Epidemiologie*, p. 21.

58. *Ibid.* Vandenbroucke used similar wordings in the interview with TB.

59. Interviews with Algra, Dekker, Grobbee, Offringa and Vandenbroucke. See also: Grobbee & Hoes, *Clinical Epidemiology*, p. xxi.; Hofman, *Veertig Jaar Epidemiologie*, pp. 19-22, 102-3; Lubsen, *Epidemiologie als Wegwijzer*; Offringa, *Met en Wegen*, pp. 12-13; J. P. Vandenbroucke & A. Hofman, *Grondslagen der Epidemiologie*. 6th ed. (Maarssen: Elsevier/Bunge, 1999), p. ix.

Graaf,⁶⁰ as well as to André Knottnerus, the professor of general practice in Maastricht, (former) chairman of the Health Council and of the Scientific Council for Government Policy. Knottnerus found Miettinen's ideas 'extraordinarily convincing'.⁶¹

Thus, Miettinen's impact in the Netherlands seems hard to overestimate. This is in remarkable contrast to the international medical and epidemiological literature, in which Miettinen was considered a significant figure in the early 1980s, but was no longer or barely mentioned in the last decades. That Miettinen largely passed into oblivion outside the Netherlands has a number of probable causes. Firstly, he was never able to develop a very strong institutional position for himself. Miettinen was a 'difficult character' who sooner or later ended up in conflict almost everywhere he worked. His publications, moreover, are extraordinarily inaccessible. It was acknowledged, also by his admirers, that Miettinen was admittedly a brilliant thinker and a good speaker, but a 'lousy writer'. He had particular significance for the development of epidemiology in the Netherlands – but probably elsewhere too – via workshops, courses and verbal, often informal contacts, without much written evidence remaining of this.⁶² His impact can therefore not be measured on the basis of the number of times that articles or books he wrote have been quoted in the international medical literature.

Yet the way in which people who had dealings with him speak about him is revealing. Knottnerus, for example, reported on his personal experiences with the Finnish teacher: 'I followed a course with Miettinen in 1982 and this was impressive.'⁶³ Comments by others are in a similar vein. Grobbee, for example, states: 'Those first Miettinen experiences, they have been indelible.' The Dutch people involved are also univocal on the exact merit of Miettinen: he taught them a *way of thinking*.⁶⁴ Exemplary is the way in which Vandenbroucke, during his inaugural speech as professor of clinical epidemiology in Leiden, addressed Miettinen in 1987: 'I learned *how to think* under your guidance and tutelage.'⁶⁵

Miettinen defined epidemiological research as 'occurrence research'.⁶⁶ Here he deviated from the (then) more common definitions of epidemiology in which the 'dissemination', 'distribution' or 'frequency' of disease within (part of) the population, as well as its

60. Interview with Van der Graaf.

61. Interview with Knottnerus. See also: J. A. Knottnerus, *Dialectiek van het Onderzoek in de Huisartsgeeneskunde* (Maastricht: Rijksuniversiteit Limburg, 1988), p. 8.

62. Interviews with Algra, Dekker, Van der Graaf, Grobbee, Offringa and Vandenbroucke.

63. Interview with Knottnerus.

64. This is literally stated in these terms by Van der Graaf and Grobbee, but several other interviewees used similar terms. And also see the words of thanks addressed to Miettinen in several inaugural lectures (see n.65 below).

65. Vandenbroucke, *Klinische Epidemiologie*, p. 23. Original italics. See for similar words of thanks in inaugural lectures: D. E. Grobbee, *Epidemiologie, Kunst en Essentie* (Utrecht: Universiteit Utrecht, 1997), p. 20; Lubsen, *Epidemiologie als Wegwijzer*, p. 18.

66. O. S. Miettinen, *Theoretical Epidemiology: Principles of Occurrence Research in Medicine* (Hoboken, NJ: John Wiley & Sons, 1985), p. viii, see also pp. 1-19.

determinants, were usually identified as subject of study.⁶⁷ In Miettinen's view, the problem with this type of description was that it only indicated an application area and not a fundamental concept. He was of the opinion that a scientific discipline was to be defined on the basis of its object of research. The central point of his theoretical work was that, in the case of epidemiology, the 'occurrence relation', or the functional relationship between a determinant and outcome, was the formal object of study.⁶⁸

The practical significance of this theoretical contribution by Miettinen to epidemiology was exceedingly great according to his Dutch students. They found that Miettinen's 'way of thinking' was very effective in setting up thorough epidemiological research. If a researcher started defining the 'occurrence relation' involved in accordance with Miettinen's instructions and, in addition, determined on what 'domain' they wished to be able to make generalisable statements on the basis of the research – for example, a category of patients, a specific part of the general population, or a certain type of situation to which the occurrence relation pertained – how the research was to be set up would follow (almost) automatically. The starting point of the determinant-outcome relationship also gave direction to the integration of statistical techniques and probabilistic reasoning in epidemiological studies.

In addition, the 'occurrence relation' proved applicable to diverse areas and types of research. In classical aetiological epidemiological population research, it could be defined as the functional relationship between the occurrence of disease (the outcome) and protective and risk factors (the determinants). However, when the researcher wanted to know to what extent a new diagnostic test accurately predicted the presence of a certain disease, he could regard the diagnostic data of this test as determinants and the presence of the relevant disease as outcome. In this case, the object of the research was the functional relationship between the diagnostic data and the disease. This way, the object of study in various types of research could be defined in the form of a determinant-outcome relationship. In prognostic research, this was the relationship between prognostic data and the clinical course of a disease, and in intervention research the relationship between a medical treatment and its effects.

With this large scope of the concept of the 'occurrence relation', Miettinen saved epidemiology in the Netherlands from fragmentation, according to several of his followers. Over time, the number of application areas of epidemiology expanded greatly. From the Second World War onwards, chronic conditions were studied, in addition to infectious diseases. Particularly from the 1980s onwards, research was no longer conducted at the level of (part of) the 'general population', as more and more (clinical-epidemiological) studies focused on clinical populations. The traditional rather unilateral focus on etiolog-

67. See a.o.: Sturmans & Valkenburg, 'Epidemiologie (I)', p. 1112; J. P. Vandenbroucke & A. Hofman, *Grondslagen der Epidemiologie*. 4th ed. (Utrecht: Bunge, 1993), pp. 1-2.

68. Miettinen, *Theoretical Epidemiology*, see pp. 1-19 in particular.

ical research also disappeared and, to an increasing extent, diagnostic, prognostic and intervention research was performed as well. From the 1990s onwards, specialisations such as pharmacological and genetic epidemiology got off the ground too. Other specialists focused on specific areas of epidemiological study such as nutrition, the environment, labour and veterinary medicine. The 'occurrence relation' may be considered to apply to all of these domains and application areas.⁶⁹

So, it is perfectly understandable that many Dutch epidemiologists were able to work with Miettinen's 'way of thinking', both in education and in research. In the most frequently used textbooks in *education* in the field of both general and clinical epidemiology, Miettinen's approach is used as a starting point.⁷⁰ In the Netherlands, generations of new epidemiologists continue to be 'raised' with the ideas of the Finnish theorist. It is therefore justified to refer to a Dutch 'school of Miettinen', which is fairly extensive. Few countries have so many epidemiologists per capita as the Netherlands.⁷¹

Perhaps most important was Miettinen's influence on the development of epidemiological *research* in The Netherlands. Those involved argue that the 'way of thinking' of the Finnish theorist enabled them to substantially improve the quality level of their research. The result of this was not only that Dutch epidemiologists started publishing in renowned international journals from approximately 1980 onwards, but also that they made considerable progress in securing subsidies for new research projects. The available data on publications, promotions and research budgets show that Dutch epidemiology ended up in a virtuous circle in the course of the 1980s. According to his followers, this was largely due to the theoretical and methodological 'quality improvement' Miettinen's 'way of thinking' had brought about.⁷²

Interesting in this context is the role the Finnish 'genius' fulfilled as advisor to the Dutch Heart Foundation during the 1970s and 1980s. Bart Dekker, the then medical

69. See on all this: Interviews with Algra, Dekker, Van der Graaf, Grobbee, Offringa and Vandenbroucke; Grobbee, *Epidemiologie, Kunst en Essentie*; Hofman, *Veertig Jaar Epidemiologie*, pp. 18-20, 131; P. Knipschild, *Epidemiologie in de Contramine* (Maastricht: Rijksuniversiteit Limburg, 1985); Lubsen, *Epidemiologie als Wegwijzer*; Miettinen, *Theoretical Epidemiology*, pp. 1-19; Offringa, *Meten en Wegen*, pp. 12-14; Valkenburg and Hofman, *Kwart Eeuw*, p. 33; Vandenbroucke & Hofman, *Grondslagen Der Epidemiologie*, pp. 1-2.

70. See a.o.: Grobbee & Hoes, *Clinical Epidemiology*; Hofman, Grobbee & Lubsen, *Klinische Epidemiologie*; Vandenbroucke & Hofman, *Grondslagen der Epidemiologie*. This is explicitly true for the master programme 'epidemiology' of UMC Utrecht, which was, in 2009, the first accredited epidemiology training program in the Netherlands. See the website of the Netherlands Epidemiology Society: www.epidemiologie.nl.

71. See a.o.: Hofman, *Veertig Jaar Epidemiologie*, p. 11.

72. Interview with Grobbee; Hofman, *Veertig Jaar Epidemiologie*, pp. 18-21, 30-32; Valkenburg & Hofman, *Kwart Eeuw*, pp. 65 et seq. These publications also provide data with respect to publications, promotions and budgets. See also databases such as PubMed with respect to the publications, and for reflection on the 'growth and flowering' of epidemiology. See from that time itself: Hofman, 'Epidemiologie, waarheen?'; Vandenbroucke, 'Overpeinzingen'.

director, regularly asked Miettinen to assess subsidy applications for scientific research submitted to the foundation, for Dekker had noticed ‘that a considerable percentage of all these subsidy applications by professors did not bear too close examination’. Problem definitions were often very ‘nebulous’. Applications merely mentioned methodology, for example, and did not focus on that which applicants wanted to know. He also regularly received research proposals that were comprised of nothing more than: ‘we have a set of data here, what can we do with it?’ He also encountered all manner of other methodological shortcomings, with the findings being that applications assumed numbers of test subjects which made the research virtually impossible.

As he was secretary of the Scientific Advisory Board of the Heart Foundation, the body that decided on the allocation of subsidy funds, Dekker was able to ‘precook’ the meetings of this group in consultation with Miettinen. As he was able to put forward the critical comments of the Finnish advisor on submitted subsidy applications during these meetings he, as he said it himself, managed to avoid ‘granting subsidies to projects that were doomed to failure.’ Yet Miettinen’s role extended beyond helping to reject unsuitable research proposals. In the event of inadequate yet ‘fixable’ subsidy requests, Dekker would ask Miettinen to talk to the researchers in question and help them to improve and rewrite their research proposal, so that they could still receive this subsidy. In addition, in this period, the Heart Foundation had more money than was spent on subsidy. This offered the opportunity to also develop projects of their own for a while. On the basis of annual themes, focused research was set up and subsidised. For several years, the Heart Foundation even had an epidemiology department of its own, of which, among others, Vandenbroucke, Lubsen and Kok formed a part for a shorter or longer period of time. Miettinen was closely involved in all of this.⁷³

A New Era in Academic Research

The course of events within the Heart Foundation described above – and in particular the critical manner in which Dekker and Miettinen reviewed subsidy applications – is exemplary for a significant change in climate surrounding (medical-)scientific research, which occurred in the Netherlands around 1980. For a long time, individual clinical professors could independently conduct research at medical faculties according to the ‘Humboldt’ ideal of *Einsamkeit und Freiheit*. They could determine for themselves what issues they wished to address and what methods they used, without having to account for this or being hindered by outside interference. As a result, *clinical* research (as supposed to laboratory research) within medical faculties invariably had the character of ‘small, ill-defined

73. All this is based on the interview with Dekker and also (partly) on the interview with Vandenbroucke.

projects, carried out by one individual, usually without bearing any relation to other projects, carried out in the same department.⁷⁴ Even when, in the 1960s and 1970s, the government increasingly adopted a directive role in the fields of healthcare and scientific education, scientific research largely remained unaffected. But around 1980, in a relatively short time, the government took 'a torrent of measures that would change the face of university research for good.'⁷⁵

These measures were, above all, intended to cut costs in times of tough economic circumstances. The government, however, also wanted to give more direction to the content of scientific research in three ways. Firstly, the government aimed for more *societally-driven* research. In the preceding decades, the number of researchers that could be appointed at each faculty was (largely) based on the number of students per faculty. This system made it virtually impossible to align the content of university research with societal priorities. In a changing society, in which the authority of traditional authorities, including universities, had come under increasing pressure, this was no longer considered to be desirable. In the funding of university research, the government therefore shifted the emphasis from the so-called 'first flow of funds' to the 'second flow of funds' (and 'the third flow of funds') from 1980 onwards. In order to achieve more 'societally-driven' research, separate financing schemes were created for the benefit of research focused on specific social needs. Management of such funds was often delegated to organisations such as the Dutch Organisation for Pure Scientific Research (Dutch Abbreviation:

74. L. H. M. Akkermans, 'Experimentele Heelkunde', in: *De Heelmeester: Professor Dr. Paul Wittebol en de Utrechtse Kliniek 1970-1988* (Utrecht, 1988), pp. 23-4. Also cited in: Klijn, *Verlangen naar Verbetering*, p. 276.

75. P. Baggen, 'De Wereld Veranderen: Universiteit en Overheidsbeleid in Nederland, 1960-2000', in: L. J. Dorsman & P. J. Knegtmans (eds.), *Universitaire Vormingsidealen: De Nederlandse Universiteiten sedert 1876* (Hilversum: Verloren, 2005), p. 101. This important change of course in the science policies of the Dutch government was initiated in 1979 with the Policy Memorandum on University Research (Beleidsnota Universitair Onderzoek) was issued by the Ministry of Education & Science. Between 1971 and 1981, three successive cabinets in The Netherlands (already) had a separate Minister (without portfolio) of Science Policy. Already in 1974, the then Minister of Science Policy, Boy Trip, issued the Nota Wetenschapsbeleid (Science Policy Memorandum) in which his ideas on the general framework for the *organisation* of effective and efficient science policy were outlined. However, it was not until approximately 1980 that these and other developments resulted in significant 'actual' science policy decisions and measures (which marked the beginning of a 'new era' for academic research). See on all this: Ministerie van Onderwijs en Wetenschappen, *Beleidsnota Universitair Onderzoek* ('s Gravenhage: Staatsuitgeverij, [1979]); Stichting voor Medisch Wetenschappelijk Onderzoek FUNGO, *Beleidsnota 1982 t-m 1986* ('s Gravenhage:, [1981]); Adviesgroep SGO, *Stimulering van Patiëntgebonden Onderzoek: Van Onbegrip tot een Begrip. Symposium ter Gelegenheid van de Afsluiting van het Stimuleringsprogramma Gezondheidsonderzoek (1986-1997)* ('s Gravenhage: SGO, 1997), pp. 14-19. See on the profound effects of these governmental policies, specifically on academic *medical* research: Van Lieburg, *Vijf Eeuwen*, pp. 114-16, 130-1; H.J. Schuurman, 'Medisch-Wetenschappelijk Onderzoek Nu en in de Toekomst: Wordt "Science" "Fiction"?', *Medisch Contact* 41: 25 (1986), pp. 796-8; C. Spreeuwenberg, 'Onderzoeksbeleid Volksgezondheid', *Medisch Contact* 43: 9 (1988), p. 227; J. Verhoef, 'Financiering wetenschappelijk onderzoek', *Medisch Contact* 46: 2 (1991) pp. 54-5.

ZWO). In 1980, the second and third flow of funds combined contributed less than 30% to the funding of university research, and in 2000 this figure had risen to approximately 50%. The share of the first flow of funds therefore dropped from over 70% to approximately 50% in the same period. The increased emphasis on social relevance also manifested itself in the name change of the ZWO in 1988. The word 'pure' was removed, so that, from then on, the Dutch acronym ZWO was replaced by NWO. As an extension of this, ZWO subsidiary FUNGO (Dutch abbreviation for the Foundation for Fundamental Medical Research) continued as NWO subsidiary MEDIGON (Foundation for Medical Research and Health Research).

Secondly, the government wanted to promote the *programming* of scientific research. Between 1960 and 1980, the number of 'man years' devoted to research at Dutch universities had risen from 1,600 to 5,700. This more than tripling of the volume of academic research activities had not or barely been accompanied by any coordination between universities. In order to do something about this lack of cohesion and the resulting 'duplicates' in Dutch scientific research, the Ministry of Education and Science took a number of targeted measures. In 1984, for example, so-called 'conditional funding' was introduced: a large part of the first flow of funds was only granted under strict conditions. One of these conditions was the presence of coherent research programmes of considerable scope. Almost simultaneously, the universities were also faced with two major rounds of cutbacks by the ministry, which were launched under the titles of 'Task Division and Concentration' (Dutch: Taakverdeling en Concentratie) and 'Selective Shrinkage and Growth' (Dutch: Selectieve Krimp en Groei) in 1983 and 1986 respectively. These operations were aimed at saving money, amongst others by encouraging universities to schedule their research programmes better, to set priorities in their research policy and to properly coordinate all this too. Furthermore, incentive measures were taken to promote research programmes that were identified as being important and promising. Decision-making during these rounds was not only left to the universities themselves by the minister, but he would regularly personally take the initiative to extract research funds from universities, faculties or departments in a targeted way or reallocate them instead.

Thirdly, in addition to social relevance and programming, the research policy of the Dutch government was focused on *quality improvement*. There was a widespread feeling that the quality of academic scientific research had strongly deteriorated in the preceding decades. The number of researchers had increased so much in this period, that there was an impression universities had not been able to be very selective in hiring scientific staff. According to this reading, the growth of the universities had come at the expense of the quality of the researchers and thus of research.⁷⁶ The abovementioned conditional fund-

76. Typical, for example, is Querido's remark that the multiplication of the number of researchers led to the 'dilution' of medical-scientific literature, see: Querido, *De Binnenkant*, p. 235.

ing was aimed at tackling this problem as well. Proposals for research programmes had to be subjected to peer review, before they were eligible for funding. This created a great deal of resistance with universities and led to time-consuming bureaucratic procedures. At the beginning of the 1990s, the universities managed to persuade the government to replace conditional funding with a system of post-control by review committees, which is used to this day.⁷⁷

Not without reason was the period of the regime of Minister Deetman at the Ministry of Education and Science (1982-1989) retrospectively described as 'remarkable'.⁷⁸ The measures that were taken then in many ways heralded a new era for academic research.⁷⁹ University researchers could no longer count in advance on monies from the first flow of funds, as the external assessment, which formed part of the conditional funding, contrary to expectations of some professors, proved to be anything but a formality. As the government also clearly shifted the emphasis from the first to the second and third flow of funds, researchers increasingly had to compete with their peers for the funds that were placed with organisations such as ZWO (subsequently NWO) and, as of the 1990s, ZON (Dutch abbreviation of Health Research the Netherlands). It became an increasingly important part of their work to try and secure subsidies by means of submitting project proposals, where only the best proposals were approved. Professors could no longer 'freely pursue their own interests'⁸⁰ either, as university administrators soon understood the importance of improved organisation, coordination and planning of research activities. This led, among other things, to targeted choices with respect to the establishment of specific 'lines' of research. From the late 1980s onwards, moreover, intra- and inter-university research schools were established that have since occupied a central position in the structure of academic research. Due to these developments, research, besides being less 'free', became less 'pure' as well. Baggen writes about this: 'Until 1960, societally

77. This overview of the developments in Dutch governmental policies on academic research is mostly based on: Baggen, 'De Wereld Veranderen'. But see also: E. J. Boer, 'Knelpunten in Structuur en Financiering Van Medisch-Wetenschappelijk Onderzoek', *Nederlands Tijdschrift Voor Geneeskunde* 135 (1991), pp. 430-5; Klijn, *Verlangen naar Verbetering*, pp. 231, 265, 269-85; Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan*; H. Knippenberg & W. van der Ham, *Bron van Aanhoudende Zorg. 75 Jaar Ministerie van Onderwijs [Kunsten] en Wetenschappen* (Assen: Van Gorcum, 1993), pp. 638-784; Ministerie van Onderwijs en Wetenschappen, *Beleidsnota Universitair Onderzoek*; Raad van Advies voor het Wetenschapsbeleid, *Jaaradvies 1983* ('s Gravenhage., [1983]); O. Schreuder, *Proeven van Eigen Cultuur: Vijfenzeventigjaar Katholieke Universiteit Nijmegen 1923-1998. Deel 2: 1960-1998*. (Nijmegen: Katholieke Universiteit Nijmegen, 1998), pp. 260-1, 276-7, 324-7; Stichting voor Medisch Wetenschappelijk Onderzoek FUNGO, *Beleidsnota*, pp. 3, 8.

78. This qualification is derived from: Knippenberg & Van der Ham, *Bron van Aanhoudende Zorg*, p. 777 (see also p. 780).

79. This is a paraphrase from: Klijn, *Verlangen naar Verbetering*, p. 269.

80. This is paraphrased from: *Ibid.*, p. 276.

relevant research within the university had been a major exception. After 1980, it almost seemed to become the rule.⁸¹

That this transformation could occur within the short period of one decade, may partly be explained by the enlightened self-interest from which university researchers and administrators (re)acted. In the implementation of its cutback policies, the Ministry of Education and Science expressly took into account scientific achievements. What specific consequences this could have, may, among others, be illustrated on the basis of a number of events in Utrecht. Many were severely shocked there when Minister Deetman decided in 1988 that the oldest academic dental school in the country, which was established in Utrecht, would be discontinued, the main reason being the ‘minimal research’ that was conducted there. The medical faculty was also hit relatively hard by the cutbacks. Unlike the situation elsewhere, in Utrecht, all clinicians were employed by the faculty (and not by the university hospital). As a result, the ministry was given the impression that the scientific productivity – the relationship between ‘output’ and number of employees – at the Utrecht medical faculty left a great deal to be desired. Funds for the Utrecht faculty were therefore cut more severely than those of other medical faculties in the Netherlands. At the same time, the ‘medical cluster’ in the city, consisting of the university hospital, the Wilhelmina Children’s Hospital and the ‘Ooglijdersgasthuis’ (a clinic for ophthalmology), was also faced with cutbacks by the Ministry of Health (see chapter 7). Faculty and hospital were driven into each other’s arms in this situation, with both doing their utmost to intensify mutual collaboration and coordination of policy in order to respond to the tight financial situation at that point. It was decided, by mutual agreement, to cut in the budgets of those departments in particular that performed poorly in the field of research. The department of anaesthesiology was even threatened with dissolution, ‘for it played no part whatsoever in research approved by external assessors within the framework of conditional funding.’⁸² Furthermore, the department of radiology underwent ‘de-academisation’, continuing as an ‘ordinary’ clinical department.⁸³

This type of specific examples and events occurred at all universities and (medical) faculties.⁸⁴ To anyone who moved in university circles it was soon clear what lesson had to be drawn from this. To avoid funding cuts or even the dissolution of departments and

81. Baggen, ‘De Wereld Veranderen’, p. 104. See on all this also (a.o.): R. S. Reneman, ‘Veranderingen in het Wetenschappelijk Onderzoek: van Onderzoeker naar Manager?’, *Medisch Contact* 53, no. 7 (1998), pp. 235-8; Verhoef, ‘Financiering wetenschappelijk onderzoek’.

82. Klijn, *Verlangen naar Verbetering*, p. 275.

83. *Ibid.*, pp. 273-85.

84. See for example; R. van Herk, *Een Schepping uit het Niets: 25 Jaar VU-Ziekenhuis* (Amsterdam: Academisch Ziekenhuis Vrije Universiteit, 1991), pp. 100-1; Knegtman, *De Medische Faculteit Maastricht*, pp. 184-209; Van Lieburg, *Vijf Eeuwen*, pp. 114-16, 118, 121, 130; Mooij, *Polsslag*, pp. 440-2, 454; Schreuder, *Proeven van Eigen Cultuur*, pp. 260-6, 274-9, 312-27; ‘Vakgroep Huisartsgeneeskunde Leiden Moet Blijven’, *Medisch Contact* 42: 17 (1987), p. 537.

institutes, it was important to meet the requirements of the ministry in respect of social relevance, programming, quality and productivity of scientific research as much as possible.⁸⁵

This lesson was taken to heart, not least by the administrators of medical faculties. As Vandenbroucke noted in his oration from 1989, 'we need to go back in time more than a century [...] before we end up in a period that is as turbulent for the Dutch Faculties of Medicine as the current period is'.⁸⁶ He referred, among others, to plans from the 1980s for a merger between the Rotterdam and Leiden faculty.⁸⁷ In addition, there was great fear in Utrecht at that time that the minister would decide to terminate the medical school there altogether.⁸⁸ Although the Rotterdam-Leiden merger did not come about, and there are no indications that the Utrecht closure was seriously considered, this does reflect something of the concerns brought about by government policy in the 1980s within the medical faculties.⁸⁹ There was more than enough reason for this. Of the 318 million guilders' worth of budget cuts during operation Task Division and Concentration, for example, a considerable part had to be financed by the medical faculties and the university hospitals. In these 'turbulent times', as Vandenbroucke calls them, administrators sought ways to better profile their faculty, particularly in the field of research. This led, among other things, to a situation in which it became the policy to concentrate money, resources and manpower as much as possible on those lines of research and areas that were most likely to 'score'.⁹⁰

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85. See n. 84 above, and also: Baggen, 'De Wereld Veranderen', pp. 103-4; Schuurman, 'Medisch-wetenschappelijk onderzoek'; Adviesgroep SGO, *Stimulering*, pp. 35-36.
86. Vandenbroucke, *Klinische Epidemiologie*, p. 22.
87. Interview with Vandenbroucke.
88. Klijn, *Verlangen Naar Verbetering*, pp. 279-80.
89. Interesting in this context is, for example, the alarming tone and message in a policy memorandum of the FUNGO foundation (subsidiary to ZWO, the Dutch Organisation for Pure Scientific Research) from 1981. In response to the policy intentions as mentioned in the Policy Memorandum University Research (BUOZ) from 1979, this memorandum discussed the 'considerable uncertainty' with respect to the budgets for medical-scientific research. According to this memorandum, the policy intentions would result in the eventual 'severe erosion' of medical-scientific university research. As 'general reductions' were still to be expected from corners other than the BUOZ as well, no less than an 'emergency' would eventually arise. See: Stichting voor Medisch Wetenschappelijk Onderzoek FUNGO, *Beleidsnota*, pp. 3, 31.
90. See on this (a.o.): Boer, 'Knelpunten'; H. H. W. Hogerzeil, 'Het Plan-Deetman. De Gezondheidszorg en de Concept-Beleidsvoornemens van de Minister van Onderwijs en Wetenschappen', *Medisch Contact* 38: 29 (1983), pp. 887-90; Klijn, *Verlangen Naar Verbetering*, pp. 273-85, 302-5; Knippenberg & Van der Ham, *Bron van Aanhoudende Zorg*, p. 749; Van Lieburg, *Vijf Eeuwen*, pp. 114-16, 130-1; Mooij, *Polsslag*, pp. 441-2; Schreuder, *Proeven van Eigen Cultuur*, pp. 324-7; Schuurman, 'Medisch-wetenschappelijk onderzoek'; Verhoef, 'Financiering wetenschappelijk onderzoek'.

Conclusion: the Growth of Epidemiology in the Netherlands in Context

With the above digressions, the context is sketched in which the increasing independence of epidemiology in the Netherlands must be placed. The improvements in epidemiological research in the Netherlands around 1980, which were partly due to the theoretical input by Miettinen, could hardly have occurred in a more favourable period. Epidemiology was admittedly still a minor and insignificant discipline, but in the new circumstances of academic research of the 1980s, the achievements of the Dutch epidemiologists did begin to be noticed, not least among university administrators. The exponents of the 'Rotterdam school', such as Hofman, Lubsen and Vandenbroucke, in particular, were very much in demand. If they wanted to, they could become professors 'anywhere', they later remembered.⁹¹

This statement is not a gross exaggeration on the part of the people involved, but may be understood very well in the light of the changes in academic research described above. While, in the eyes of many, the Institutes for Social Medicine fell short in scientific productivity, epidemiology in the Netherlands seemed to be able to cope much better with the era of conditional funding and competition for research subsidies. This was also explicitly mentioned in 1985 by the Royal Netherlands Academy of Arts and Sciences (Dutch abbreviation: KNAW) in an influential advisory report on the planning of medical research in Dutch universities. The report stated that social medicine at medical faculties 'was poorly represented in terms of research', while epidemiological research in the Netherlands was 'on the rise'.⁹²

It is not by chance that, in the mid-1980s, new full and extraordinary professors of (general or clinical) epidemiology were appointed at various universities, mainly at the expense of the academic position of social medicine. Cases in point are the appointment of Ferd Sturmans in 1982 and Paul Knipschild in 1985 in Maastricht, and Vandenbroucke in 1987 in Leiden. Vandenbroucke was put in charge of a new department of clinical epidemiology, which occurred with the same budget and number of full-time posts, as an Institute for Social Medicine which, just previously, had been fully disbanded. Hofman and Lubsen stayed in Rotterdam, but did become professors there (in 1988 and 1986 respectively), as did Grobbee in 1992.⁹³

91. Interview with Vandenbroucke; Hofman, *Veertig Jaar Epidemiologie*, p. 22.

92. Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan*, p. 73.

93. Interviews with Grobbee and Vandenbroucke; Hofman, *Veertig Jaar Epidemiologie*, pp. 20, 23, 27, 32; Knipschild, *Epidemiologie in de Contramine*; Lubsen, *Epidemiologie als Wegwijzer*; Valkenburg & Hofman, *Kwart Eeuw*, pp. 27-41, 65 et seq.; Vandenbroucke, 'Opkomst Van De Medische Statistiek'; Idem, *Klinische Epidemiologie*. In 1987, moreover, Miettinen was appointed as full professor in the theory of medicine at VU University, where he became director of the Institute for Health and Care Research (Dutch abbreviation: EMGO-instituut), which would develop into an important centre in the field of

Under the leadership of this new generation of professors, epidemiological research in the Netherlands saw strong growth from the late 1980s and early 1990s onwards. The Rotterdam department still led the way here. Within several years, the 'unregulated mess' from the days of Valkenburg was transformed into a large, well-organised department in which tens of PhD students and as many other staff members found employment. For the purpose of the training for PhD students, the research school NIHES (Netherlands Institute for Health Sciences) was founded in 1992, with general, clinical and genetic epidemiology as spearhead disciplines. Grobbee points out that in Rotterdam a 'very business-like approach to research' developed where, above all, an 'entire machinery for PhD research' was created, 'with a good training programme, a solid infrastructure in which data could be collected, and major scientific production, which by any standard could compete with that resulting from internal medicine, cardiology, and so on.'⁹⁴ The flagship of Rotterdam epidemiology was a new major cohort study, launched in 1989 and officially bearing the name ERGO (Erasmus Rotterdam Health and the Elderly Study), but primarily known as the 'Rotterdam Study' in the international literature. At the fortieth anniversary of the department in 2009, it was proudly announced: 'In the top 25 of most frequently quoted Dutch researchers, six alone are affiliated to the ERGO research.'⁹⁵

This trend of expansion and commodification also occurred (to a greater or lesser extent) with other university epidemiological departments, such as the Institute for Health and Care Research (Dutch abbreviation: EMGO-instituut) at VU University in Amsterdam.⁹⁶ This general trend was noted by a joint report in 1999 by the KNAW and the Association of Cooperating Dutch Universities in which epidemiology (including clinical epidemiology) was identified as one of the areas in which the Netherlands excelled internationally. More recent reports by such organisations also mentioned epidemiology as being one of the most 'prominent' areas of scientific research in the Netherlands, from an international perspective. As a profession, too, epidemiology strongly developed from the late 1980s onwards with, among others, an active Netherlands Epidemiology Society, certified training courses and a registration system.⁹⁷

epidemiology (under Miettinen's successor Lex Bouter). Due to conflicts that soon arose, Miettinen's professorship did not turn out to be a great success, but it is illustrative of the academic status epidemiology managed to acquire and of the significance that was attached to the role Miettinen had played as a theorist (interview with Dekker). See also: O. S. Miettinen, *Theory of Medicine: At the Core of Post-Flexnerian Education in Medicine?* (Amsterdam: Vrije Universiteit, 1987).

94. Interview with Grobbee.

95. Hofman, *Veertig Jaar Epidemiologie*, p. 11, see also pp. 27-32. See also: Van Lieburg, *Vijf Eeuwen*, pp. 122, 131; Valkenburg & Hofman, *Kwart Eeuw*, pp. 66-9.

96. See n. 93 above, and: www.emgo.nl.

97. Hofman, *Veertig Jaar Epidemiologie*, pp. 26-32; Koninklijke Nederlandse Akademie van Wetenschappen, *Discipline Report on (Bio)Medical and Health Science Research in the Netherlands 1998* (Amsterdam: KNAW, [1999]); Raad voor Medische Wetenschappen, *Gezondheidsonderzoek: Het Investeren Waard* (Amsterdam: KNAW, [2007]); W. A. van Stiphout, R. de Vet & M. Reij, 'De Kracht van de Epidemiolo-

The rapid rise of epidemiological research was not without criticism and, not least from within, critical comments were made.⁹⁸ In addition, within the total spectrum of medical research, epidemiology has always continued to occupy a modest position. Basic laboratory research has always held the highest status, thus managing to attract the most money and attention.⁹⁹

The point here, however, is not to precisely indicate if and to what degree epidemiology in the Netherlands developed into a 'success'. More importantly, the methodological development, acquired independence, growth and commodification of this discipline, both in Rotterdam and elsewhere, must be placed against the background of the metamorphosis experienced by university research over the past decades, particularly at medical faculties. The transformation of the scientific climate in the Netherlands did not occur on its own, moreover, but may largely be interpreted as being part of an international trend that is sometimes described as the transition from 'little science' to 'big science'.¹⁰⁰

This is not to say that the blossoming of epidemiology, given the changing circumstances of the 1980s, was almost inevitable, or happened via a more or less compelling logic. This chapter explicitly brought to the fore that personal and contingency factors greatly impacted the manner in which epidemiology developed in the Netherlands. In this context, the special roles Querido and Miettinen fulfilled, in particular, were addressed. The latter was able to make his mark on Dutch epidemiology more or less 'by chance': via Hugenholtz, who brought him to Rotterdam as advisor and also put him in touch with Bart Dekker of the Heart Foundation. It has furthermore been pointed out, for example, that the synergy among the small group of epidemiologists in Rotterdam was a major 'success factor'.

Both aspects of this brief history of epidemiology in the Netherlands – on the one hand, personal, local and contingent factors and, on the other hand, the broader context of the (both nationally and internationally) changing climate of university science – cast their shadow, as it were, on the way in which clinical epidemiology subsequently also

gie', *Medisch Contact* 56: 23 (2001), pp. 896-8; Vandenbroucke, 'Opkomst Van De Medische Statistiek', p. 628. See also the website of the Netherlands Epidemiology Society: www.epidemiologie.nl. In the 1999 report of the Koninklijke Nederlandse Akademie van Wetenschappen (Royal Academy of the Sciences), the departments of Hofman in Rotterdam and of Vandenbroucke in Leiden, in particular, are praised: both the current quality of the research efforts there and the future prospects of these departments were qualified as 'excellent'.

98. Valkenburg & Hofman, *Kwart Eeuw*, pp. 20-3; Vandenbroucke, 'Opkomst van de Medische Statistiek', p. 2628.

99. This was discussed, a.o., in the interview with Van der Graaf.

100. See on this, for example: De Solla Price, *Little Science, Big Science*; Galison & Hevly, *Big Science*; Heilbron, Van Bottenburg and Geesink, *Wetenschappelijk Onderzoek*; Mooij, *Polsslag*, pp. 440-2; F. Miedema, *Science 3.0.: Real Science, Real Knowledge* (Amsterdam: Amsterdam University Press, 2012); Ravetz, *Scientific Knowledge*.

managed to acquire a strong academic position in the Netherlands. The following chapters will be dealing with this.

Chapter 5.

Patient-related Research in Motion

In a publication from 2009 on the occasion of the fortieth anniversary of the Rotterdam department of epidemiology, Esther van Osselen argued that it was not so much the quantitative blossoming of population-oriented epidemiology which was the most striking development in the recent history of the discipline, but rather a ‘qualitative’ change, namely: ‘the breakthrough to the clinic’. With this, Van Osselen referred to the rise of clinical epidemiology in the Netherlands, explicitly mentioning Sackett and Feinstein as great inspirations.¹

The question is, however, whether the ‘breakthrough to the clinic’ is the right description for this, as it suggests that clinical epidemiology originated from epidemiology, and that the initiative lay with ‘population-epidemiologists’ who managed to progress to the clinic. In this respect, the reference to Sackett and Feinstein as inspirations is problematic, as they were not the product of epidemiology but of the clinic. They were both internists who encountered issues and problems in clinical practice and, while searching for answers and solutions, discovered that methods from epidemiology could be helpful here. Their relationship with population-epidemiologists has always been tense.² The relationship between the clinical ‘branch’ they founded and (general) epidemiology has therefore always been more complex than qualifications such as ‘breakthrough to the clinic’ suggest.

This also applies to the situation in the Netherlands. It is striking how long the developments at McMaster and Yale, which were detailed in chapter 3, remained far outside the scope of Dutch epidemiologists. The courses by Miettinen and others from the beginning of the 1980s and the major epidemiological studies that were carried out were fully focused on the ‘population’ and not on the clinic. In Rotterdam, there was hardly any contact between Valkenburg’s department and the clinical departments – except for the Thorax Centre to which Lubsen was affiliated as an epidemiologist. Elsewhere in the Netherlands the situation did not essentially differ. Epidemiologists followed the example

1. Hofman, *Veertig Jaar Epidemiologie*, p. 22.
2. See chapter 3.

of community medicine in England and the various schools of public health in the Anglo-Saxon world³ rather than that of Feinstein and Sackett.

There was even a growing demand for the foundation of a 'school of public health' in the Netherlands – which, for that matter, was eventually founded in 1991 after 10 years of preparation. This way, there was an attempt to 'catch up' with other countries.⁴ Ironically, this happened precisely in a period when the Rockefeller Foundation – which had financially facilitated and supported many schools of public health from 1916 onwards – had embarked on a different course. As discussed in chapter 3, in 1981, on the occasion of a report in which the alleged gap between the schools of public health and medical schools was criticised, the board of the Rockefeller Foundation decided to shift its focus (and thus its financial flows) from public health to clinical epidemiology.⁵

This development was soon noticed in the Netherlands and explicitly addressed by the Rotterdam epidemiologists, Hofman and Vandenbroucke,⁶ but this seems to have had little impact. In general, Dutch epidemiologists did see opportunities to expand their scope outside the usual aetiological population research. Yet most of them did not focus so much on the clinic as on the field of policy and management. One of the most prominent examples of this was Ferd Sturmans. In his oration from 1979 he argued that there were roughly two areas of application for the epidemiological method:

'The *first direction* aims to contribute to the identification of *aetiological* factors and factors that influence the pathogenesis of diseases [...]. The *second direction*, epidemiology serving *healthcare policy*, aims to provide the required data for "planning", management and evaluation of services for prevention, control and treatment of diseases and for the establishment of priorities. This direction in epidemiology forms part of what is also known as "health services research".⁷

3. Interviews with Algra, Van Gijn, Grobbee and Vandenbroucke; the focus on 'community medicine' was already mentioned in chapter 4, in the section on the founding of the Rotterdam department of epidemiology. See on this, for example: F. Sturmans & H. A. Valkenburg, 'Epidemiologie ten Dienste van het Gezondheidszorgbeleid', *Medisch Contact* 32: 18 (1977), pp. 559-63. See also the remainder of this section and notes 4, 6-9.

4. 'Jaarverslag 1976 Geneeskundige Hoofdinspecteur'; 'Plaats van de Sociale Geneeskunde in de Gezondheidszorg. Rapport Taakgroep Sociale Geneeskunde LAD/ANVSG', *Medisch Contact* 33: 37 (1978), pp. 1121-9; E. Iwema Bakker, 'Steen aan een Nederlandse "School of Public Health"', *Medisch Contact* 44: 33/34 (1989), p. 1028; Ch. O. Pannenberg, 'Een Nederlandse "School of Public Health": "School of Public Health" of "School of Social Medicine", oftewel het Oneigenlijk Gebruik van de Gezondheidszorgwetenschap', *Medisch Contact* 31: 43 (1976), pp. 1367-70; C. Spreeuwenberg, 'A Dutch School of Public Health', *Medisch Contact* 46: 38 (1991), p. 1099; Van Wijngaarden & Schnabel, 'School of Public Health'.

5. Evans, *Health of Populations*. See for more on this chapter 3.

6. Hofman, 'Epidemiologie, Waarheen?'; Vandenbroucke, 'Overpeinzingen'.

7. Sturmans, *Asklepios en Hygieia*, pp. 12-13. TB's italics.

Several times, in 1976 and 1977, Sturmans had emphasised the role epidemiology could play as ‘intelligence service to healthcare policy’ in articles in *Medisch Contact*,⁸ which were co-written with Valkenburg. In 1982, along with several co-authors, he fleshed this out further in a series of articles in the same journal under the title ‘Epidemiology and Planning of Healthcare Provisions.’⁹ A great deal of what Sturmans pleaded for was integrated within two new doctoral programmes, which were launched in 1980 and 1982 respectively: Social Health Science at the General Faculty (so not the medical faculty!) in Maastricht, and General Healthcare at a new Interfaculty in Rotterdam.¹⁰

Thus, at the beginning of the 1980s, Dutch epidemiology did not tend towards a ‘breakthrough to the clinic’, but to public health and health services research. In a way, the ‘macro-dimension’ of what would subsequently be called evidence-based medicine or evidence-based healthcare was thus established earlier in the Netherlands than the ‘micro-dimension’. This was, for example, expressed in Lubsen’s oration from 1986, in which he stated:

‘That epidemiology has [...] a signpost role in the formulation of policy in healthcare will not come as a surprise to you. *Considerably less known*, however, is that epidemiology has the same signpost role in the clinic at the bedside of the patient or in the consultation room of the general practitioner.’¹¹

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8. Sturmans & Valkenburg, ‘Epidemiologie (I)’; Idem, ‘Epidemiologie (II)’; Idem, ‘Epidemiologie ten Dienste’.
 9. F. Sturmans & W. G. van Arkel, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. 1: Evaluatie als Essentieel Onderdeel van de Planningscyclus,’ *Medisch Contact* 37, no. 18 (1982), pp. 550-6; Idem, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. 2: Evaluatie van het Diagnostisch Proces (a),’ *Medisch Contact* 37: 20-21 (1982), pp. 610-14; Idem, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. 2: Evaluatie van het Diagnostisch Proces (b),’ *Medisch Contact* 37: 22 (1982), p. 670-74.; A. Ament, W. G. van Arkel & F. Sturmans, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. 3: Over Besluitvorming en Beslissing,’ *Medisch Contact* 37: 30 (1982), pp. 901-4; F. Sturmans & W. G. van Arkel, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. 4: Het Onderzoeken van Effectiviteit en Veiligheid,’ *Medisch Contact* 37: 38 (1982), pp. 1200-06; A. Ament, W. G. van Arkel & F. Sturmans, ‘Epidemiologie en Planning van Gezondheidszorgvoorzieningen. Slot: Beslissingsmodellen voor het Therapeutisch Proces,’ *Medisch Contact* 37: 43 (1982), pp. 1386-92.
 10. F. A. Bol, ‘Gezondheidskunde,’ *Medisch Contact* 34: 50 (1979), p. 1571; Idem, ‘Algemene Faculteit Maastricht: Een Nederlandse “School of Public Health”?’; *Medisch Contact* 33: 10 (1978), p. 299; Idem, ‘Een School voor Gezondheidskunde?’; *Medisch Contact* 33: 11 (1978), p. 331; T. Landheer, ‘Gezondheidszorgonderzoek,’ *Medisch Contact* 36: 44 (1981), pp. 1369-70.; H. L. Leunissen, ‘De Studierichting Sociale Gezondheidskunde aan de Rijksuniversiteit Limburg,’ *Medisch Contact* 34: 50 (1979), pp. 1589-94; Van Lieburg, *Vijf Eeuwen*, p. 127; J. Moen & A. de Roo, ‘Een School voor Algemene Gezondheidszorg: Plannen aan de Erasmus Universiteit Rotterdam,’ *Medisch Contact* 34, no. 50 (1979), pp. 1595-98; ‘Een Nieuwe Algemene Faculteit: Rijksuniversiteit Limburg Introduceert Opleiding Soicale Gezondheidskunde,’ *Medisch Contact* 33: 10 (1978), pp. 315-16; Valkenburg & Hofman, *Kwart Eeuw*, pp. 16-17; ‘Van “School of Public Health” naar “Health Science Center”,’ *Medisch Contact* 37: 38 (1982), p. 1206.
 11. Lubsen, *Epidemiologie als Wegwijzer*, p. 1.TB’s italics. See also: Hofman, ‘Epidemiologie, Waarheen?’; Vandenbroucke, ‘Overpeinzingen’.

It follows from this that the introduction of clinical epidemiology did not automatically shadow the previously described evolution of 'general' or 'population epidemiology'. The emergence of the new discipline in the Netherlands 'stands apart' to a certain degree and will therefore be discussed separately in the next two chapters. However, this story does largely take place in the same context of the transformation of the university research climate after 1980.

The 'breakthrough' of clinical epidemiology in the Netherlands took place in the 1990s. Yet the foundation for this was already laid in the preceding decade. This will be further developed in this chapter on the basis of a description and analysis of a *movement* in and on behalf of *patient-related research*, which originated in the 1980s and which, both in a practical and ideological sense, greatly contributed to the 'success' of clinical epidemiology in the Netherlands. At the end of this chapter, all this will be placed in an international perspective while, at the same time, 'typically Dutch' aspects will be identified.

The 'Weakness' of Patient-related Research in the Netherlands (early 1980s)

In the early 1980s, several authorities sounded the alarm bell about the purportedly deplorable state of applied clinical research, also termed 'patient-related research'. The most influential was a report by the Advisory Council for Scientific Policy (Dutch abbreviation: RAWB) which stated, among others: 'With concern the Council observes, and it is not alone in this, that, generally speaking, patient-related research in the Netherlands is weak.'¹² According to the RAWB, this was not due to a lack of financial resources. Patient-related research included approximately 70% of the total number of research projects and over 50% of the total number of man years devoted to health research. That the quality of this type of research was nevertheless poor, had to do with 'the organisational structure of the (cooperation between) medical faculties and university hospitals'. By this, the Council meant, among others, that patient care generally took precedence over re-

12. Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten in het Gezondheidsonderzoek* ('s Gravenhage: [1983]). For a similar qualification of clinical research, see, for example: Stichting voor Medisch Wetenschappelijk Onderzoek FUNGO, *Beleidsnota*; Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan Onderzoek*. See also, for example, the remarks by Van Bekkum from 1980 on the lack of clinical researchers in the Netherlands, and that 'very little focused medical research with subjects' took place in the Netherlands – which he regarded as one of the explanations as to why there was so little attention for and so little being done about the protection of human subjects in medical research (in the form of 'informed consent' procedures for example). See: D. W. van Bekkum, 'In Nederland Worden Proefdieren Beter Beschermd dan Proefmensen', in W. H. G. Wolters (ed.), *Medische Experimenten met Mensen: Mogelijkheden en Grenzen* (Utrecht: Bohn, Scheltema & Holkema, 1980).

search. Care duties were said to constitute such a heavy burden to clinical professors, that they had (too) little time to perform or carefully direct their research activities. ‘Research management’ failed too, as a result of which patient-related research in the Netherlands came to be characterised by fragmentation, duplication and a lack of coherence, cooperation and coordination.¹³

Such criticism was not new in itself. In the previous decades, the complaint that applied clinical research in the Netherlands amounted to little or nothing could regularly be heard.¹⁴ Yet the context in which criticism of Dutch patient-related research was expressed had fundamentally changed. The ‘Advice Regarding the Priorities in Health Research’, in which the RAWB made the statements above, fitted within the sea change in government policy regarding research at the beginning of the 1980s, which was described in chapter 4. In 1981, the RAWB had been requested by the government ‘to advise on possible improvements in the way in which priorities in health research may be set.’¹⁵ This resulted in three reports that were published in 1983. The first two reports were background studies in which the scope, nature and achievements of health research were mapped out.¹⁶ On the basis of these data, the third report, the final advice, not only detailed *how* priorities and posteriorities could be set in health research, but also *which* priorities and posteriorities needed to be set. The RAWB assessed the desirability of research, both on the basis of possible priorities in health policy, and on the basis of quality considerations. The first criterion did benefit patient-related research on a few occasions, but in no way did this apply to the second criterion. Only one clinical department belonged to the nine ‘top groups’ in health research, which were identified by the RAWB. In addition, only one third of the groups designated as ‘good’ were involved in clinical research.¹⁷

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13. Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten*, pp. 70-2. See also: H. Rigter, *De Omvang en de Aard van het Gezondheidsonderzoek in Nederland* (‘s Gravenhage: RAWB, [1983]); Idem, *De Prestaties van het Nederlandse Gezondheidsonderzoek* (‘s Gravenhage: RAWB, [1983]); Idem, ‘Evaluation of Performance of Health Research in the Netherlands’, *Research Policy* 15 (1986), pp. 33-48; Adviesgroep SGO, *Stimulering*, p. 28; J. C. van Es, *Een Halve Eeuw Huisartsgeneeskunde: van Ambacht naar Professie* (Houten: Bohn Stafleu van Loghum, 2006), p. 149.
 14. See the forthcoming PhD-thesis of Noortje Jacobs from Maastricht University.
 15. Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten*, p. 3 and ‘bijlage I’.
 16. The analyses of the performance of health research in the Netherlands comprised: (a) the numbers of papers published in international journals (in 1977!); (b) the numbers of times they were cited two years later (in 1979); (c) the numbers of editorships held by Dutch scientists on the editorial boards of major international journals; (d) the number of times that Dutch scientists were named as “outstanding researchers” by foreign scientists; (e) the judgment of some 100 Dutch experts. See: Rigter, ‘Evaluation of Performance’. See also n. 17 below.
 17. Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten*; Rigter, *Omvang en de Aard*; Rigter, *De Prestaties*. This is also discussed in the interview with Rigter.

The three reports by the RAWB caused quite a stir within academic medicine.¹⁸ The discipline was not used to this type of far-reaching government interference. With a sense of drama, Querido – who welcomed this interference for that matter – wrote about this several years later: ‘For the first time in the history of Dutch healthcare research, it was [...] attempted to improve the method of prioritisation in health research.’¹⁹ That the clinical departments were rated so poorly in the reports was, in addition, perceived as downright shocking. Apart from the fact that it was a serious and, for those involved, a painful matter that patient-related research in the Netherlands was apparently in such a poor state, immediate financial consequences were to be feared as well. The advice of the RAWB was closely linked to the vast cost-cutting operation Task Division and Concentration, which the Ministry of Education & Science launched in 1983. It was also explicitly within this context that the advice of the RAWB included posteriorities in addition to priorities; not only were proposals made for the growth of certain research areas, but so-called ‘shrinkage areas’ were appointed as well.²⁰ Already in 1983, J.C. van Es, the then chief editor of *Medisch Contact* – the journal of the Royal Dutch Medical Association (Dutch abbreviation: KNMG) – wrote in an editorial that the report by the RAWB had taken on a life of its own. According to him, ministers and faculties trusted this report blindly when making decisions regarding task division and cutbacks.²¹ As he anticipated at the time, operation Task Division and Concentration, as well as the system of conditional financing, which was introduced in 1984, comparatively negatively affected clinical research (compared to basic biomedical (laboratory) research).²²

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18. See for example several reactions to the RAWB-report in *Medisch Contact*: H. G. van Bueren, ‘Prioriteiten in het Gezondheidsonderzoek. De Raad van Advies voor het Wetenschapsbeleid en de Moed om Keuzen te Maken’, *Medisch Contact* 38: 51 (1983), pp. 1597-8; J. C. van Es, ‘Wetenschapsbeleid’, *Medisch Contact* 38: 43 (1983), p. 1351; Idem, ‘Patiëntgebonden Onderzoek’, *Medisch Contact* 40: 50 (1985), p. 1543; Hogerzeil, ‘Het Plan-Deetman’; M. B. J. A. Janssens & L. K. J. Romunde, ‘Klinisch Wetenschappelijk Onderzoek: Research en Patiëntenzorg Splitsen’, *Medisch Contact* 40: 50 (1985), pp. 1547-9; ‘RAWB Bepleit Verschuivingen in het Medisch Onderzoek’, *Medisch Contact*: 37 (1983), p. 1168; M. J. de Vries, ‘Prioriteiten in het Gezondheidsonderzoek. Een Advies van de Raad van Advies voor het Wetenschapsbeleid: Onkunde of Misleiding?’, *Medisch Contact* 38: 40 (1983), pp. 1279-81. See also: Van Es, *Halve Eeuw*, p. 149.
 19. A. Querido, ‘De “Discipline Geneeskunde” en de Nieuwe Prioriteiten, Weergegeven in het Stimuleringsprogramma Gezondheidsonderzoek 1985’, *Nederlands Tijdschrift voor Geneeskunde* 131 (1987), pp. 278-84, on p. 278.
 20. Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten*, pp. 70, 75-7; Idem, *Jaaradvies 1983*.
 21. Van Es, ‘Wetenschapsbeleid’. Van Es made essentially the same point in: Van Es, ‘Patiëntgebonden Onderzoek’; Adviesraad SGO, *Stimulering*, p. 8.
 22. Hogerzeil, ‘Het Plan-Deetman’; Klijn, *Verlangen naar Verbetering*, pp. 273-5; M. F. Kramer, ‘Operationele mogelijkheden’, *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), pp. 81-3, on p. 82. See also chapter 4 on this.

The Health Research Promotion Programme (the SGO)

The reports by the RAWB were the main impetus behind the creation of the so-called ‘Health Research Promotion Programme’ (Dutch abbreviation: SGO) by the Ministry of Education & Science and the Ministry of Health in 1985. This programme consisted of two parts. Firstly, measures were taken to safeguard the infrastructure of the top institutes identified by the RAWB and of several ‘good groups’ in the light of the ongoing cuts in expenditure. To this end, an amount of 25 million guilders was made available (as an additional part of the ‘first flow of funds’), spread over a period of five years. The second part of the SGO focused on strengthening the ‘weak’ patient-related research in the Netherlands, which was nevertheless considered to be very important in societal terms. 40 million guilders was released in order to ‘provide a focused stimulus for research in a number of condition areas involving a high disease burden, and for research focused on improvement of medical practice in general and on improvement of effectiveness in the healthcare sector.’²³

The SGO was largely the brainchild of Querido, who used the reports by the RAWB to launch the idea of an incentive fund for the lagging patient-related research. What undoubtedly helped here was the fact that Minister Deetman from the Ministry of Education & Science had appointed him as his personal advisor for the policy on the university hospitals in October 1983.²⁴ From the outset, Querido was given full support by the Ministry of Education & Science in the elaboration of his plans. The ministry was also the main sponsor of the SGO.²⁵ This support did not come as a surprise as the stimulation programme fitted seamlessly within the science policy of the department, which, in recent years has been based on the three pillars of societal relevance, programming and quality of research. Via ZWO (the Dutch Organisation for Pure Scientific Research), the Ministry of Education & Science had been a major sponsor of fundamental biomedical research for decades. Applied clinical (and thus patient-related) research, however, was not funded by ZWO, as it was not ‘pure’ scientific research. This situation changed in the 1980s, when ‘societal relevance’ became an important issue within Dutch science policy, resulting in the name change of ZWO to NWO (Dutch Organisation for Scientific

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23. This citation is derived from the letter by both the minister of Education & Science and the state secretary for Health, d.d. 18 December 19 december 1985, to the Second Chamber of the Dutch Parlement, which accompanied the SGO memorandum of 1985. See: Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek* (‘s Gravenhage: Staatsuitgeverij, [1986]). See also: Idem, *Discussienota Stimuleringsprogramma Gezondheidsonderzoek* (‘s Gravenhage: Ministerie van Onderwijs en Wetenschappen, [1985]).
 24. ‘Prof. Querido Persoonlijk Adviseur van Deetman’, *Medisch Contact* 38: 43 (1983), p. 1350.
 25. The Ministry of Health also joined and subsidized 25% of the SGO, but the unconditional support of Querido and the (Advisory Group for the) SGO by the Minister (personally) and the Ministry of Education & Science was the crucial factor here. See for more details on this: Adviesgroep SGO, *Stimulering*, pp. 8, 17-18; Van Es, *Halve Eeuw*, pp. 150-1.

Research – the word 'pure' was removed). NWO subsequently started funding applied clinical research as well as basic laboratory research. This underlines that SGO was not launched 'out of the blue', but under generally more favorable circumstances for patient-related research.²⁶

The development and coordination of the second and 'actual'²⁷ stimulation part of the SGO was left to an 'Advisory Group', of which Querido was himself a member and for which he selected the other members as well. The aforementioned Jan van Es, then chief editor of *Medisch Contact* and former professor of general practice in Utrecht, became chairman of this advisory group, after having been personally approached by Querido.²⁸

The Advisory Group for the SGO was largely given a free hand in the spending of 40 million guilders for the benefit of patient-related research. Compared to the approximately 270 million guilders the university hospitals and medical faculties specifically spent on patient-related research in 1985, the annual budget of 8 million guilders the Advisory Group for the SGO could 'dole out' was rather limited, but sufficient for the focused launch of research and research groups. In twelve sub-programmes, clinical research and the development of methodology in this area – matters that would now considered to be 'clinical epidemiological' activities by many – was stimulated. In the evaluation of this programme, it was stated that, as a result of this, both the quality and the quantity of patient-related research in the Netherlands had been raised considerably. This was purported to be apparent from, among others, the 'excellent publications' in renowned journals, which were a direct result of the SGO. In addition, a total of 62 researchers, of whom 53 were physicians, were trained. The training of physician-researchers was often organised via PhD trajectories in accordance with the 'physician-assistants training to become researchers' model (Dutch abbreviation for this model: 'AGIKO') where physicians combined their general medical training with PhD research. The fact that this training model was formally recognised (eventually) in 1996 by the Central Board of the Royal Dutch Medical Association (Dutch abbreviation: KNMG) was explicitly mentioned in the evaluation as one of the spill-over effects of the SGO.²⁹

Perhaps even more interesting than these specific results was the 'nonconformist' character of the incentive programme according to those involved as, by Dutch stan-

26. See (the last two sections of) chapter 4. See also, a.o.: Adviesgroep SGO, *Stimulering*, pp. 8-10, 14-19.

27. Van Es, *Halve Eeuw*, p. 150.

28. Adviesgroep SGO, *Op Zoek naar Leemten*; Van Es, *Halve Eeuw*, pp. 150-1; Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek*, pp. 28-9.

29. Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 20-32; J. C. van Es, H. W. Benneker & M. M. van Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). I. Achtergronden en Werkwijze', *Nederlands Tijdschrift voor Geneeskunde* 138 (1994), 1631-5; Es, *Halve Eeuw*, pp. 158-9; M. M. van Rees-Wortelboer, E. C. Klasen & J. C. van Es, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie', *Nederlands Tijdschrift voor Geneeskunde* 143 (1999), pp. 41-5. See also the several contributions (including a dissenting one) in: Adviesgroep SGO, *Stimulering*.

dards, it used a very unusual ‘top-down’ approach for the financing of medical research. Rather than the common ‘bottom-up’ procedure where the field was invited to submit research proposals, the Advisory Group for the SGO formulated specific objectives, which were subsequently further developed into twelve strategic research programmes by programme committees specially appointed for this purpose. From the very start, this method was met with a great deal of resistance. Already when the RAWB, the Royal Netherlands Academy for Arts and Sciences (Dutch abbreviation: KNAW) and the Health Council were asked for advice during the drafting of the SGO memorandum in the course of 1985, the response of these institutions to the plans was ‘largely positive’, yet they were ‘rather adverse’ to the intended ‘top-down’ method. The members of the Advisory Group for the SGO rather quickly discovered that the incentive programme was not welcomed by the Netherlands Organisation for (Pure) Scientific Research (Dutch abbreviation: ZWO and later NWO), and that any form of collaboration or ‘embedding’ was out of the question.³⁰ In addition, a great deal of criticism was expressed by the ‘field’ of scientists on the ‘top-down’ character of the SGO.³¹

There were various reasons for this resistance, but the discussions on the SGO mainly focused on an issue of principle: it was perceived as fundamentally inappropriate that (in the second, ‘actual’ incentive part of this programme) financial support was not given to research areas and researchers of proven high quality, but, on the contrary, to research areas and researchers considered to be ‘weak’. This not only had to do with the idea that it was more honest and wiser to give money to people and groups with good performance records, for they deserved this the most and were probably best qualified to make adequate use of it. Certain notions about the way in which proper research should come about also played an important part. According to a broadly shared opinion, new research could only result from existing research that was already at an eminent level. The consequence of this presupposition was that only quality should count in (policy decisions about) research funding.³²

The members of the Advisory Group for the SGO showed scant regard for this resistance, partly because they enjoyed the full support of the Ministry of Education & Science. They even took ‘delight’ in going against the grain and being a ‘thorn in the side.’³³

30. Van Es, *Halve Eeuw*, p. 150. See also: Rees-Wortelboer, Klasen & Van Es, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie’, p. 42.

31. Adviesgroep SGO, *Stimulering*, pp. 8-9, 27-33; Idem, *Op Zoek naar Leemten*, pp. 16-17, 20-6; Van Es, Benneker & Rees-Wortelboer, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). I. Achtergronden en Werkwijze’; Van Es, *Halve Eeuw*, pp. 150-151; Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan*, p. 170; Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek*, pp. 1-2, 14-28; Rees-Wortelboer, Klasen & Van Es, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie’.

32. See n. 31 above.

33. Adviesgroep SGO, *Stimulering*, p. 9; Van Es, *Halve eeuw*, p. 151.

They did, however, make efforts to acquire as much support as possible for the SGO. In a report from 1988, for example, they went great lengths to justify the 'top-down' character of the programme. They stated that 'bottom-up' procedures often led to 'fragmentation' of research efforts. This increasingly posed a problem, they subsequently maintained, for it had become only rare that 'the individual' could successfully conduct research. Instead, an era had begun in which research was usually performed in groups and a good performance could only be delivered when there was a certain 'critical mass'. It had therefore become more important than ever to ensure increased concentration of knowledge, skills and activities in the field of research. 'Top-down' procedures were highly conducive to this end. They could be used, for example, to create or strengthen research groups in a focused way, which were able to cope with the demands of modern research and (as a result) were forceful enough to be able to continue independently after expiry of the incentive period.³⁴ Thus, the Advisory Group for the SGO used the developments within (medical) research at the time, which the literature often characterises as the transition from 'little science' to 'big science', as an argument for the legitimacy of the top-down approach of the SGO.³⁵

When several members of the Advisory Group for the SGO evaluated the incentive programme in *Nederlands Tijdschrift voor Geneeskunde* in 1994, they also addressed the criticism that only the quality of research should be decisive for its financing. This was, they argued, a good assumption in itself, yet it could have negative consequences when implemented all too rigorously: 'If, in times such as the present times, in which faculties are faced with great financial dilemmas, all weak research fields were to be eliminated, this could harm healthcare in its entirety.'³⁶ In other words, it was sometimes simply necessary to stimulate 'weak' but relevant research areas. Medicine was simply 'not a non-committal area of science', but was 'at the service of the sick human being'.³⁷

It is difficult to assess if and to what extent these and other arguments of the Advisory Group for the SGO convinced the 'field'. It is a fact, however, that the 'top-down' approach with the subsidising of research, which was still a largely new phenomenon in 1985, was followed up in subsequent years. A similar approach was used in several subsidy schemes and rounds. The resistance against it, moreover, seems to have decreased proportionately. This was evident, among others, from the gradual improvement of the relationship

34. Adviesgroep SGO, *Stimulering*, p. 9; Idem, *Op Zoek naar Leemten*, pp. 15-17. See also: Adviesgroep SGO, *Voortgangsrapportage 1986-1989* ('s Gravenhage: SGO, [1989]).

35. See chapter 4 and, a.o.: De Solla Price, *Little Science, Big Science*; Galison & Hevly, *Big Science*; Heilbron, Van Bottenburg and Geesink, *Wetenschappelijk Onderzoek*; Mooij, *Polsslag*, pp. 440-2; Miedema, *Science 3.0*; Ravetz, *Scientific Knowledge*. See on this transition specifically in The Netherlands a.o.: Reneman, 'Veranderingen in het Wetenschappelijk Onderzoek'.

36. Van Es, Benneker & Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). I. Achtergronden En Werkwijze', p. 1633.

37. *Ibid.*, pp. 1633-4.

between SGO and NWO, the successor of the initially rather dismissive ZWO, which even led to formal integration in 1993. Van Es therefore later rightly suggested, with the necessary pride, that *due to the SGO* ‘the top-down approach is entirely common now.’³⁸ This makes the SGO perhaps *indirectly* a great catalyst for the rise of clinical epidemiology in the Netherlands in the 1990s. As will be discussed later, clinical epidemiology in The Netherlands was greatly propelled by the much larger Investigative Medicine Fund (in Dutch: Fonds Ontwikkelingsgeneeskunde), where a combination of a bottom-up and top-down approach was used. It could be argued that the SGO paved the way for that.³⁹

‘The Discipline of Medicine’ and Clinical Epidemiology

Querido and the members of the Advisory Group were not only driven by their desire to stimulate clinical research. At the basis of their activities lay an ideological discussion that extended much further. Querido, as well as others who were involved, used the commotion about the apparent dire state of patient-related research in the Netherlands to plead for a fundamental rethink about the nature, essence and future of medicine. The set-up and implementation of the SGO was not only a practical result of this, but also offered them the opportunity and a platform to stimulate this debate.

The core of the issue was summarised in a nutshell years later by Van Es. About his motives to say ‘yes’ to Querido’s request to become a member of the Advisory Group for the SGO, he wrote: ‘[Querido] had stolen my heart with his belief that medicine was an *independent knowledge area*. I myself had always considered that other sciences such as physics, chemistry, endocrinology and subsequently epidemiology too, are or can merely be ancillary sciences to medicine, a view that was loudly and clearly propagated by Dries.’⁴⁰

‘Dries’ Querido did the latter, among others, in an article on the SGO, published in 1987 in the *Nederlands Tijdschrift voor Geneeskunde* under the title ‘The “Discipline of

38. Van Es, *Halve Eeuw*, p. 159.

39. Van Es, Benneker & Rees-Wortelboer, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). I. Achtergronden En Werkwijze’, p. 1634; Rees-Wortelboer, Klasen & Van Es, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie’, p. 44. See for views on this from outside the circles of the SGO for example: Boer, ‘Knelpunten’, p. 434. In this article, E.J. Boer mainly praises the ‘important role of the SGO in the identification of priorities in health research’, and thus, in fact, the top-down approach as well. See also: J. H. Mulder & J. T. M. Rokx, ‘Ontwikkelingsgeneeskunde: Eerste Beleidsplan Noemt Voorkeursgebieden van Onderzoek’, *Medisch Contact* 46: 10 (1991), pp. 299-301. See also the several contributions (from both people from ‘inside’ and ‘outside’ the SGO) to the symposium that was organized at the occasion of the formal closure of the stimulation programme in 1997 – a symposium that had the telling title (in Dutch:) ‘Van Onbegrip tot een Begrip’ (freely translated: ‘From Disregard to High Regard’): Adviesgroep SGO, *Stimulering*, see in particular pp. 9-10, 12, 25-57, 61.

40. Van Es, *Halve eeuw*, p. 150.

Medicine” and the New Priorities, Presented in the 1985 Health Research Promotion Programme.⁴¹ The starting point Querido adopted in this article was that medicine was an *independent knowledge area*, which, as any knowledge area, is ‘determined by the nature of the research questions it generates.’ This knowledge area, which was to be explicitly distinguished from the *practice* of medicine, was referred to by him as the ‘discipline of medicine.’ Querido argued that, in the latter half of the twentieth century, the discipline of medicine had become ‘trapped’ ‘between the rapid and exciting developments of the life sciences and the technological opportunities offered by other knowledge areas.’

In itself, it was not a problem that medicine was influenced by other knowledge areas, and what is more: (practical) medicine had frequently benefited from this in the course of its history. Essential here, however, was that the new opportunities and insights contributed from outside were used for medicine’s ‘*own research questions*’. At this point, things had gone awry, according to Querido. The spectacular technological developments of the preceding decades, in, among others, the fields of chemical analysis, medical imaging and industrial pharmacy, had ‘flooded’ the actual practice of medicine and ‘demanded so much attention that it seemed as if they dominated the image of health research’. In addition, under the influence of the post-war rise of biochemistry and biophysics, the increase in knowledge of life sciences had occurred so rapidly that the balance between, on the one hand, ‘efforts aimed at increased knowledge of biological processes (research in the so-called basic subjects of medicine)’ and, on the other hand, ‘those aimed at patient-related research’, had been lost. Thus, the discipline of medicine had increasingly lost sight of its own research questions.

Querido described these ‘own’ research questions as being focused on the sickness and health of the human being and as being subdivided into the categories of classification and diagnostics, prevention, cure and care. In his view, this study object of the discipline of medicine was ‘extremely complicated’, which implied ‘that which is provided by natural sciences, which focuses on lifeless matter, is not sufficient [...]. The study of the sick human being and the measuring of the state of being ill requires other research methods as well.’

Querido subsequently explained in detail why these ‘other research methods’ had to be sought with *clinical epidemiology*. He wrote about the methods of clinical epidemiologists, for example: ‘Observations are used [...] of the object of study, the sick human being [...]. The research questions are [...] medical and are generated with those – the physicians – who are daily confronted with care.’ According to Querido, this constituted the discipline of medicine’s *own methodology*, which made it possible to assess whether new knowledge and technological opportunities offered by other knowledge areas actually contributed to prevention, cure or improvement of care. He moreover described the

41. Querido, “Discipline Geneeskunde”. All citations in the following paragraphs are from this paper.

methods of clinical epidemiology as: '*indispensable* where it concerns the optimisation of the practice of medicine, in terms of cost control and the decrease of the disease burden of the individual and society as well as in terms of improving the structure of healthcare.'

From the recent international literature, Querido continued, it could be concluded that 'such a practice of the discipline of medicine [...] was needed more than ever'. He quoted work from John Evans who, with his 1981 report, had strongly contributed to a change of course in the policy of the Rockefeller Foundation, where the priority shifted from public health to clinical epidemiology. Querido additionally referred to a series of articles on clinical epidemiology from 1983 published by Feinstein, with the common title 'An additional basic science for clinical medicine' as well as to the 'remarkable book' by Sackett and colleagues with the title *Clinical epidemiology: a basic science for clinical medicine*.⁴²

The 'new ideas' of these foreign sources of inspiration formed the foundation for the choices that had been made within the SGO, Querido argued.⁴³ This also became clear from the various official 'SGO publications' which appeared over the course of time. They repeatedly and consistently featured the ideas from Querido's article described above. Sometimes literally the same formulations were used. The ideological and ambitious character of the incentive programme could therefore not escape anybody's attention. As soon as the Minister of Education & Science and the State Secretary for Health sent the SGO memorandum to the Lower House of Parliament in 1985, they spoke of the need for 'innovation' and 'reorientation' in the accompanying letter.⁴⁴ In subsequent years, the advisory group explicitly stated that the main objective of the SGO was the creation of a 'change of course in the research policy of the medical sector',⁴⁵ a 'change process in thinking about health research'⁴⁶ and a 'cultural change [...] within the field of health research'.⁴⁷ Moreover, the 'mission' of the SGO extended beyond the area of research. 'Subsidiary objectives' were established as well. These objectives specified that the programme, through stimulation of the dissemination of clinical-epidemiological skills, should positively impact upon medical training courses at all levels; in medical practice as well as in the efforts geared towards cost control and improvement of the structure of healthcare.⁴⁸ Thus, a clinical epidemiological 'revolution' was preached!

42. All quotes and paraphrases in this section are derived from: Ibid.

43. Ibid., p. 283.

44. Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek*, p. 3.

45. Adviesgroep SGO, *Op Zoek naar Leemten*, p. 27.

46. Ibid.

47. Rees-Wortelboer, Klasen & Van Es, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie', p. 43.

48. Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 15, 33-6; Idem, *Stimulering*, p. 12; Van Es, Benneker & Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). I. Achtergronden En

During the meetings of the Advisory Group for the SGO, in particular Querido proved to be a passionate 'revolutionary'. Van Es wrote about this: 'Dries [Querido – TB] often used the meetings as a forum to vent his extended considerations [...].'⁴⁹ Outside the scope of the activities of the SGO, too, Querido used almost every opportunity to propagate his message. In 1993, for example, he was the driving force behind an international symposium on 'The discipline of medicine' organised under the auspices of the Royal Dutch Academy of Science (Dutch abbreviation: KNAW), and of which the 'proceedings' were published a year later under his editorship.⁵⁰ To what extent the autumn of his career was dominated by this matter, also became evident with the publication of his autobiography in 1990. In the preface he wrote that the book 'was the result of discussions on the direction in which research in medicine is heading'. He subsequently described how he himself had been voicing the opinion that 'the experimental biological direction' in health research was given too much attention, while patient-related research, 'which should be the source of medical questions', 'languished away'.⁵¹ The contemplative final chapter of this autobiography ends with a plea for clinical epidemiology:

'In Western countries, (numerical) epidemiology recently generated an important specialisation that may rightly be termed a basic science for clinical medicine [...]. I am convinced that the recent new, quantitative and logical approach to medical problems has heralded a period of reconsideration and productive research, with far-reaching consequences for general policy-making, cost control and the promotion of healthcare quality [...]. *From within*, medicine has acquired a basis on which future developments may be built.'⁵²

A Movement in Clinical Research

It is not the aim here to crown Querido as the great promoter of clinical epidemiology in the Netherlands. The idea is to give an impression of the great personal drive with which he championed the 'discipline of medicine' and clinical epidemiology. In this respect, he was not the only one. Several 'pioneers' in the field of clinical epidemiology and EBM in the Netherlands were imbued with a similar ideological enthusiasm (see chapter 6).

Werkwijze', p. 1633; Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek*, pp. 7, 14-15; Querido, De "Discipline Geneeskunde", p. 283; Rees-Wortelboer, Klasen & Van Es, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie', p. 42.

49. Van Es, *Halve Eeuw*, p. 151. See also: Adviesgroep SGO, *Stimulering*, pp. 7, 12.

50. A. Querido, L. A. van Es & E. Mandema (eds.), *The Discipline of Medicine: Emerging Concepts and their Impact upon Medical Research and Medical Education* (Amsterdam: KNAW, 1994).

51. Querido, *De Binnenkant*, preface.

52. *Ibid.*, pp. 261-2. TB's italics.

It is of importance, moreover, that Querido was supported by various esteemed peers in influential positions. To start with, this applied to the members of the Advisory Group for the SGO, who were all ‘prima donnas in their own field’⁵³. In addition to Querido and Van Es, two other professors had a seat in the advisory group as well: Henk Visser, professor of paediatric medicine at Rotterdam and also dean of the medical faculty of Erasmus University between 1986 and 1990 and Enno Mandema, professor of internal medicine at Groningen up to his retirement. The odd man out here was the psychiatrist and organisational advisor, Jan de Kock van Leeuwen, who was also advisor to the Ministry of Health at the time and knew this department ‘inside out’ according to Van Es.⁵⁴

These people were, each in their own way, capable of ‘sowing’ their ideas on clinical research within both the medical profession and policy circles. Van Es, for example, was able to do this in his capacity as chief editor of *Medisch Contact*. This journal had an extensive reach: all members of the KNMG received the journal and a survey from 1987 revealed that 82% read the journal often or always.⁵⁵ Van Es did not hesitate to use this platform to focus attention on the RAWB report and on the SGO, for example, also propagating the ideological ideas on the ‘discipline of medicine’ which he shared with Querido.⁵⁶

After his retirement, Van Es became a member of the Advisory Council on Health Research (Dutch abbreviation: RGO). This so-called ‘sector council’ was established in 1987 to create ‘a structural framework for the provision of advice to the ministers involved on the policy to be conducted, the promotion of the coordination of research with social developments and the reinforcement of cohesion within health research.’⁵⁷ Van Es was asked to participate in the RGO by Enno Mandema, who had been appointed chairman of this council, and who, in turn, was a member of the Advisory Group for the SGO which was chaired by Van Es.⁵⁸ Thus, two of Querido’s kindred acquired a position in which they could exercise a more direct influence on government policy with respect to medical research.

Outside the circle of the SGO too, Querido had important allies. This became apparent, for example, when the Ministry of Education & Science decided in 1986 to launch a further study into the backgrounds of the (alleged) poor state of patient-related research in the Netherlands. This assignment was entrusted to an interdisciplinary research group at Limburg University, supervised by a committee of which Querido and Mandema were

53. Van Es, *Halve Eeuw*, p. 151.

54. See a.o.: Ibid.; Adviesgroep SGO, *Op Zoek naar Leemten*; Idem, *Stimulering*, p. 4.

55. Van Wandelen, ‘Lezers over *Medisch Contact*’.

56. See a.o.: Van Es, ‘Wetenschapsbeleid’; Idem, ‘Patiëntgebonden Onderzoek’; Idem, ‘Raad Voor Gezondheidsonderzoek’, *Medisch Contact* 42: 13 (1987), p. 387; R. A. te Velde, ‘Prof. Dr. J.C. Van Es: “Structureel Denken binnen de Beroepsgroep Niet Sterk Ontwikkeld”’, *Medisch Contact* 42: 36 (1987), pp. 1127-30.

57. This was how the RGO’s commission was formally defined by the government, this definition is a.o. cited in: Van Es, ‘Raad Voor Gezondheidsonderzoek’, p. 387.

58. Van Es, *Halve Eeuw*, p. 151.

also members. The chairman of this supervisory committee was Dolf Schweitzer, professor of paediatric medicine at Leiden. The other members were the Rotterdam professor of biochemistry, Wim Hülsmann, Jan Touber, professor of internal medicine at the University of Amsterdam and Hein Wellens, professor of cardiology in Maastricht.

This committee carried out a great deal more than just the supervision of the researchers, as became clear when the report of this study was published in 1987, as it had remarkable structure. In the second part of this report, the Maastricht research group limited itself to a factual analysis of the 'contributing and impeding factors' impacting upon the quality of patient-related research in the Netherlands. This was preceded by a much less factual first part that included the commentary and the recommendations by the *supervisory committee*. Querido's authorship was overly visible in the contents of this part of the report. In fact, it was a reiteration of his recently published article in *Nederlands Tijdschrift voor Geneeskunde* discussed above.⁵⁹

It cannot be deduced from this that the other members of the supervisory committee simply allowed Querido to have the upper hand. These prominent figures knowingly associated their name with the commentary and recommendations that so strongly bore Querido's signature. It therefore seems improbable that they did not support them in essence. This at least applied to the chairman, Schweitzer who, during a symposium organised in 1988 on the occasion of the publication of this research report, gave a speech in which the affinity between his views and Querido's was clearly brought to the fore.⁶⁰

At this symposium, which was held in Maastricht under the title 'patient-related research in jeopardy', many renowned and distinguished speakers made an appearance. They included Querido himself and, for example, Visser, the dean of the medical faculty at Rotterdam, who was also a member of the Advisory Group for the SGO. In addition, there were several important speakers not connected to the SGO, including the Leiden professor of general surgery, Co Greep, the director-general for Higher Education of the Ministry of Education & Science, Roel in 't Veld, Els Borst-Eilers, the then vice-chair of the Health Council, Ad Dunning, professor of cardiology at the University of Amsterdam and Mebius Kramer, dean of the Utrecht medical faculty. It would exceed the scope of this study to discuss all the contributions by these speakers here, which have been published elsewhere. In a broad sense, it may be argued that during this symposium 'the lamentable state of clinical research in the Netherlands was discussed and deplored'.⁶¹ It was

59. See on all this: Y. W. Bally, J. F. A. Spangenberg & R. Starmans, *Achtergronden van de Kwaliteit van het Patiëntgebonden Onderzoek in Nederland* ('s Gravenhage: Ministerie van Onderwijs en Wetenschappen, 1987).

60. A. Th. Schweitzer, 'Commentaar en Aanbevelingen van de Begeleidingscommissie met Betrekking tot het Onderzoek "Achtergronden van de Kwaliteit van het Patiëntgebonden Onderzoek in Nederland"', *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), pp. 57-61.

61. This is how Bossuyt summarized this symposium in the interview conducted by TB.

furthermore agreed that it was of the utmost importance to do something about this and that *clinical epidemiology*, as supplier of the ‘own’ methodology for this ‘special research area’, could play an important role here. Of course, there were differences of opinion as well, but these mainly pertained to nuances. There was a widespread agreement on the ‘core of the issue’.⁶²

Not only did speakers of stature make an appearance at this symposium, they also managed to attract a large number of people to the event in Maastricht: 200 people, including many clinical professors, took part.⁶³ Moreover, this symposium was not an isolated event. In 1989 and 1990, conferences entitled ‘patient-related research’ and ‘health research in motion’ had been organised by the Advisory Group for the SGO and the RGO respectively, featuring (partly the same) prominent speakers who managed to generate considerable attention.⁶⁴

The conclusion seems justified that, towards the end of the 1980s, a movement of some weight, a ‘lobby’ for patient-related research and clinical epidemiology had emerged, which was perhaps not large as far as the number of people involved is concerned, but did consist of prominent representatives of academic medicine, who exercised influence within the medical profession as well as on the policymakers of the Ministries of Health and of Education & Science.⁶⁵

A ‘Cultural Map’ of Medicine

The motives and objectives of this movement or ‘lobby’ may be further clarified with the help of the work of the sociologist Gieryn. To use Gieryn’s terminology, Querido, with his reflections on the ‘discipline of medicine’, ‘drew’ a ‘cultural map of science’ in which he identified a number of features that were characteristic of this ‘discipline’ and also clearly

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- 62. See on all this the theme issue on this symposium: J. M. Greep et al., ‘Teksten van de Inleidingen Gehouden op het Symposium “Patiëntgebonden Onderzoek in Het Geding”’, *Tijdschrift voor Gezondheidswetenschappen* 3: no. 2 (1988), pp. 38-83. See in particular the summary of the symposium by M. F. Kramer on pp. 80-3.
 - 63. *Ibid.*, p. 40. One of the participants was Niek Urbanus, the then new director of the Academic Hospital of Amsterdam (now known as AMC). In the late 1980s and 1990s, Urbanus was a key figure in stimulating patient-related research, clinical epidemiology and EBM in the AMC, which became one of the leading centre in these fields in the Netherlands (personal communications between Urbanus and TB).
 - 64. See resp. J. H. M. Lockefeer, ‘Patiëntgebonden Onderzoek’, *Nederlands Tijdschrift voor Geneeskunde* 133 (1989), pp. 38-9; E. J. Boer, ‘Gezondheidsonderzoek in Beweging’, *Nederlands Tijdschrift voor Geneeskunde* 134 (1990), pp. 398-402.
 - 65. See also on this: J. van Gijn, ‘Randomised Trials’, *Lancet* 347 (1996), pp. 1234-5; Hijdra et al., *Vernieuwingen in de Neurologie*, p. 13; R. van Schilfaarde, ‘Gezondheidswinst door Technologische Vooruitgang’, *Medisch Contact* 45: 49 (1990), pp. 1473-6; W. Wieling, ‘Het Spectrum van Klinisch Wetenschappelijk Onderzoek’, *Nederlands Tijdschrift voor Geneeskunde* 135 (1991), pp. 643-5.

indicated the boundaries between medicine and other knowledge areas.⁶⁶ In particular, he placed the preclinical laboratory sciences outside the (core) domain of medicine in his 'map'. For example, Querido concluded the previously extensively discussed article from 1987 with the following final sentences:

‘The contemplations in connection with the SGO do not deny the significance of research in life sciences for patient care, but contest the opinion that this type of research is the most significant area of health research to contribute to optimisation of knowledge for patient care. To this end, patient-related research plays a pivotal role.’⁶⁷

Querido's 'map of the discipline of medicine' may be analysed from two different perspectives. In the first place, epistemological, philosophical and conceptual aspects may be further explained with what Gieryn calls an 'upstream' approach. In this context, one could think of the argument of the sociologist Marc Berg on the 'reconceptualisations' of the relationship between science and medical practice that occurred in the latter half of the twentieth century (see chapter 3).⁶⁸ From Berg's perspective, the stance Querido and kindred spirits took against the domination of medicine by biomedical 'basic sciences' may be considered to be a rejection of the 'conceptualisation' such as had been common up to and including the 1950s, where medical practice was interpreted as 'artful application' of (mostly 'basic' biomedical) scientific knowledge. Instead, Querido and his supporters emphasised that medicine was an *independent* knowledge area. This corresponds well with the various subsequent 'reconceptualisations' which, according to Berg, gained acceptance from the 1960s onwards, in which medical practice *itself* was regarded as (ideally) a form of science – instead of just *application* of scientific knowledge.⁶⁹

The importance attached within the SGO to the 'spill-over effects' of patient-related research in education may be understood against this background. Querido and the other members of the Advisory Group for the SGO were part of the swelling chorus voicing sharp criticism of the strict separation between science and practice, which had long been in effect in the medical curricula, in other words the separation between, on the one hand, the preclinical 'basic subjects' and, on the other hand, the acquisition of skills in the clinic. This separation existed in harmony with the way in which the relationship between science and practice was conceptualised up to the 1950s, but no longer fitted in

66. The suitability of Gieryn's map-metaphor is underlined by the frequent use by Querido of the term 'knowledge area'.

67. Querido, "Discipline Geneeskunde", p. 283.

68. See the section of chapter 3 on this, and see: Berg, 'Turning a Practice into Science'.

69. Incidentally, Dutch advocates of clinical epidemiology generally handled the various conceptualisations of medical practice from figures such as Feinstein and Sackett fairly eclectically. The more procedural, clinimetric approach by Feinstein and the more 'cognitivist' viewpoint of Sackett were often both referenced in the same breath, as it were.

with the more recent notions of a *scientific* medical practice, in which an important role was envisaged for clinical-epidemiological and decision analysis methods.⁷⁰

Also significant is the fact that Querido emphasised that apart from forming an independent knowledge area, medicine also formed a *complex* knowledge area. He explicitly set this against the reductionism and determinism of preclinical laboratory sciences. He did this, among others, by arguing that (excessive) confidence in the blessings of biochemistry and biophysics for medicine ‘would be a sign of naive optimism, mirroring 19th century notions on a mechanistic-physical worldview that completely failed.’⁷¹ He also elaborated to a fairly great extent on the changing thinking on disease causality. Due to developments within the epidemiology of chronic diseases, mono-causal thinking had made way for multi-factorial thinking, ‘where concepts such as necessary, sufficient and contributory cause were introduced.’⁷²

These remarks reflected Henrick Wulff’s ideas, as, among others, expressed in his famous book *Rational Diagnosis and Treatment* from 1976. Interestingly, Querido himself, together with Lubsen, had prepared its Dutch translation, which was published in 1980.⁷³ The Danish advocate of clinical epidemiology and clinical decision analysis was held in exceptionally high regard in the Netherlands.⁷⁴ This is why a subsequent book by Wulff

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70. Querido, “Discipline Geneeskunde”, pp. 282-3. Together with Van Gijn, Querido addressed this more specifically during a joint contribution to the 1993 symposium on ‘the discipline of medicine’: A. Querido & J. van Gijn, “‘The Wisdom of the Body’: The Usefulness of Systems Thinking for Medicine”, in A. Querido, L. A. van Es & E. Mandema, *The Discipline of Medicine: Emerging Concepts and their Impact upon Medical Research and Medical Education* (Amsterdam: KNAW/Elsevier, 1994), pp. 76-8. Furthermore, the last day of this symposium, on which 5 (other) speeches were made, was entirely devoted to the theme ‘adapting medical education to new developments’. Miettinen’s oration from 1987, too, for example, was entirely dedicated to this matter. See: Querido, Es & Mandema, *Discipline of Medicine*, pp. 171-204; Miettinen, *Theory of Medicine*. See furthermore on the preclinic/clinic issue: Van Lieburg, *Vijf Eeuwen*, pp. 104, 126.
71. Querido, “Discipline Geneeskunde”, p. 279.
72. *Ibid.*, 281.
73. H. R. Wulff, *Principes van Klinisch Denken en Handelen. Nederlandse Bewerking van Prof. Dr. A. Querido en Dr. J. Lubsen* (Utrecht: Bohn, Scheltema & Holkema, 1980).
74. This is evident, for example, from the way in which he is repeatedly referred to/written about in *Medisch Contact* over the course of the years. See for several examples: A. Ankoné, ‘Over de Vier Plichten van de Dokters. De Klinische Imperatief van Henrik R. Wulff’, *Medisch Contact* 50: 51/52 (1995), pp. 1641-3; A. J. Dunning, “‘Medische Besliskunde’: het Medisch Handelen als Proces”, *Medisch Contact* 39: 9 (1984), pp. 269-71; J. C. van Es, ‘Medische Besliskunde’, *Medisch Contact* 39: 9 (1984), p. 263; *Idem.*, ‘Rekenaars en Protocollen’, *Medisch Contact* 40: 14 (1985), p. 411; I. Schretlen & E. Menert, ‘Filosofie van de Geneeskunde: een Terreinverkenning’, *Medisch Contact* 36: 41 (1981), pp. 1273-6; C. Spreeuwenberg, “‘Evidence-Based Medicine’”, *Medisch Contact* 51: 2 (1996), p. 41; *Idem.*, “‘Evidence-Based Policymaking’”, *Medisch Contact* 51: 3 (1996), p. 73. See also: interview with Van Gijn (as will be discussed in chapter 6); Hijdra et al., *Vernieuwingen in de Neurologie*, p. 11. Wulff was also often asked for advice and so on; for example, he was one of the members of the evaluation committee of the sub-programme ‘Clinical epidemiology and medical decision analysis’ of the SGO and of the SGO as a whole, see: A. J. C. Petit & M. M. van Rees-Wortelboer, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). IV. Evaluatie van het Deelprogramma “Klinische Epidemiologie en Medische Besliskunde”’, *Nederlands Tijdschrift voor*

and two co-authors, which appeared in 1986 under the title *Philosophy of Medicine: an Introduction*⁷⁵ generated considerable attention in the Netherlands.⁷⁶ A Dutch translation of this work was already published after two years.⁷⁷ In this book, Wulff (and his co-authors) provided a further philosophical elaboration of his ideas on a more rational medicine. He did the same during his contribution to the symposium on 'The Discipline of Medicine'⁷⁸, which was held in 1993 and initiated by Querido. Both in this speech and in the book from 1986, Wulff pointed out the shortcomings of the 'biological-organic' concept of disease. He argued that a more refined clinical picture had recently become increasingly popular, 'especially within (clinical) epidemiology and clinical decision analysis', where disease was understood as an 'effective-causal complex'. Wulff and co-authors explicitly thought in terms of a paradigm shift here. They argued that medicine had been through a period of 'paradigmatic instability' ever since the 1960s. Like Querido, they spoke of a nineteenth century mechanistic, naturalistic way of thinking which had been dominant in medicine for a long time, but was increasingly considered to be inadequate. This is why, partly under the influence of the randomised controlled trial and the (other) sophisticated statistical methods that were developed and used in (clinical) epidemiology, more empirically-oriented, rivalling theories and approaches had emerged.⁷⁹

Especially in the book from 1986, Wulff and co-authors explicitly and consistently placed this 'paradigm shift' within the framework of the contradiction between the two philosophical viewpoints of realism and empiricism. They considered 'biological medicine' and the accompanying mono-causal concept of disease to be realistic, while the clinical-epidemiological approach to disease was characterised by a (methodological) empiricism. It is an interesting fact that those directly involved in the rise of clinical epidemiology such as Wulff and (slightly more implicitly) Querido too, used this contradiction as a starting point, especially since they localised 'theory' in the laboratory and 'empiricism' in the clinic. That they also thought in terms of a paradigm shift here, reveals the fundamental nature of their criticism of the (in their view) excessive focus in medicine on (the acquisition of) laboratory knowledge of biological processes in the body.

Geneeskunde 138 (1994), pp. 1779-80; Rees-Wortelboer, Klasen & Van Es, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie'.

75. H. R. Wulff, S. A. Pedersen & R. Rosenberg, *Philosophy of Medicine. An Introduction* (Oxford: Blackwell, 1986).

76. See for example the review in the leading Dutch medical journal: E. van Leeuwen, 'Filosofie van de Geneeskunde. Een Inleiding', *Nederlands Tijdschrift Voor Geneeskunde* 131: 51 (1987), pp. 2376-8. See also: Wieling, 'Spectrum'.

77. H. R. Wulff, S. A. Pedersen & R. Rosenberg, *Filosofie van de Geneeskunde. Een Verkenning* (Amsterdam: Meulenhoff, 1988).

78. H. R. Wulff, 'The Disease Concept and the Medical View of Man', in A. Querido, L. A. van Es & E. Mandema (eds.), *The Disciplin of Medicine: Emerging Concepts and their Impact upon Medical Research and Medical Education* (Amsterdam: KNAW/Elsevier, 1994), pp. 11-19.

79. See on this not only Wulff's own work (as referred to in the above notes), but also: Van Leeuwen, 'Filosofie'.

Besides ‘upstream’, Querido’s map of the discipline of medicine may also be viewed ‘downstream’ as well. Not only did Querido object to the dominant position of preclinical sciences in medicine on philosophical and conceptual grounds, but also for more *practical* reasons. As was the case with many of his supporters, he found that the introduction of all manner of new medical technologies as of 1950 onwards, and the progress made in basic biomedical laboratory research in the same period, had their downside as well. Academic medicine, for example, which had been at the forefront of these ‘tempestuous developments’, is purported to have been preoccupied with this to such an extent that the essential tasks of the medical faculties in the field of education and research had become ‘eroded and replaced with executive tasks in healthcare.’⁸⁰ In addition, the increased knowledge in the field of biological (micro) processes did not always yield significant value for medical practice. During the 1993 conference on ‘the discipline of medicine’, which was organised by Querido, remarks were repeatedly made to the effect of: ‘the direct contribution of molecular biology to medicine has been more modest than many had expected’⁸¹. At this conference, but in other sources from the late 1980s and early 1990s as well, it was argued that, in particular, the care for patients with chronic diseases was not aided much by laboratory knowledge. While basic research had its focus on diagnostics and cure, for the ‘quality of life’ of the increasingly large number of chronically ill people in society, it was much more important to acquire knowledge of the ‘impeding and contributing determinants of the course of their conditions.’⁸² Both at a substantive level and due to the terminology used, it became quite apparent here to what extent the

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80. Bally, Spangenberg & Starmans, *Achtergronden*, p. V. The original quote is also cited in; H. K. A. Visser, ‘Is de Huidige Financiering van het Patiëntgebonden Onderzoek Effectief?’ *Tijdschrift Voor Gezondheidswetenschappen* 3: 2 (1988), p. 64.
81. This is argued *twice* (in the exact same wordings) in: A. J. van der Eb, ‘Molecular Biology; the Link between Matter and Life’, in A. Querido, L. A. van Es & E. Mandema (eds.), *The Discipline of Medicine: Emerging Concepts and their Impact upon Medical Research and Medical Education*, eds. (Amsterdam: KNAW/Elsevier, 1994), pp. 55-65, on pp. 55 and 56. See for similar remarks in other papers from this conference, published in the same volume: p. 139 (in a paper by L.A. van Es, entitled ‘Research as an Effort to Solve Medical Problems’), p. 141 (in a paper by K. Peters, entitled ‘Will Basic Immunology Solve Immunological Diseases?’), and p. 147 (in a paper by R. Williamson & C. Coutelle, entitled ‘Gene Technology as a Model for Rapid Scientific Advance: The Barriers to Clinical Applications’).
82. All this is paraphrased from: Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 9-10, 13-14. The ‘condition-oriented’ sub-programmes of the SGO above all focused on chronic diseases; in various ‘publications on the SGO’ similar arguments may be found, as well as for example (slightly more explicitly so) in the previously discussed article by Querido in the *Nederlands Tijdschrift voor Geneeskunde*. With the RGO and the Ministry of Health, too, there was a great deal of attention at this time for chronic diseases and the importance of an increased focus on the promotion of ‘quality of life’ in addition to/rather than a focus on diagnostics and cure. This trend, which was accompanied by significant funding programs for research on chronic diseases, became (a.o.) strongly apparent during the study of successive annual issues of *Medisch Contact*. See for example: Boer, ‘Gezondheidsonderzoek in Beweging’. See also for example: L. A. van Es & A. Hofman, ‘The Dichotomy of Medicine’, *Lancet* 347 (1996), pp. 1233-4.

post-war epidemiology of chronic conditions contributed to a change in thinking about disease and disease causality.

All this testifies to a certain response to mechanistic biomedical thinking in medicine. This response was not so much the result of philosophical considerations as of the experience of medical professionals that 'laboratory knowledge' was not always useful to them in the complex clinical practice. In this context, Querido and the neurologist Jan van Gijn spoke of the 'failure of medical reductionism,'⁸³ at the 1993 symposium on 'the discipline of medicine'. Using specific examples, they aimed to demonstrate that patients were treated less well and sometimes even put in harm's way when confronted with physicians using a 'blindly reductionist approach'. They – like many others – pleaded for a more 'integrative' approach instead.⁸⁴ They emphasised that the integration of the various forms of knowledge that could inform a physician of the status of a specific, individual patient took place in the clinic (or the GP practice) and not in the laboratory. With this, they voiced a sentiment that was not new, but which had been voiced increasingly often and louder in the course of the 1970s and 1980s.⁸⁵ A good example of this is the following quote from the farewell lecture of the professor of internal medicine of the University of Amsterdam, A.M. van Leeuwen, in 1985:

'But as a physician I notice the increasingly widening gap between this – what is called fundamental – research and the problems the patients present their physician with. Here too, a 'translation' is required. Physicians who conduct actual patient-related research are a prerequisite for this, and the university clinics the designated place [...]. *With all due respect for the molecule, the basis of medicine is the human being.*'⁸⁶

Not only the 'success story' of basic biomedical laboratory research, but also the many new technological possibilities were called into question. Obviously, the spectacular rise of new medical technologies brought many benefits, but in the course of time their less favourable (side) effects became increasingly manifest. In this context, reference was made within the movement for patient-related research to 'negative medicalisation', exponentially rising costs, a healthcare system without a rational structure which threatened to become uncontrollable (and not only in a financial respect).⁸⁷

83. Querido & Van Gijn, "The Wisdom of the Body", p. 75.

84. Ibid., pp. 69, 75-8.

85. See on this almost all contributions to the 1993 symposium on 'the discipline of medicine': Querido, Van Es & Mandema, *The Discipline of Medicine*. This trend was also noticed in: Hijdra et al., *Vernieuwingen in de Neurologie*, p. 13; Wieling, 'Spectrum'. See for more on this: chapter 7.

86. A. M. van Leeuwen, *Universitaire Inwendige Geneeskunde* (Utrecht: Bunge, 1985), pp. 22-23. TB's italics.

87. See n. 88 below.

Thus, it would seem that the movement on behalf of patient-related research was largely the result of sincere concerns about the undesired effects of the rapid and drastic changes that had occurred in medicine and healthcare. Both at the micro and macro level, and both in medical research and in education and practice, (reflections and discussions on) adaptations were required to a certain extent. Querido and many of his supporters therefore thought in terms of ‘correcting the imbalance’ and ‘restoring the balance’, with the ultimate aim of ensuring better healthcare.⁸⁸

Gieryn’s notion of a ‘downstream perspective’ also directs attention towards more profane considerations that may have played a role here. The cutbacks and the more controlling role of the Ministry of Education & Science in the 1980s had led to a situation where scientists, more than before, had to compete with each other in order to be eligible for research funding. The recurrent pleas for a correction of the ‘imbalance’ between patient-related and non-patient-related research should at least partly be considered to be expressions of a fiercer competition between both forms of research and (thus) between laboratory and clinic. It is important to realise that this simultaneously often boiled down to a competition between medical professionals and non-medical professionals. This was particularly evident during the ‘patient-related research in jeopardy’ symposium held in Maastricht in 1988. Schweitzer, for example, phrased a widely shared concern when he concluded during his speech: ‘So, to an increasing extent, *it is the non-medical professionals who determine the course of modern medical research nowadays.*’⁸⁹

This, in their view, undesired situation was partly attributed by Schweitzer and several others to the upscaling and increasing complexity of both medical research and patient care. It had simply become more difficult to combine a clinical and a scientific career, for in both fields ever more specific knowledge, skills and experience were required. This is why laboratory research mainly employed medical professionals who were *not* (also) active in clinical practice as well as non-medical specialists, such as biochemists, biologists and physicians. Clinically-oriented physicians who were affiliated to hospitals and medical faculties ‘often had the problem and always the frustration that one of the tasks assigned to them is not given sufficient attention.’ In many cases, this led to ‘escape behaviour in the direction of patient care, education and training.’⁹⁰

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88. See a.o. Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 7-10, 27-9; Bally, Spangenberg & Starmans, *Achtergronden*, pp. V, VIII-X, XV. See also chapter 7.
89. Schweitzer, ‘Commentaar en Aanbevelingen’, p. 58. TB’s italics. The same remark was made in: Bally, Spangenberg & Starmans, *Achtergronden*, p. IX. Similar statements can be found in almost all papers of the symposium ‘patient-related research at stake’, see: Greep et al., ‘Teksten van de Inleidingen’. See, in addition: Adviesgroep SGO, *Stimulering*, p. 29.
90. All quotes are derived from: Schweitzer, ‘Commentaar en Aanbevelingen’, p. 58. See also on this: Wieling, ‘Spectrum’.

Another factor often mentioned was the insufficient consideration given to scientific development during the training of physicians and medical specialists. It is argued that this created a huge 'unexploited area' in the field of medical research for *non*-medical professionals, who *did* have a thorough scientific training. That, as a result, the 'famous "bench-to-bedside connection" which, at the time, proved so fertile for progress in the medical-scientific field is virtually disappearing' was therefore mainly the fault of medical professionals themselves. They simply carried out too little research and also acquired too little expertise in this area, it was argued by Schweitzer, among others.⁹¹

However, the representatives of the movement for patient-related research also repeatedly complained that the way in which the government implemented cutbacks was (wrongly) to the benefit of the laboratory and to the detriment of the clinic. In 1985, Van Leeuwen devoted his previously mentioned farewell lecture almost entirely to this issue.⁹² In it, he argued that the Minister of Education & Science demanded 'objectively measurable results in a predictable time' now cutbacks were required, so as to ensure he obtained his money's worth. According to Van Leeuwen, however, patient-related research was much harder to fit into this financing concept than 'activities where the actual patient is not needed'. He explained in a detailed way how substantially clinical studies with *human subjects* differed from laboratory research with material in a test tube. Patient-related research was characterised, for example, by a much greater degree of unpredictability. The researchers hardly controlled the moment at which their subjects were presented. They were confronted with a variety of complaints and courses of disease, which was great, even among 'seemingly similar patients', as was the diversity in terms of constitution, personal characteristics and living conditions. This lack of 'equal' subjects complicated the statistical consideration of evidence, and this could prevent publication in a highly acclaimed journal. The time-consuming character, the many uncertainties and the countless practical and ethical obstacles of patient-related research also prevented the researchers from easily and quickly 'scoring' with their research. However, in its efforts to exclusively fund excellent research, the government used the number of publications in (prominent) scientific journals as one of the criteria for 'excellence'. According to Van Leeuwen, non-patient-related research was thus perhaps unintentionally accentuated. He therefore warned:

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91. Schweitzer, 'Commentaar en Aanbevelingen'. Schweitzer's analysis was derived from the report: Bally, Spangenberg & Starmans, *Achtergronden*. See, in addition, for essentially similar accounts and analyses: Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 13-14; Boer, 'Knelpunten'; A. J. Dunning, 'Nachtgedachten van een Klinisch Onderzoeker', *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), pp. 77-9; J. M. Greep & L. M. L. Ch. Siezenis, 'Patiëntgebonden Onderzoek in Beweging', *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), p. 41; Kramer, 'Operationele Mogelijkheden'; A. Querido, 'Overwegingen bij de (Huidige) Wijze van Toekenning van Subsidies voor Patiëntgebonden Onderzoek bij Beperkte Middelen', *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), pp. 74-5.
92. Van Leeuwen, *Universitaire Inwendige Geneeskunde*.

‘The concept of ‘excellence’ threatens to take on a one-sided organic-biological meaning in academic medical research [...], with a laboratory for an address, and as practitioners medical professionals who do not work as physicians, besides biologists, chemists and engineers.’

It makes sense to suggest that the criticism by Van Leeuwen and many others⁹³ on the government policy was largely motivated by an enlightened self-interest. For clinicians affiliated to university hospitals and medical faculties and aspiring to academic careers, it had become necessary in the circumstances of the 1980s to profile themselves in research. As a rule, they relied on patient-related research here, in which the methods of clinical epidemiology proved very helpful.

Against this it may be argued that many advocates of patient-related research and clinical epidemiology did not have any immediate interests here themselves with regard to money, status and career. Many of them had already achieved top positions or had already (or almost) retired. The case could therefore perhaps be made that they championed the interests of their own disciplines and of their (younger) peers more so than their own interests. In addition, it is important not to reduce the words and actions of those involved in the movement for patient-related research to the mere pursuit of material and financial (professional) interests. From conversations with and publication by those involved it appears that the attraction of clinical epidemiology and applied clinical research perhaps lay in more subtle and immaterial matters.

Interesting in this context is the advice Feinstein gave to Vandenbroucke, when the latter had just started as professor of clinical epidemiology in Leiden in 1987. Vandenbroucke said of this:

‘Feinstein then said to me: when you go to the new faculty, you should look for internists approximately aged between forty and fifty who can no longer keep up with the latest laboratory research, but who do understand it and are good clinicians and good teachers. They are interested in clinical epidemiology. Why? *It lends them a new distinctiveness.* Clinical epidemiology is something only they can do. People of the lab cannot do it, nor can a pure statistician. But they can do it, for they know medicine intrinsically, understand the lab, have learnt to understand statistics, *and so are able to move forward again with conducting research.*’⁹⁴

93. See on this (a.o.) several contributions to the symposium ‘patient-related research at stake’, published in: Greep et al., ‘Teksten van de Inleidingen’. See in particular the papers by In ’t Veld (pp. 44-7), Borst-Eilers (pp. 69-71), Dunning (pp. 79-80), and Kramer (p. 82). See also, for example: Rees-Wortelboer, Klasen & Van Es, ‘Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie’, p. 44; J. Verhoef & M. F. Kramer, ‘Is het Einde van de Faculteit der Geneeskunde in Zicht?’ *Medisch Contact* 48: 23 (1993), pp. 714-5.

94. Interview with Vandenbroucke.

In the context of the 1980s, 'being able to move forward again with conducting research' was necessary for those who aspired to an academic career, and may thus be considered to be of 'material importance'. However, Vandenbroucke also and especially emphasised that clinical epidemiology did lend (a category of) clinicians a 'new distinctiveness' or 'new identity'. This ties in with several statements made by Van Es in 1987 during his farewell as chief editor of *Medisch Contact*. Firstly, he argued: 'Medicine has its *own research* in the shape of patient-related and clinical-epidemiological research.' This was, according to Van Es, 'the *common denominator*' which, in a time of ongoing specialisation and differentiation, needed to be reinforced in order to 'further define the *identity of the profession*'. It was important to prevent 'common, patient-related, clinical thinking which forms the *core of medicine* from disappearing in 'the maelstrom of technology and other ancillary sciences'.⁹⁵

The use of terms such as 'distinctiveness', 'own research', 'common denominator', 'identity of the profession' and the 'core of medicine' suggests that fundamental issues formed the basis of all the pleas for clinical epidemiology and patient-related research. The 'maelstrom of technology and other ancillary sciences' which threatened to sweep across medicine was contrasted by the notion that physicians needed to be in charge of their own profession (again). The warnings that non-medical professionals largely determined the direction of medical research may be considered in this light, for example, as may arguments such as that by Querido that medicine was an *independent* knowledge area with its own research questions and methods. Also typical is the remark by the supervisory committee on the research into 'the backgrounds of the quality of patient-related research' from 1987 that proper medicine 'must not be limited to adaptation to the achievements of the biomedical and physical-technical revolution'.⁹⁶ The message was reiterated time and again that not 'external' people, disciplines and developments, but medical professionals themselves should take control of medicine and healthcare. A central role was envisaged here for experienced, practising clinicians who were also active in research, and who formed the link between laboratory and clinic. By definition, these key figures should either be clinical epidemiologists or they should have ample clinical-epidemiological expertise.⁹⁷ In this context, Querido referenced the publication by Feinstein and Sackett et al. on clinical epidemiology as 'basic science for clinical medicine':

95. All quotes are derived from : Te Velde, 'Prof. Dr. J.C. van Es.' TB's Italics.

96. Bally, Spangenberg & Starmans, *Achtergronden*, p. X.

97. See a.o.: Adviesgroep SGO, *Op Zoek naar Leemten*, pp. 11, 32; Bally, Spangenberg & Starmans, *Achtergronden*, pp. X-XI; Querido, "Discipline Geneeskunde", pp. 282-3; Rees-Wortelboer, Klasen & Van Es, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). XIV. Eindevaluatie'.

‘Feinstein and Sackett et al. expressly point out that this deepening of knowledge for medical practice is *a specific medical issue*, which requires both a *professional medical training* and involvement with, and the accompanying *responsibility for patients*.⁹⁸

Thus, in the eyes of Querido and many of his supporters, clinical epidemiology offered the medical profession – and in particular physicians (also) working in practice – the opportunity to take control again and remain in control. This was of importance especially in the 1980s, when not only academic science but also healthcare came under severe pressure as a result of the financial constraints of that time. There were also regular cutbacks to healthcare and a more directive, controlling role of the government was to be expected. In this context, there were repeated warnings that the medical profession had to ensure it kept a grip on these developments itself, and that it had to prevent the initiative from lying with other parties.⁹⁹ Clinical epidemiology was regularly presented here as one of the instruments enabling medical professionals to be at the helm, not only in medical research and medical practice, but also in policy and management in healthcare at the meso and macro level.¹⁰⁰

Vandenbroucke aptly summarised all this:

‘This has to do with the *ideology* of Sackett and of Feinstein that the *primacy should return to the clinical*. The primacy of the decisions in healthcare does not originate from cell biology; you cannot treat a patient in intensive care with ten cell biologists at the same time. You just cannot, you need a kind of macro-integration for this. *Only the clinician* can carry out this macro-integration. *Clinical research* too, may *only* be done by him (or her). [...]. In the future, *healthcare will be controlled* by people who are able to do or assess this research. As Feinstein said to me somewhat irreverently: clinical epidemiology is something for jaded people, or something for people who no longer conduct acute cellular research, but are more *broadly-oriented*. This gives them a *new distinctiveness*, but above all: *they become leaders of healthcare this way*. This is what is appealing about clinical epidemiology!¹⁰¹

98. Querido, “Discipline Geneeskunde”, p. 283.

99. See chapter 7.

100. See the previous discussion of Querido’s article on the ‘discipline of medicine’ as well as that of the ‘subsidiary objectives’ of the SGO. This development is also visible with Sturmans who, (see the introduction to this chapter) already at the end of the seventies, explicitly typified epidemiology as the ‘intelligence service of healthcare policy’, yet as of the mid-eighties onwards also focused attention the role clinical epidemiology could fulfil in policy and management. See for example: F. Sturmans, ‘Is de Gezondheidszorg Beheersbaar? Budget en Protocol als Instrumenten voor de Planning van Kostenbeheersing’, *Medisch Contact* 40: 14 (1985), pp. 417-21.

101. Interview with Vandenbroucke. Indeed, several (clinical) epidemiologists did become ‘leaders of healthcare’, for example: André Knottnerus was (vice) chair of the Health Council and subsequently of the Scientific Council for Government Policy, and Louise Gunning-Schepers was chair of the Board of Directors of the AMC in Amsterdam and subsequently chair of the Health Council.

International versus Specifically Dutch

The references of Querido and Vandenbroucke to Feinstein and Sackett demonstrate this is not a typically Dutch discussion. It was not only in the Netherlands that there was scarcity in both science and healthcare, this was the case in all Western countries. The concerns about the insufficient quality of patient-related research were just as much an international phenomenon. The same themes as in the Netherlands were covered in the discussions on this, such as the extinction of physicians who could combine practice and research, the increasing share of non-medical specialists in medical laboratory research, the dominance of the laboratory and the increased competition to acquire scarce research funds.¹⁰² In 1979, for example, the president of the Association of American Physicians (AAP), James B. Wyngaarden, devoted his speech during the AAP annual conference entirely to this matter, in which all these aspects were addressed. Shortly afterwards, Wyngaarden edited his speech into an article that was published in *The New England Journal of Medicine* under the title: 'The Clinical Investigator as an Endangered Species'.¹⁰³ As discussed in chapter 3, Feinstein and Sackett were actively involved in these debates, in which they explicitly presented clinical epidemiology as the ideal solution to the problems identified.¹⁰⁴

In the Netherlands, the developments in this field and the resulting discussions in the Anglo-Saxon countries were rather closely monitored. The supervisory committee to the research into the backgrounds of the quality of patient-related research wrote for example: 'An illustrative example of the loss of territory of medical professionals [...] is provided by the steady decline of the percentage of medical professionals eligible in the USA for a research grant of the National Institutes of Health – the lion's share of the monies intended for healthcare goes to the PhDs ("scientists") nowadays and no longer to the MDs ("physicians")'.¹⁰⁵ Only subsequently was it noted that the same trend also seemed to be evident in the Netherlands. The work of Feinstein and Sackett too, was regularly quoted precisely in this context by Dutch advocates of patient-related research. In particular the handbook by Sackett et al. on clinical epidemiology from 1985 was rather widely known and was highly acclaimed as well, for example in a review in *Nederlands Tijdschrift voor Geneeskunde*, written by the then editor-in chief Dunning, in which the

102. All these issues were addressed at the international symposium, held in 1993, about 'the discipline of medicine' in 1993. See in particular in the paper by J.D. Swales, in: Querido, Van Es & Mandema, *The Discipline of Medicine*, pp. 33-42.

103. Wyngaarden, 'Clinical Investigator'.

104. See for example: Sackett, 'Zlinkoff Honor Lecture'.

105. Bally, Spangenberg & Starmans, *Achtergronden*, p. IX.

book is described as ‘compulsory literature for everybody who wishes to conduct scientific work or provides training to this end’.¹⁰⁶

It may thus be clear that the Dutch movement for clinical research and clinical epidemiology which materialised in the latter half of the 1980s did not exist in isolation, but was rather in line with international developments and debates. On the other hand, there are clear indications that clinical epidemiology in the Netherlands, compared to other Western countries, acquired a rather exceptional, strong academic position.¹⁰⁷ It is obvious to seek explanations for this in the *specific* Dutch context. Although the problem of scarcity in science and healthcare was an issue virtually everywhere in the world, the way in which research and healthcare were organised differed in each country, as did the way in which governments and other stakeholders coped with the scarcity issue. For this reason, it is quite conceivable that the circumstances in the Netherlands were different to those elsewhere and, as a result, more conducive to the academic foundation of clinical epidemiology.

With respect to the specific Dutch context, two factors are conspicuous. Firstly, the dominant position of the Ministry of Education & Science is striking. When Deetman, the then Minister of Education & Science, presented the policy intentions regarding the operation Task Division and Concentration in 1983, a commentary in *Medisch Contact* noted: ‘In fact, the Minister of Education has been able to draw up a new Structure Memorandum for *Healthcare*’.¹⁰⁸ In addition, the question was raised regarding ‘how it is possible that a Minister of Education & Science wishes to, and is able to, change the structure of healthcare’. The main thrust of this article was that those directly involved in healthcare, medical education and medical research mainly had themselves to thank for this. They had devoted too little attention to a number of essential problems in their field, with the result that these were now tackled by an outsider, the Minister of Education & Science. At the same time, the strong position of this ‘outsider’ was pointed to: ‘The central system of scientific education places *all power with the minister*, who provides the universities with guidelines and controls their financing.’ Furthermore, since the appointment of the then Lubbers cabinet in 1982, the policy field of healthcare was no longer in the hands of a minister but a state secretary – a situation that was to last until 1994. This meant that, during the cabinet meetings, there was no longer a minister ‘who primarily looks after the interests of healthcare in the cabinet, which facilitates cutbacks and changes in healthcare.’ In the 1980s, such contemplations on the considerable influence of the

106. A. J. Dunning, ‘Clinical Epidemiology’, *Nederlands Tijdschrift voor Geneeskunde* 130 (1986), p. 1375. Dunning already mentioned the ‘famous clinical epidemiology department of McMaster University’ here. In several interviews it was discussed, in addition, that by this time the ‘group’ and the handbook of Sackett et. al were recognised and appreciated in the Netherlands. See for more on this: chapter 6.

107. See both the introduction to part II and chapter 6..

108. This and the following quotes are from: Hogerzeil, ‘Het Plan-Deetman’, p. 897. TB’s italics.

Minister of Education & Science and the relatively subordinate role of the department of Health led by the state secretary were recurrent.¹⁰⁹

A second specific Dutch issue was the discussion on the reduction of the insured package of the Health Insurance Fund (Dutch term: 'Ziekenfonds'), which, at the time, was the compulsory health insurance for a major part of the Dutch population. This discussion was not entirely new, but flared up increasingly often in the course of the 1980s. The Health Insurance Council (Dutch name: Ziekenfondsraad), the body that supervised the health insurance funds and also provided advice in this area to the Ministry of Health, played a large part in this debate. In 1983, the Council published the 'Interim Advice regarding Limits to the Expansion of the Statutorily Insured Package'.¹¹⁰ The authors of this report concluded that, as a result of all the rapid scientific and technological developments, new diagnostic methods and therapies were regularly introduced, which were subsequently automatically included in the health insurance package. In a time of dwindling financial resources, this automatism could no longer be sustained, according to them. Moreover, this automatic cycle would also have to be broken 'for reasons of quality'. They therefore pleaded for a procedure in which strict assessment criteria were used to verify whether or not new diagnostic methods and therapies were to be admitted to the statutorily insured package. These criteria included, among others, that effectiveness and efficiency had to be known. The drawing up of cost/benefit analyses would be inevitable here. In addition, new provisions also needed to be more effective and/or efficient, or be accompanied by fewer undesired side effects than already existing ones. Moreover, not only did the Health Insurance Council intend to screen new developments, but 'the *current* healthcare' as well. Old and barely effective diagnostic methods and therapies would have to be removed from the package, to make way for new ones.

This advice by the Health Insurance Council and the debates on the health insurance package which, partly as a result of this, were conducted in the Netherlands, did not exist in isolation. Chapter 7 and 8 will focus in more detail on the broader context in which this conflict occurred and in which the theme of the 'boundaries of healthcare' was high on the political and social agenda. Specifically for the establishment of clinical epidemiology as an academic research discipline – the subject of the present chapter – it is significant that in the Netherlands, under the influence of the 'package discussion', there was an increasing interest in two specific subjects: 'Medical Technology Assessment' (also one of the sub-programmes of SGO) and 'Investigative Medicine'.¹¹¹

109. See for example: F. A. Bol, 'Minister van Volksgezondheid', *Medisch Contact* 36: 34 (1981), p. 1031; Spreeuwenberg, 'Onderzoeksbeleid Volksgezondheid'.

110. Ziekenfondsraad, *Interim-Advies inzake Grenzen aan de Groei van het Verstrekkingspakket* (Amstelveen: Ziekenfondsraad, 1983).

111. This is a paraphrase from: Dunning, 'Nachtgedachten'.

The concept ‘Medical Technology Assessment’ (MTA) actually summarised what the Health Insurance Council pursued: the evaluation of medical technologies, where both the term ‘evaluation’ and ‘technology’ needed to be interpreted broadly. Not only ‘equipment’, but basically all preventive, diagnostic and therapeutic methods, techniques and procedures were eligible for ‘assessment’ where not only effectiveness and safety were examined but ethical, social and financial aspects as well. In practice, MTA was usually not applied as broadly as its advocates wished, for that matter. The ‘evaluation’ remained largely limited to (in particular) cost-effectiveness and cost/benefit analyses of new (and much less often of existing) technologies.¹¹²

Technology Assessment was often mentioned in the same breath as ‘investigative medicine’, a term that referred to the development of new medical means and methods still in its infancy and of which the (potential) effectiveness and efficiency were not yet clear. In its interim advice from 1983 (and in subsequent reports as well), the Health Insurance Council emphasised that the ‘cutting off’ of such new provisions, because they did not (yet) meet the criteria for admission to the statutorily insured package, should not adversely affect the progress of medical science. The Council therefore pleaded for the availability of special budgets facilitating the further development of new interventions or technologies, which were (still) excluded from the standard package of insured healthcare.¹¹³

The Health Insurance Council backed its words up with deeds. In 1984, the Council started pursuing an active subsidy policy in order to support research in these fields. This started with approximately 7 million guilders annually, but increased to over 70 million guilders annually over the course of the years.¹¹⁴ A substantial part of this was spent on the Investigative Medicine Fund, to which the Ministry of Education & Science also contributed 25% for that matter. This fund was launched in 1985 as a subsidy scheme of the Ministries of Education & Science and Health, as part of the then policy of the ‘role expansion’ of university hospitals. In 1988, this subsidy scheme was ‘adopted’ by the Health Insurance Council and converted into an independent fund, which was also open to non-university hospitals. The Health Insurance Council moreover increased the yearly budget of the fund from 9 to 36 million guilders. This meant that the fund accounted for over a quarter of the total amount (of 130 million guilders) made available by the government and the health insurers for the financing of medical research.¹¹⁵

112. See a.o.: D. Banta, ‘What is Technology Assessment?’, *International Journal of Technology Assessment in Health* 25: Supplement S1 (2009), pp. 7-9; Gezondheidsraad, *Grenzen van de Gezondheidszorg* (‘s Gravenhage: [1986, no. 29]); Ziekenfondsraad, *Eindadvies inzake Grenzen van de Groei van het Verstrekkingenpakket* (Amstelveen: Ziekenfondsraad, 1986). See for more on this: chapter 8.

113. See a.o.: Ziekenfondsraad, *Interim-Advies inzake Grenzen*; Idem, *Eindadvies inzake Grenzen*.

114. Bottenburg, De Vries & Mooij, *Zorg tussen Staat en Markt*, pp. 150, 166.

115. Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies inzake Ontwikkelingsgeneeskunde 1990* (Amstelveen, [1989]); G. L. Engel, ‘Ontwikkelingsgeneeskunde: Hoe Werkt het?’, *Medisch*

Although the Health Council, the Netherlands Organisation for Scientific Research (NWO) and the Ministries of Health and Education & Science were all involved in this, policy, implementation and assessment of applications were largely the responsibility of the Investigative Medicine Committee of the Health Insurance Council, which had been specially set up for this. In its policy memoranda and decisions on applications it was continually explicitly evident that the fund had a high MTA calibre and that its mission was primarily practical in nature. The research to be funded was described as '*evaluation research* into new (or already existing) methods and techniques within patient care', which was to generate data that would lead to *specific decision-making*. This mainly pertained to decision-making with respect to 'whether or not to include or remove provisions from the statutorily insured package'. In addition, the committee mentioned several other 'decisions' to which investigative medical research could contribute, namely: 'limiting the indication; taking other measures to ensure more efficient and effective use of diagnostic and curative techniques; a planning decision [...]'.¹¹⁶

As it was so abundantly clear that the purpose of the Investigative Medicine Fund (Dutch: Fonds Ontwikkelingsgeneeskunde) was the restriction of the statutorily insured package and indication areas, it was also informally and jokingly referred to as the '*Corrective Medicine Fund*' (in Dutch: Fonds Afwikkelingsgeneeskunde).¹¹⁷ In no way did this undermine its importance, not least for clinical epidemiology, the discipline that in large part supplied the methods for patient-related evaluation research and MTA. As noted by Grobbee, the Investigative Medicine Fund 'generously injected money into clinical-epidemiological projects, although they were perhaps not always referred to as such'.¹¹⁸

Contact 47: 13 (1992), pp. 401-4; Gezondheidsraad, *Functieverruimingsplannen 1988: Onderdeel Ontwikkelingsgeneeskunde* ('s Gravenhage, [1987]); Gezondheidsraad, *Projecten Ontwikkelingsgeneeskunde 1986* (Den Haag, [1991]); J. H. P. van der Meulen & R. M. Timmermans, 'Ontwikkelingsgeneeskunde: Onderzoek ter Onderbouwing van Besluitvorming; een Bespreking van de Derde Bijeenkomst van het Landelijk Forum Medische Besliskunde', *Nederlands Tijdschrift voor Geneeskunde* 138 (1994), pp. 2356-61; Mulder & Rokx, 'Ontwikkelingsgeneeskunde'; J. H. Mulder & C. A. Ladage, 'Ontwikkelingsgeneeskunde', *Medisch Contact* 43: (1988), pp. 233-4; Ziekenfondsraad, *Besluit Instelling Commissie Ontwikkelingsgeneeskunde* (Amstelveen: Uitgave van de Ziekenfondsraad, nr. 406 [1988]).

116. Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies 1990*, "bijlage II, blad 2".

117. Interview with Bossuyt, and Van Gijn.

118. Interview with Grobbee. The importance of the Investigative Medicine Fund (in Dutch: Fonds Ontwikkelingsgeneeskunde) was stressed by almost all interviewees in the interviews conducted by TB, as well as in: H. D. Banta, W. J. Oortwijn, & W. T. van Beekum, *The Organization of Health Care Technology Assessment in the Netherlands* (The Hague: Rathenau Institute, 1995), pp. 79-92; A. Boer, *Onderzoek op Maat. Een Verkenning van Factoren voor het Gebruik van Technology Assessment* (Rotterdam: Erasmus Universiteit, 2002), pp. 75-92; Van Es & Hofman, 'Dichotomy of Medicine'; Van Gijn, 'Randomised Trials'; Raad voor Gezondheidsonderzoek, *Advies HTA-Onderzoek: Organisatie van het HTA-Onderzoek* (Den Haag: RGO, 2004), pp. 18-21. This is further elaborated on in chapter 6.

Conclusion

In the foregoing, two ‘typically Dutch’ factors were mentioned which partly explain the successful rise of clinical epidemiology in this country (compared to other countries). These are the ‘stranglehold’ of the Ministry of Education & Science in which academic medical research found itself and the Investigative Medicine Fund, which resulted from the ‘package discussion’. This requires further elaboration (see chapter 6), but first of all, a third factor should be indicated, namely the movement for patient-related research itself, which formed the main subject of this chapter.

At first glance, this movement was nowhere near ‘typically Dutch’, for it was strongly influenced by international trends in medical research. Its champions derived most of their ideas from foreign examples such as Wulff, Feinstein and Sackett. This applied, for example, to Querido’s views on the ‘discipline of medicine’ as independent knowledge area. The concerns expressed by Querido and kindred spirits about a medicine that was ‘flooded’ by developments from the laboratory and in technology, were shared by physicians in many other countries. That a certain response originated with regard to the dominance of basic preclinical sciences was therefore not unique to the Netherlands. In addition, academic medical professionals across the world needed to develop in parallel with the changes in the scientific enterprise, which may be referred to as a transition from ‘little science’ to ‘big science’. Another international phenomenon was the increasing difficulty of being both a full-fledged clinician and a full-fledged scientist – and that, partly as a result of this, medical research was increasingly being conducted by non-medically trained specialists. Not only in the Netherlands, but elsewhere too, (some) academic clinicians in clinical epidemiology saw, to use Vandembroucke’s words, an opportunity to acquire a ‘new distinctiveness’ and ‘to move forward again with conducting research’.

On the other hand, however, the movement for patient-related research described in this chapter consisted of Dutch individuals operating in the Dutch context. The leading figures were prominent medical professionals who, using their enthusiasm, decisiveness and networks in both medical and government and policy circles, were capable of developing a powerful lobby for patient-related research. The circumstances of a relatively small and egalitarian country, with a high mobility of people and ideas, made it perhaps easier to actually exercise influence.¹¹⁹ Whatever the circumstances, the ‘weak state’ of applied clinical research in the Netherlands at the beginning of the 1980s – which was also skilfully rhetorically deployed by Querido and others in order to plead for incentive measures – is in remarkable contrast to the obvious flourishing of this type of research and the introduction of clinical epidemiology as academic discipline at the end of this decade.¹²⁰

119. Interview with Knottnerus; Van Gijn, ‘Randomised Trials’.

120. See, among others: Wieling, ‘Spectrum’; and the ‘country profile’ of the Netherlands, which was published in *the Lancet* in 1996, in which the striking transformation of medical and in particular clinical

Yet this does not tell the entire story of the successful introduction of clinical epidemiology in the Netherlands. Only three 'success factors' were identified in this chapter, namely the movement for patient-related research, the science policy of the Ministry of Education & Science and the establishment of the Investigative Medicine Fund, which (partly) laid the foundation in the 1980s for the rise of clinical epidemiology in the 1990s. In what way this discipline acquired a (relatively) strong academic position and what role said 'success factors' exactly played, will be further explored in the following chapter.

research in the Netherlands was one of the main themes: 'The Netherlands', *Lancet* 347 (1996), pp. 1229-39. See for more on this: chapter 6.

Chapter 6.

The Academic Establishment of Clinical Epidemiology in the Netherlands

The Netherlands acquired its first professors of clinical epidemiology in the second half of 1980s. Clinical epidemiology subsequently managed to gain a solid foothold within Dutch academic medicine during the 1990s. In the conclusion of chapter 5, it was argued that three ‘success factors’ played an important role here: (1) the post-1980 science policy of the Ministry of Education and Science and the accompanying transformation of the academic research climate; (2) the movement for patient-related research and the input and motivation of the individuals involved; and (3) the Investigative Medicine Fund.

This chapter supports this claim on the basis of a reconstruction of the way in which clinical epidemiology acquired a position at four universities/academic hospitals, namely those in Rotterdam, Amsterdam,¹ Utrecht and Maastricht. This limitation to four places does not mean that clinical epidemiology did not gain purchase elsewhere. Eventually, all medical faculties as well as the larger general hospitals acquired departments of clinical epidemiology. Yet for the purpose of this chapter – a historical interpretation of the academic establishment of clinical epidemiology in the Netherlands – the four aforementioned ‘cases’ suffice.

These instances make it possible to very specifically identify and analyse the rise of epidemiology in the Netherlands in terms of time, location and context. They also offer a ‘peek behind the scenes’, which will make clear that fairly local and personal factors as well as fortuitous concurrences of coincidences sometimes played a decisive role. At the same time, however, the aim is to obtain insight into a more general issue, which transcends the local level of the four cases, namely: the hows and whys of the relatively great ‘success’ of clinical epidemiology in the Netherlands – in an international respect, but also compared to, for example, clinical decision analysis. The conclusion of this chapter will therefore attempt to make substantiated statements on this, based on the findings of all three chapters from this second part of this book. There will also be a brief discus-

1. There are two universities (University of Amsterdam and Free University) and (corresponding) University Medical Centre’s (AMC and VUmc) in Amsterdam, the case-study in this chapter concerns the University of Amsterdam and the AMC.

sion as to the questions these findings raise regarding the introduction of evidence-based medicine in the Netherlands.

'The First Sub-department' in Rotterdam

As far as is known, Koos Lubsen was the first person in the Netherlands to call himself a 'clinical epidemiologist'. After earning his PhD with the IMIR research in 1978 (see chapter 4), he fell into a 'black hole' in his own words. He did still have a small room in the Thorax Centre in Rotterdam and, at one time, decided to hang a sign on the door there with the text 'clinical epidemiology group'. This way, 'the first sub-department of clinical epidemiology' in the Netherlands came into being.² Looking back on this approximately thirty years later, Lubsen described his activities as a pioneering clinical epidemiologist as follows:

'I had a kind of engineering bureau for the setting up of clinical and epidemiological research, taught residents in cardiology and was present at the weekly discussion of patients, in order to provide comments on decisions every now and then in light of the available "evidence"'.³

Lubsen was not wrong in placing himself so explicitly in the tradition of what subsequently developed into EBM. As early as 1975, he gave a presentation on his promotional research with the title 'Parameters in *clinical epidemiology* of ischaemic heart disease'.⁴ He and fellow PhD student, the future professor of general practice, Van der Does, always propagated this IMIR study as *clinical-epidemiological* research, which could provide a '*rational foundation*' for the practice of physicians with regard to individual patients.⁵ Lubsen and the people with whom he worked closely, for example, were among the first in the Netherlands to explicitly try to operate in the 'spirit' of the work of founders of clinical epidemiology such as Feinstein, Sackett and Wulff. Together with Querido, he also took care of the Dutch translation of Wulff's *Rational Diagnosis and Treatment*, which was published in 1980. This book subsequently appeared on the mandatory read-

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2. Hofman, *Veertig Jaar*, pp. 22-3. The 'sub-department' of Lubsen was also discussed in the interviews with Algra, Dekker, Grobbee, Hugenholtz, Offringa and Vandenbroucke.
 3. Cited in: A. Hofman, *Veertig Jaar*. pp. 22-3.
 4. Van der Does & Lubsen, *Acute Coronary Events*, p. 33, n. 27. TB's italics.
 5. E. van der Does, 'Huisarts en Epidemioloog', *Medisch Contact* 35: 16 (1980), pp. 485-90. It appears that in this article the term 'klinisch-epidemiologisch' ('clinical epidemiological') was used for the very first time in the journal *Medisch Contact*. See also: Geleijnse, De Jong & Simoons, *1968 Thoraxcentrum 2008*, p. 124. This was also discussed in the interview (by TB) with Hugenholtz.

ing list for all residents in cardiology at Erasmus University, reaching other clinical departments in Rotterdam as well.⁶

Yet the main part of the work of Lubsen's sub-department of 'clinical epidemiology' consisted of assisting, coordinating and executing randomised controlled trials. In his word of thanks in his oration from 1986 to his 'patron' Hugenholtz, the Rotterdam professor of cardiology and founder of the Thorax Centre, Lubsen said about this:

'It is due to your vision that I am standing here now. Already a very long time ago, you recognised the need for our own in-house clinical epidemiological expertise to support our own patient-related research.'⁷

With this 'own patient-related research' Lubsen was referring to clinical trials. Already at an early stage, Hugenholtz and Lubsen cottoned on to the fact that – irrespective of its medically substantive and social relevance – especially within cardiology, a great deal of money could be made with them, which could benefit the Thorax Centre. Pharmaceutical companies were embroiled in fierce competition surrounding the development of blood pressure and cholesterol-lowering medicines and other medicines against, or for the prevention of, cardiovascular diseases. Additionally, in virtually all Western countries, the regulations with which new medicines had to comply before becoming available on the market had been tightened towards the end of the 1970s. They had to be tested for efficacy in well-conducted comparative clinical studies. Thus, an industry surrounding RCTs was able to develop in which a great deal of money was involved.⁸

For a long time, Lubsen's small sub-department managed to combine the execution of patient-related research within the Thorax Centre with the coordination of international 'multi-centre trials'. Yet the latter activity developed so rapidly that it was accommodated in a separate organisation in 1987, which was named 'Cardialysis'. Over the course of time, Cardialysis would develop into a large, independent company, employing over 100 people, very successfully venturing into the area of international multicentre clinical cardiological research.⁹ In the meantime, Lubsen and Hugenholtz had chosen their own commercial path: in 1988, after the retirement of the latter, they founded an international branch of Cardialysis, SOCAR Research in Switzerland.¹⁰

6. Wulff, *Principes van Klinisch Denken*; Hofman, *Veertig Jaar*, p. 23.

7. Lubsen, *Epidemiologie als Wegwijzer*, p. 17.

8. Interviews with Hugenholtz and Offringa. See for the broader, international context: chapter 2, and: Greene, *Prescribing by Numbers*; Vos, *Drugs Looking for Diseases*.

9. Geleijnse, De Jong & Simoons, *1968 Thoraxcentrum 2008*, pp. 128-32. All this was also discussed in the interview with Grobbee.

10. Interview with Hugenholtz. See also: <http://www.socar.ch>.

Apart from being lucrative, the organisation of RCTs was also attractive with a view to scientific status and career. In the context of the government policy pursued in the 1980s with regard to academic research, it was important for the Thorax Centre and for Hugenholtz and Lubsen personally that their involvement in clinical trials yielded tens of publications in high-impact journals, including the *British Medical Journal* and *the Lancet*.¹¹ This also greatly contributed to the fact that Hugenholtz's department received two million guilders from the 'first part' of the Health Research Promotion Programme (Dutch abbreviation: SGO) – the part of the SGO aimed at maintaining the infrastructure of the 'top institutes'. The Thorax Centre was admittedly classed as 'good' and not as 'top' by the RAWB, but was allocated a contribution all the same because of the solid *clinical* research that was conducted there, as was explicitly mentioned in the SGO memorandum from 1985. This was a direct reference to the clinical trials by Lubsen and staff.¹²

Lubsen himself was appointed extraordinary professor 'of clinical epidemiology of ischaemic heart disease' in Rotterdam (and Utrecht) in 1986. According to Lubsen himself, this was a 'logical consequence' of the contribution he had made to two – for that time – large Dutch trials.¹³ Not only did he elaborate on the importance of Miettinen's theoretical work in his inaugural lecture, but he also repeatedly quoted – to general approval – the handbook by Sackett, Haynes and Tugwell that had been published the year before: *Clinical Epidemiology: a Basic Science for Clinical Medicine*¹⁴. Thus, for the first time in the Netherlands, clinical epidemiology acquired an academic position in the form of an (extraordinary) chair. An important fact here is that this did not occur within Valkenburg's ('population-oriented') department of Epidemiology or otherwise as a branching off from the 'mother discipline', but within cardiology – or: within a clinical department.

Clinical epidemiology in Rotterdam soon acquired the support of the SGO, as Lubsen himself established with glee in his inaugural lecture.¹⁵ The sub-programme 'clinical epidemiology and clinical decision analysis' was entrusted to Lubsen and Dik Habbema, the then professor of public health at Erasmus University. Lubsen was already (extraordinary) professor of clinical epidemiology, Habbema was appointed professor of clinical decision analysis in 1987. Together they led a new department financed by the SGO: the Centre for Clinical Decision Analysis (Dutch abbreviation: CKB), which was modelled

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11. See: PubMed. See, in addition: Geleijnse, De Jong & Simoons, 1968 *Thoraxcentrum 2008*, pp. 134-5; Hofman, *Veertig Jaar*, pp. 23-6.
 12. Ministerie van Onderwijs en Wetenschappen, *Stimuleringsprogramma Gezondheidsonderzoek*, pp. 2, 7, 12, 29. See also on the Thorax Centre: Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan*, pp. 113-14, 168; Van Lieburg, *Vijf Eeuwen*, p. 130.
 13. Quoted in: Hofman, *Veertig Jaar*, p. 23.
 14. Lubsen, *Epidemiologie als Wegwijzer*.
 15. *Ibid.*, p. 16.

after the Centre for Clinical Decision Making in Boston and officially opened in 1988. The purpose of this sub-programme of the SGO was the formation of a scientific staff and the development of methodologies. This meant that the CKB was mainly concerned with education and training. Workshops and courses in clinical decision analysis were developed, both for specialist registrars (Dutch term: AGIO's) and for the basic curriculum in Rotterdam. In addition, staff training was set up in which, during the SGO period, five physicians were eventually trained to be 'clinical researchers with a specialisation in clinical epidemiology/decision analysis'.¹⁶

Only on a modest scale did the CKB conduct its own research. More important was the *consultative* role the centre fulfilled for clinical departments. This mainly concerned consultancy and assistance in the set-up and implementation of 'decision analysis and patient-related research'. In the evaluation of this sub-programme, it was explicitly noted that research in the field of investigative medicine was key here. Thus, the important role of the Investigative Medicine Fund as catalyst of patient-related research was pointed out. Moreover, this shows that the clinical departments could really use the input of clinical-epidemiologists and clinical-epidemiological methods in the set-up and implementation of such research. During the performance of these consultative tasks, for that matter, the CKB worked closely with, among others, the institute for Medical Technology Assessment (iMTA), which was also founded at Erasmus University in 1988 with funds from a different SGO sub-programme, as well as with the department of Epidemiology and Biostatistics, which was now led by Hofman, Valkenburg's successor.¹⁷

The direct impact of the CKB in respect of the further development of clinical epidemiology as a research discipline in the Netherlands was minor. There was too much emphasis on educational tasks for this and also on clinical decision analysis, in which, unlike clinical epidemiology, the emphasis was not on research and research methodology, but on practical decisions in medical practice. Furthermore, it was not beneficial that Koos Lubsen left for Switzerland shortly after the foundation of the CKB and – although he remained affiliated to the Rotterdam faculty – subsequently devoted his energies mainly to SOCAR, the company he founded together with Hugenholtz medical faculty.¹⁸ Patrick Bossuyt, who was affiliated to the CKB as a methodologist and decision analysis expert, subsequently said about this:

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16. Petit & Van Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). IV'.
 17. Ibid.; M. M. van Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). VII. Evaluatie van het Deelprogramma "Medische Technology Assessment"', *Nederlands Tijdschrift voor Geneeskunde* 140 (1996), pp. 792-5.
 18. Interview with Hugenholtz; Petit and Van Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). IV'.

'Then the medical faculty of Erasmus was faced with a problem, for there was a commitment to take over the centre – which was only small for that matter – if it proved to be a success. But what do you do if management shuts up shop just like that, halfway during the subsidy term? So they wanted to quit and all the people who were in the centre at that time started looking for other opportunities then.'¹⁹

Precisely because of this somewhat curious state of affairs, the CKB was of essential importance for the rise of clinical epidemiology and evidence-based medicine in the Netherlands after all. This is because several people who had worked at this centre in Rotterdam and/or at the sub-department of 'clinical epidemiology' within the Thorax Centre prior to that, left for somewhere else and for Amsterdam in particular, for what is now known as the Academic Medical Centre (AMC).²⁰ It is there that the first 'proper' hospital department of clinical epidemiology and biostatistics in the Netherlands was formed. Among others, Jan Tijssen, who had worked under Lubsen in Rotterdam, and (several years later) Bossuyt were appointed as professors there. Towards the end of the 1990s in addition, Martin Offringa, a former employee of the CKB, became the director of the Dutch Cochrane Centre, which was embedded in the department of clinical epidemiology of the AMC. So it happened that several people with a strong Rotterdam influence ended up in Amsterdam. Bossuyt noted in this context that this was the reason for the joke that if the train between Rotterdam and Amsterdam derailed, nobody would be present at the department of clinical epidemiology.

Thus, the AMC, for a large part due to what Bossuyt calls 'double Rotterdam import', acquired a leading position in the field of clinical epidemiology and evidence-based medicine in the Netherlands. However, the breeding ground for this was already established fairly early in the 1980s, when clinical-epidemiological methods and ways of thinking were already accepted by a number of clinical departments of (the precursors of) the AMC. It is therefore sensible to reconstruct below how this fertile breeding ground came about and how the successful department of clinical epidemiology of the 1990s subsequently resulted from this.²¹

19. Interview with Bossuyt.

20. This 'disintegration' of the CKB is also mentioned in the evaluation of the SGO sub-programme on clinical epidemiology and clinical decision analysis. This was not considered by the evaluation committee to be alarming, for the following reason: 'From a national perspective, after all, the spreading of staff members across the country promotes the emanation of knowledge and experience.' see: Petit & Van Rees-Wortelboer, 'Het Stimuleringsprogramma Gezondheidsonderzoek (SGO). IV'.

21. Interviews with Bossuyt, Büller, and Offringa. See also: P. Bossuyt & J. Kortenray (eds.), *Schaatsen op Dik IJs: Evidence-Based Medicine in de Praktijk* (Amsterdam: Boom, 2001).

Fertile Amsterdam Soil

In 1983, David Sackett and his close colleagues at McMaster featured prominently on the pages of *Nederlands Tijdschrift voor Geneeskunde* for the first time. The journal published the Dutch translation of the five instalments of their article series ‘How to read clinical journals’, which was published in 1981 in the *Canadian Medical Association Journal*. The translator was Harry Büller, an internist associated with the thrombosis (sub)-department of the Wilhelmina Gasthuis in Amsterdam – one of the precursors of the AMC.²²

Büller was among the first Dutchmen to become acquainted with the ideas of clinical epidemiologists from Hamilton. After he had obtained his PhD in 1981 with a research on venous thrombosis, he left for McMaster University to further develop as a researcher at the recommendation and through the mediation of his supervisor, the internist Jan Wouter ten Cate. For the record, Büller did not head for Canada because of Sackett and associates, but in connection with the department of the haematologist, Jack Hirsh, who enjoyed a great international reputation. For over a year, Büller stayed in this ‘Valhalla in the field of thrombosis and hemostasis research.’²³ Yet it was in this period that he also frequently came into contact with people from the department of clinical epidemiology and biostatistics at McMaster – and in particular with David Sackett and the biostatistician, Michael Gent – for Hirsh and his staff collaborated very intensively with them.²⁴

Many years later, Büller had no trouble calling to mind his first encounter with Sackett: ‘The very first time I met Dave Sackett, which was in relation to a certain patient problem, he asked me: “What is the *evidence* for what you just said?” This was, as Büller was to notice repeatedly, Sackett’s standard reaction to statements and opinions on clinical issues. The young Dutch researcher was totally unaccustomed to anything like this. During his training in the Netherlands, he had been taught that you had to be ‘apo-

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22. D. L. Sackett, ‘Hoe Moeten Medische Tijdschriften Worden Gelezen? I. Waarom en in Welke Geest?’, *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), pp. 2286-90; R. B. Haynes, ‘Hoe Moeten Medische Tijdschriften Worden Gelezen? II. Het Beoordelen van een Diagnostische Test’, *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), pp. 2331-7; P. X. Tugwell, ‘Hoe Moeten Medische Tijdschriften Worden Gelezen? III. Het Beoordelen van het Klinische Beloop en de Prognose van een Ziekte’, *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), pp. 2367-71; K. S. Trout, ‘Hoe Moeten Medische Tijdschriften Worden Gelezen? IV. Het Bepalen van Oorzakelijke Verbanden’, *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), pp. 2414-19; D. L. Sackett, ‘Hoe Moeten Medische Tijdschriften Worden Gelezen? V. Het Onderscheiden van Nuttige en Nutteloze of Zelfs Schadelijke Behandelingen’, *Nederlands Tijdschrift voor Geneeskunde* 128 (1984), pp. 21-5.
 23. F. van den Bosch, ‘Rebellie tegen het Ingebakken Gelijk’, in P. Bossuyt & J. Kortenaar (eds.), *Schaatsen op Dik Ijs: Evidence Based Medicine in Praktijk* (Amsterdam: Boom, 2001), pp. 15-19, on p. 15.
 24. Unless otherwise stated, the description of Büller’s experiences in Hamilton and (subsequently) in Amsterdam, as well as the accompanying quotes in the following pages, are derived from the interview TB conducted with Büller, as well as from the interview with Büller – which greatly overlapped with this – in: Van den Bosch, ‘Rebellie’. For more information on the collaboration between (the department of) Sackett and (that of) Hirsh, see: Daly, *Evidence-Based Medicine*, pp. 59-60, 105-7.

dictic' and that, as a physician, you had to (be able to) make firm statements with great self-assurance such as: "We always treat this in this way", or: "this clinical picture looks like such and such a disease". What impressed Büller most here was that Sackett – and Hirsh, Gent and others in Hamilton too – approached themselves just as critically. They continually wondered: is what I think actually right? That even the 'bosses' acted this way was 'a complete eye-opener' to Büller. In his view, the 'undisputed strong point' of Sackett and the others of McMaster was that they were able to honestly admit they did not know something, for example when making visits to patients and encountering a question or a problem. Twenty years after the fact, Büller was still able to recount in colourful detail the extent to which he had been turned upside down by this:

'Then they would just say: "Sorry, I do not know the answer." I had never heard that before! A medical director or a professor would always have an answer! Whether it was true or not!'

During his stay at McMaster, for example, Büller 'continually' had the feeling 'he stared like a duck in a thunderstorm'. Many years later, his analysis is that he experienced a collision between two 'ways of thinking'. He had been raised in what he himself calls the 'Austrian-German school of medicine' and came into contact with the 'Anglo-Saxon model' in Canada, which was geared towards generating, testing, and falsifying hypotheses. This may seem too schematic a representation of affairs, but it does express something of how strongly Büller experienced the contrast between his experiences in Dutch medicine and those at McMaster. The transition from a 'German' to an 'Anglo-Saxon orientation' in Dutch medicine is also explicitly mentioned by others.²⁵

Büller was not only gripped by the culture and mentality prevalent at McMaster; in his own words, he was also 'greatly mesmerised' by Sackett, whom he describes as 'some kind of Jesus Christ' and an 'apostle-like figure'. This entirely corresponds with the way in which the appearance, manner, actions and charisma of this undisputed leader of the EBM movement have been repeatedly described.²⁶

Yet Büller also emphasises the immediate practical applicability of what he learned at McMaster. According to him, the basis of everything was 'intrinsic doubt', or admitting that you are not completely sure about something, but this did subsequently lead to focused action. Anyone who does not doubt and does not pose any questions, will not feel the need to search for answers. At McMaster they did do this, either by seeking evidence in the literature, or by producing this evidence themselves by conducting focused

25. Interviews with Algra, Hugenholtz and Knottnerus.

26. See a.o. Bossuyt, 'Evidence-Based Medical Testing', p. 11; Daly, *Evidence-Based Medicine*, in particular p. 57. See also chapter 3.

research. According to Büller, extraordinarily practical, effective and useful instruments were developed for both activities. Shortly before he arrived in Hamilton, Sackett and staff had published the series of articles ‘How to Read a Clinical Journal’ in the *Canadian Medical Association Journal*. In his view, these articles possessed an ‘utterly biblical greatness’. To him, the remarkable aspect was that the authors had kept things very simple. To start with, the entire clinical literature was divided into four categories, namely into articles on diagnostics, prognostics, aetiology and treatment methods, respectively. It was subsequently indicated for each category what to look for in order to be able to appreciate the value of an article. For example, for every article on diagnostics, whether it concerned diagnostics of thrombosis, tuberculosis, or anything else, the same principles applied. This simple framework enabled one to critically assess the literature in a quick and effective manner, according to Büller. This was a revelation to him: ‘Up until that time, I thought that everything in print was true, and this framework enabled you to see that, sometimes out of ignorance of course, the biggest nonsense was written down.’

Even more important to Büller was that the articles on ‘how to read a clinical journal’ were a ‘double-edged sword’²⁷. If you critically scrutinised scientific articles in this manner, it would be odd not to do the same with your own research. This is why the department of epidemiology and biostatistics of McMaster not only organised courses on ‘how to read a clinical journal’, but also courses on ‘how to write a research protocol’ and ‘how to do my own statistics’. In these courses, research was similarly grouped into the previously mentioned categories, after which the main principles and technique were discussed for each category. In order to underline the consistency between these courses, Büller called them the ‘trinity in Hamilton’. To him, the applicability of the ‘principles’ for setting up and conducting individual research, which he learnt at McMaster, was the most relevant. After all, he had come to Hamilton as part of his training to become a researcher. He experienced the course ‘how to write a research protocol’ ‘as an explosion of sorts’, particularly as conducting proper research turned out to be not difficult at all. What he was mainly taught at McMaster was the discipline of posing an answerable question, taking a small step, and only then the next one. With these appropriate, answerable research questions as a foundation, setting up proper research appeared not to be difficult at all and you barely required any complex statistical calculations anymore.

Büller’s experiences at McMaster would leave a lasting impression on his professional life, which was mainly dominated by research. Looking back on his career, Büller very much emphasised that what he learnt in Hamilton helped him ‘tre-men-dous-ly’.

Büller was not the type to keep everything he had experienced at McMaster to himself. During his time in Hamilton he thought: ‘Everyone should know this!’ Back in the Neth-

27. Van den Bosch, ‘Rebellie’, p. 18.

erlands, as already mentioned, he provided the translation of the five-part article series 'How to read a clinical journal' by Sackett et al., which appeared in *Nederlands Tijdschrift voor Geneeskunde* in late 1983 and early 1984. The first part was followed by a commentary by Büller's former supervisor Ten Cate. As far as is known, this commentary featured the term 'clinical epidemiology' for the first time in the history of this journal. Ten Cate pleaded for 'accelerated incorporation of clinical epidemiology into the medical curriculum'. He pointed, among others, to the 'textbook example' of the department of clinical epidemiology at McMaster University, which was closely involved in medical education. Interestingly, not only did he elaborate on the importance of critical analysis of the literature and other 'educational' aspects, but he also emphasised the significance of clinical research:

'Departments for clinical epidemiology or medical statistics proved to be *indispensable*, among others, to the formulation of research questions and research protocols for clinical research, and to the implementation and the analysis of the research.'²⁸

Besides Ten Cate, Büller reportedly managed to infect more people of the Amsterdam Wilhelmina Gasthuis – where he started working upon his return from Canada – with his enthusiasm about his experiences in Hamilton. In addition, he looked around him to see if there were any people elsewhere who could help launch clinical epidemiology in the Netherlands. He met a number of these protagonists during a 'workshop' on clinical epidemiology that was held in the Royal Tropical Institute in Amsterdam in 1983. One of these proponents was Jan Vandenbroucke, who had ended up at this workshop via his then Rotterdam boss, Valkenburg. Lex Muller, the manager of the Royal Tropical Institute, who also organised the workshop, was an epidemiologist who had obtained his PhD under the supervision of Valkenburg. In 1984, Muller, together with Vandenbroucke and S.A. Danner, an internist at the University Hospital of the University of Amsterdam (Dutch abbreviation: AZUA), also organised the publication of a report of this workshop in *Nederlands Tijdschrift voor Geneeskunde*.²⁹ This was (probably) the second time that the term 'clinical epidemiology' appeared in this journal.

At first sight, the Tropical Institute was not the most obvious location for a meeting on clinical epidemiology. Yet the occasion for the workshop accounts for a great deal: the institute received an important visitor in the person of Ken Warren, the 'director for health sciences' at the Rockefeller Foundation, who attempted to lend more substance to

28. J. W. Ten Cate, 'De Betekenis van de Klinische Epidemiologie voor het Klinische Denken', *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), pp. 2290-1.

29. S. A. Danner, A. S. Muller, & J. P. Vandenbroucke, 'Klinische Epidemiologie; Verslag van een Workshop', *Nederlands Tijdschrift voor Geneeskunde* 128 (1984), pp. 2280-3. The account of this workshop and all quotes in the following paragraphs are all derived from this article.

the shift from public health to clinical epidemiology, which the board of this organisation had decided upon only two years previously. As discussed in chapter 3, there was a strong focus on the launch of Clinical Epidemiology Units in developing countries. To this end, the INCLEN – International Clinical Epidemiology Network – was founded in 1982. An important policy aspect was the training of young medical professionals from developing countries in special training centres, one of which was the department of clinical epidemiology and biostatistics at McMaster. Warren came to the Royal Tropical Institute with the apparent intention of investigating whether a similar training centre could be launched in the Netherlands as well. The report of the workshop states there was talk of ‘the development of clinical epidemiology within the medical faculties in the Netherlands *and of training facilities for clinicians from developing countries*’. This also explains why Warren was accompanied by Brian Strom, the ‘co-director’ of one of the existing training centres within the context of the INCLEN, the Clinical Epidemiology Unit of the University of Pennsylvania. During the workshop, Strom gave a presentation on the educational programme of his unit.

During his speech, Warren himself particularly emphasised the importance of the integration of clinical epidemiology into the clinical departments of a medical faculty. This was entirely in line with the message the Rockefeller Foundation had been propagating for two years that, in retrospect, it had not been a good idea to set up separate Schools of Public Health, and that it was better to develop epidemiology in the *clinic*. The two other speakers during the workshop, the aforementioned Danner and Vandenbroucke, explicitly echoed these sentiments. Danner pleaded for the foundation of departments of clinical epidemiology which were ‘literally’ ‘embedded in the clinic’, so that there could be an ‘ongoing cross-fertilisation between clinical epidemiologists and clinicians’. Vandenbroucke argued that in the Netherlands too, epidemiology and clinical medicine had grown too far apart over time. According to him, it could be an advantage that ‘schools of public health’, existing independently of the medical faculties, had never actually been founded in the Netherlands. As a result, there was no major institutional obstacle for a closer relationship between epidemiology and clinic in the form of clinical epidemiology.

Strikingly, both speakers – as well as Muller in his contribution to the report of the workshop – explicitly placed the necessity of clinical epidemiology within the framework of the scarcity issue. The idea behind the establishment and expansion of the INCLEN was that *developing countries* in particular would benefit from clinicians skilled in clinical epidemiology. They would be the people who, in the context of limited financial options and major health problems among the population, were capable of making sharp choices with regard to ‘the influx of diagnostic tools, of therapeutic agents and of preventive opportunities’ – as Vandenbroucke, referring to Feinstein, identified the ‘the three major challenges’ with which medicine was faced. Vandenbroucke and the two Dutchmen, however, argued that the same actually applied to *Western* countries. Muller stated for example: ‘It is the right of patient and society that the effect of these agents on health – in

relation to the costs – is established as accurately as possible. This indicates the essence of clinical epidemiology: critical assessment of the effect of medical practice and the development of methods to measure this.' Danner added to this in his contribution that the developments in medicine had occurred at such a rapid rate, that countless diagnostic methods and therapies as well as organisational forms had been introduced in healthcare without first having been adequately tested for safety, efficacy and cost-effectiveness. He subsequently stated: 'All these problems cannot be solved from the laboratory or from a hospital department or outpatient clinic. They require clinical epidemiological research with methods other than the ones the classical clinical researcher is used to.'

Vandenbroucke identified the 'financing problems of healthcare' as one of the forces driving 'the epidemiologist and the clinician' closer together again. Under the influence of the cutbacks, Dutch physicians were forced to practise 'a more streamlined (possibly protocol) medicine. As a result, there was a growing interest among them in the techniques of decision analysis and the cost-benefit analysis, and they discovered that clinical epidemiologists mastered them like no others. Vandenbroucke was the only one to also point to the scarcity in a different area: 'The struggle for scarce publication space is intensifying in medical science too'. As a result, he argued, a new impetus had originated for academic clinicians to collaborate more closely with (clinical) epidemiologists: 'Clinicians discover that epidemiologists have a range of methods and techniques at their disposal which are highly applicable in clinical research, and which – ultimo ratio – are also very popular with editors and reviewers of journals.' It is perhaps no coincidence that Vandenbroucke made this remark in 1983 – the year in which the RAWB commented on the weakness of patient-related research and Minister Deetman launched the cost-cutting operation, Task Division and Concentration.³⁰

Thus, in 1983, two years before the launch of the SGO and two years before the publication of Querido's article on the 'discipline of medicine', some of the central ideas of the movement for the benefit of patient-related research were already being highlighted.³¹ This confirms the impression that interest in clinical epidemiology had already started to increase fairly early in the 1980s. This still occurred within a small circle, but apparently the germ of the movement that went increasingly public at the end of this decade was already present. In addition, it was clear that this trend occurred in the context of scarcity in both healthcare and in medical research.

As a specific outcome of the workshop Müller mentioned that an informal working group had been formed, consisting of people from the University Hospital of the University of Amsterdam (AZUA), the Institute for Epidemiology of Erasmus University and

30. See chapters 4 and 5.

31. See chapter 5.

the Royal Tropical Institute. The purpose of this working group was to free up a small core of clinical-epidemiological expertise within the AZUA, which could provide services with regard to both clinical research and clinical education. A 'clinical epidemiology unit' within the context of the INCLLEN would subsequently have to be established within three to five years.³²

Although little came of this, an informal group of people did originate, in particular within the AZUA/AMC, which advocated the further development of clinical epidemiology in the Netherlands. Its driving forces were Büller and Vandenbroucke. They had met for the first time during the workshop at the 'Tropical Institute' and discovered on this occasion how much they had in common. As people in their early thirties, who were still at the beginning of their careers, they were both 'gripped' by clinical epidemiology, in which they saw the future of medicine. And in the same way Büller was strongly formed by his spell abroad at McMaster, Vandenbroucke was formed by his time in Boston with Miettinen. They both found, just like Lubsen, that the ideas of the Finnish theorist and those of Sackett's group could be combined perfectly.

Together with several other people from Rotterdam and Amsterdam, they started organising courses for assistants, which usually took place in the AZUA/AMC. McMaster's famous courses served as a basis here, but elements from those by Miettinen were also used. According to Vandenbroucke and Büller, this happened strictly informally, in their leisure time, on Monday evenings. The courses were simply announced on a notice board, but the news about them 'travelled on the grapevine'. There appeared to be great interest in these informal courses among assistants from Rotterdam, Utrecht and, in particular, Amsterdam.³³

Vandenbroucke noticed that these participants mainly 'wished to learn this research'. Büller and Vandenbroucke themselves, too, were first and foremost scientists, so perhaps it is not strange that the focus in the courses – even though they dealt with, among others, critical appraisal – was on research. Looking back, both Büller and Vandenbroucke stressed that they were driven by an almost religious zeal: 'It was pure enthusiasm and belief. The aim was: spreading the gospel.'³⁴

The 'holy fire' and the missionary activities of Büller, Vandenbroucke and several others have probably contributed to interest in clinical epidemiology, such as applied in Hamilton, being aroused among the established clinical researchers within the AMC. Besides the previously mentioned Ten Cate and Danning, this also pertained, among others, to the professor of cardiology, Dunning, and above all, to the professor of neurology, Van

32. See on this and for all citations and paraphrases in the preceding paragraphs: Danner, Muller & Vandenbroucke, 'Klinische Epidemiologie'.

33. Interviews with Vandenbroucke and Büller.

34. Interview with Vandenbroucke. Büller made similar remarks in the interview (by TB) with him.

Crevel.³⁵ On the recommendation of these leading figures, Sackett was invited in 1984 or 1985 to come to the AMC. The conversations with Sackett resulted in, among others, a programme for staff members of clinical departments, who, after first having attended the course evenings by Büller and Vandenbroucke, went to Hamilton during the summer period in order to follow the summer courses organised by the department of clinical epidemiology and biostatistics. The emphasis here was very much on the acquisition of research skills (once again). For several consecutive years, four or five clinical *researchers* were dispatched to Hamilton, the idea being that, upon their return to the AMC, they could help improve the quality of clinical research in their own departments. This generally involved cardiologists, internists and neurologists.³⁶

That this approach worked, became evident from, among others, publications in renowned journals and success in obtaining research funds. This also began to be noticed within the AMC. Büller notes about this:

'I think that success in the scientific field played a very important role. If people who were able to formulate the right research questions and do the right research managed to end up in *the Lancet* and the *New England Journal of Medicine* with this, then this was bound to turn heads and make people wonder: how did they pull this off? And I myself am an example of this. By applying these principles from McMaster in an exact manner, I saw that we scored almost 90% in the circuit of subsidy applications in those first years [...]. So you would also see these principles appear in the subsidy circuit. Those who had it in them therefore received the subsidies, so could conduct these researches, proceeding to publish them in renowned journals. And of course you are bound to get groups – this is a factor that I think has played a major role – saying: “what the blazes, how come they do manage to do it and we don't?” I think this has been an incentive for a lot of people to think: “Hey, I need to find out more about this”. I know a number of people in this house [the AMC] who have significantly furthered their career in science by working in this way.'

Büller's account may be supported by multiple sources. It is true that many publications by Büller and other researchers at the AMC with a strong clinical-epidemiological bent may be found in high-impact journals. Furthermore, there are many reports by subsidisers and there is, for example, the discipline plan of the KNAW, from which a number

35. See for more about Van Crevel: A. Hijdra et al., *Vernieuwingen in de Neurologie*; D. Kraft, 'De Jonge Specialist: Ervaring is de Laagste Vorm van Bewijsvoering', in P. Bossuyt & J. Kortzenray (eds.), *Schaatsen op Dik Ijs: Evidence Based Medicine in Praktijk*, (Amsterdam: Boom, 2001), pp. 49-53, on p. 49; M. Vermeulen, *De Onlogische Redelijkheid van het Klinisch Wetenschappelijk Onderzoek* (Houten/Zaventem: Bohn Stafleu van Loghum, 1991) p. 13.

36. Interview with Büller; Van den Bosch, 'Rebellie'. Sackett visited the AMC more than once, see for example: Hijdra et al., *Vernieuwingen in de Neurologie*, p. 76, n. 18.

of things may be deduced on the scientific performance and status of the cardiologists, internists and neurologists from Amsterdam.³⁷ Chapter 4 already discussed how, within the Heart Foundation, partly due to the input of the advisor Miettinen, submitted applications were critically assessed. This was also deemed necessary because many project proposals were considered to be of poor quality. Advisory reports that appeared in the course of the 1980s within the framework of subsidy programmes for medical research repeatedly complained about this. The success of ‘those first years’ in obtaining subsidies, spoken of by Büller, may be partly explained because the applications from the AMC due to the ‘input’ of McMaster compared favourably to an (initially) rather meagre competition.³⁸

As had previously been the case with the Dutch Heart Foundation, not even the full subsidy research budget was spent during the first years of the Investigative Medicine Fund – not because there was insufficient interest in it, but because the vast majority of the applications submitted were of insufficient scientific quality. This resulted in a very high percentage of rejections. In the ‘round’ for subsidy year 1989, approximately 90% of the submitted project applications was rejected: only 11 of the 113 projects were accepted. The following year, the percentage was slightly more favourable: 13 of the 53 projects were accepted, so approximately 75% were rejected. The Investigative Medicine Committee of the Health Insurance Council noted that the quality of the applications had ‘further improved’, but that many projects were still discarded because of flaws in the research design.³⁹ The committee subsequently made a recommendation (implicitly) expressing that the methodological input of clinical epidemiology could be decisive for the acceptance of projects – and it also expressed which basic shortcomings occurred in the applications that were submitted *without* such a methodological input:

‘According to the view of the Committee for Investigative Medicine, *assistance of the applying researchers [will], in many cases, lead to a better result* than is the case now. Exhaustiveness and correctness are often lacking, particularly when it comes to the composition of the control groups, inclusion and exclusion criteria, representativeness of the patient groups, standards and measuring procedures. In multi-centre trials, questions may sometimes be raised regarding the mutual comparability of results obtained in various centres, for ‘instructions’ are not exact enough.’⁴⁰

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37. Gezondheidsraad, *Functieverruimingsplannen*, pp. 29-32; Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan*, pp. 19-23, 88-115.
 38. See for example: Gezondheidsraad, *Functieverruimingsplannen*, p. 11; Idem, *Projecten Ontwikkelingsgeneeskunde 1986*. See also n. 39 and 40 below.
 39. Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies inzake ontwikkelingsgeneeskunde 1990* (Amstelveen: Ziekenfondsraad, 1989) pp. 15-18. See also on this: Engel, ‘Ontwikkelingsgeneeskunde’, p. 403; Mulder & Rokx, ‘Ontwikkelingsgeneeskunde’, p. 299.
 40. Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies 1990*, p. 18. TB’s italics.

Büller himself was involved in one of the first research projects to be accepted by the Investigative Medicine Committee, for that matter. This study into diagnostics with deep vein thrombosis resulted in, among others, a publication in the *New England Journal of Medicine*.⁴¹

The 'input' of clinical epidemiology at the AMC was such a success that several professors who excelled in clinical research, including Dunning and in particular Van Crevel, started pleading in favour of the foundation of a *separate* department of clinical epidemiology and biostatistics taking inspiration from McMaster. They had experienced how, due to the input of people who had been in Hamilton, clinical research at the AMC ended up in a virtuous circle. Those who had obtained research funds and had 'good' publications to their name enjoyed a major advantage in subsequent subsidy rounds. In the distribution of research funds, subsidisers increasingly looked at the 'quality' of applying research groups, which was measured using precisely these 'performance indicators': the publications and obtained research funds of the preceding years. The government also used a similar working method, for example in conditional financing. Thus, the financing of medical research became a self-enhancing system of sorts.⁴² For research groups, it was critical to jump on this bandwagon and stay on it; otherwise their survival would be in jeopardy. They had succeeded relatively well in doing so at the AMC, but at McMaster they had seen it could be done even better. Many clinical departments of the medical school in Hamilton did very well in the field of clinical research, in part due to the intense cooperation with the department of clinical epidemiology and biostatistics. 'We should have this too', they will have thought in Amsterdam.⁴³

This is not to say, incidentally, that the Amsterdam advocates of clinical epidemiology exclusively looked at the great example in Hamilton. They drew inspiration from the work of Wulff and Feinstein too. They were also interested in technology assessment and many of them felt strongly attracted by David Eddy's ideas on clinical decision analysis and the 'explicit approach' in medicine. It is also known of the neurologists, Van Crevel and Vermeulen, that due to contacts with Scottish researchers, they had become vocal

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41. H. Heijboer et al., 'A Comparison of Real-Time Compression Ultrasonography with Impedance Plethysmography for the Diagnosis of Deep-Vein Thrombosis in Symptomatic Outpatients', *New England Journal of Medicine* 329 (1993), pp. 1365-9. See also: Van der Meulen & Timmermans, 'Ontwikkelingsgeneeskunde'.
 42. See chapter 4, and, for example: J. M. Spanjer, 'Financiering van Gezondheidsonderzoek. Minder "Telegenieke" Ziekten en Minder Bekende Fondsen', *Nederlands Tijdschrift voor Geneeskunde* 137 (1993), pp. 1787-9.
 43. Interview with Buller; P. Bossuyt & A. Semin-Goossens, 'Verantwoording Afleggen: Expliciet Kiezen in een Academisch Bastion', in P. Bossuyt & J. Kortenray (eds.), *Schaatsen op Dik IJs: Evidence Based Medicine in Praktijk* (Amsterdam: Boom, 2001) pp. 55-5, on pp. 58-9.

supporters of so-called ‘pragmatic’ trials as early as the beginning of the 1980s.⁴⁴ Thus, there were many foreign influences in Amsterdam. Nevertheless, the idea of a separate department of clinical epidemiology had been explicitly ‘copied’ from McMaster.

By 1990, the AMC was the first university hospital in the Netherlands to actually acquire a *hospital department* of Clinical Epidemiology and Biostatistics.⁴⁵ According to insiders, this was not only due to the pleas of renowned clinical researchers, but above all to the vision of the then president of the Board of Directors, the ENT physician, Niek Urbanus. There are indications that Urbanus took great personal interest in clinical epidemiology and patient-related (evaluation) research. As a director, he moreover recognised the importance of scientific success. In addition, the new department of clinical epidemiology and matters such as evaluation research fitted well within the strategy he had outlined. With the opening of the AMC in the mid-1980s, ‘a giant Moloch, a temple in the polder’ had been created.⁴⁶ In 1988, its daily management was entrusted to a modern, professional three-man board headed by Urbanus. This Board of Directors was keen to prove the added value of this gigantic conglomerate. In reference to this, Bossuyt said Urbanus was of the opinion that the AMC should not only be leading with “the latest and the greatest technology” and acquire a top position in international research, ‘but should also provide a response to the societal challenges that started to become increasingly clear.’⁴⁷

Another policy objective of the Board of Directors was to increase the cohesion of the AMC. From the word go, Urbanus and his fellow directors strived for an ‘administrative integration’ of the university hospital and the medical faculty of the University of Amsterdam. In 1994, the merger had become reality. Urbanus became chairman of the Board of Directors and dean, thus ending up at the helm of the first University Medical Centre (UMC) in the Netherlands – several more were to follow. Characteristic of a UMC was that, for the first time in Dutch history, the three tasks of research, medical education and patient care were accommodated in one organisation.⁴⁸ In order to increase and emphasise the involvement of these three roles with one another, the Board of Directors introduced the term ‘translational medicine’ at the end of the 1980s. It expressed that the

44. This ‘eclectic’ openness for influences from abroad was emphasized by Borst-Eilers and Bossuyt in the interviews TB conducted with them, and is also stressed in: Bossuyt & Kortenray, *Schaatsen op Dik IJs*; Hijdra et al., *Vernieuwingen in de Neurologie*. See for more on the neurologists and ‘pragmatic trials’ the following section on the ‘Utrecht-case’.

45. Bossuyt & Semin-Goossens, ‘Verantwoording Afleggen’, p. 58. Original italics.

46. Interview with Bossuyt.

47. Interview with Bossuyt. See also: interview with Borst-Eilers; Borst-Eilers, *Geneeskunde op Recept?*, pp. 10-11, 26-7; Bossuyt & Kortenray, *Schaatsen op Dik IJs*, pp. 11-12; Bossuyt & Semin-Goossens, ‘Verantwoording Afleggen’, pp. 58-9.

48. Mooij, *Polsslag*, 419-22. See for more on (the history of one of the) unique Dutch ‘UMC’s’: Klijn, *Verlangen naar Verbetering*.

AMC aimed to bridge the gap between, on the one hand, science, and, on the other hand, patient care and education. The research that was conducted should eventually serve to improve the practice of healthcare and education. This is why there had to be the possibility of the *translation* – to the greatest extent possible – of the results of research into what was relevant to the other two fields. Although Büller thought ‘translational medicine’ was a terrible managers’ term, he also noted that under this umbrella, which was communicated ‘under rather strong management’, clinical epidemiology and evidence-based medicine were firmly embraced by the directors of the AMC. Büller does not believe that they did this out of a deep-rooted inner conviction, but primarily because it fitted seamlessly within their policy. In clinical epidemiology, after all, everything mainly revolved around ‘translation’ of knowledge into clinical problems: ‘For they wanted to verify whether something that had been researched with mice could also be applied to humans, but you had to do this in an ‘evidence-based’ way.’⁴⁹

Whether it was based on personal conviction, on insight into the way in which the financing system of medical research worked, as part of the establishment strategy of the new AMC and the still to be formed UMC, or on a combination of these motives, the Board of Directors forcefully backed the department of Clinical Epidemiology and Biostatistics from the very start. This was also the case during the first years of the department, which saw Van der Helm in charge as the first head in these reportedly difficult years. According to Büller, the department only flourished after the arrival of Bossuyt in 1991, who was subsequently appointed professor of clinical epidemiology in 1995, and was head of the department from 1997 until 2007. Bossuyt himself felt ‘privileged’ for he became head of a department that had the full support of the higher echelons of the AMC. This went very far according to him. Other departments, for example, had to detail in quarterly reports the extent to which they cooperated with Bossuyt and associates, the idea behind this being that intense contacts and ‘cross-fertilisation’ between the department of clinical epidemiology and biostatistics and clinical researchers would form the key to ‘top research’, as was also the case at McMaster. All the activities of Bossuyt and his colleagues from the department of Clinical Epidemiology and Biostatistics – whether it involved education, training, consultancy, advice or focused participation as a researcher – were dominated by one main objective: assisting clinical research at the AMC.⁵⁰

When it came to appointment of new professors, according to Bossuyt, Urbanus ‘explicitly looked to recruit people who were capable of conducting patient-related research that was relevant to daily practice.’ In this context, Bossuyt mentions the names of the

49. Interviews with Bossuyt, Büller, Borst-Eilers and Thomas; Bossuyt and Semin-Goossens, ‘Verantwoording Afleggen’, p. 59.

50. See notes 47 and 49 above.

professors, Vermeulen (neurology),⁵¹ Gouma (surgery) and Obertop (surgery) who were appointed during the leadership of Urbanus. This way, fine researchers were placed at the helm of the large clinical departments of the AMC and of many smaller departments as well. ‘This may seem self-evident now, but the situation was a far cry from this in the 1980s and early 1990s’, according to Bossuyt.⁵²

A remarkable appointment, in addition to this, was that of Els Borst-Eilers, the then vice-chair of the Health Council, as extraordinary professor of ‘evaluation research of clinical practice’ in 1992.⁵³ In 1987, during the Maastricht symposium ‘Patient-related research in jeopardy’ Borst-Eilers had already commented on the special position of evaluation research upon which she would focus as professor (several years later). She had first argued that, with regard to ‘creative, innovative research’, there was no reason to favour one kind of medical research – patient-related or non-patient-related – over the other. Quality should be the only criterion for the allocation of subsidies. She subsequently explained why this was a very different matter for evaluation research:

‘In the field of patient-related research, however, we also know a different type of research, the so-called “mandatory work” or evaluation research. In this context, I refer to the targeted testing of technologies for their efficacy and their usefulness for medical practice [...]. This type of patient-related research is absolutely necessary to make healthcare more rational and effective. This is why there should not be cuts in the money needed for this evaluation research; outlay must precede returns.’⁵⁴

What Borst-Eilers pleaded for, as vice-chair of the Health Council, corresponded closely with what the Health Insurance Council intended with the Investigative Medicine Fund, to which she also referred in her speech, for that matter. Later in 1987, at the request of the Minister of Education & Science, a committee of the Health Council which, besides Borst-Eilers, also included Dunning and Mandema as members, would become actively involved in the subsidising of investigative medical research.⁵⁵ Previously, immediately upon taking up her duties as vice-chair of the Health Council in 1986, she had become

51. Vermeulen’s inaugural lecture from 1991 was a plea for clinical research. He also stressed in it the importance of the new department of clinical epidemiology in the AMC. See: Vermeulen, *Onlogische Redelijkheid*, p. 11.

52. Interview with Bossuyt. See also: Bossuyt & Semin-Goossens, ‘Verantwoording Afleggen’, p. 66.

53. Borst-Eilers, *Geneeskunde op Recept?*; Bossuyt & Semin-Goossens, ‘Verantwoording Afleggen’, p. 59; Mooij, *Polsslag*, p. 447.

54. E. Borst-Eilers, ‘Is de Huidige Financiering van het Patiëntgebonden Onderzoek Effectief? Enkele Kanttekeningen’, *Tijdschrift voor Gezondheidswetenschappen* 3: 2 (1988), pp. 69-2, on p. 72.

55. At the time, this occurred within the framework of the ‘role expansion policy’ of the government with regard to university hospitals. But even after the Health Insurance Council had ‘adopted’ the subsidy scheme for investigative medicine, the Health Council continued to play an advisory role. See: Gezondheidsraad, *Funcieverruimingsplannen*; Idem, *Projecten Ontwikkelingsgeneeskunde 1986*.

involved in the international technology assessment movement. Shortly beforehand, the International Society of Technology Assessment in Health Care (ISTAHC) had been founded and the Health Council had become a member. In 1987, she, together with the then general secretary of the Council, Henk Rigter, who had also performed the two background studies of the RAWB from 1983, for that matter, organised the international annual conference of the ISTAHC in Rotterdam. She subsequently also fulfilled the role of secretary of this society for several years. During this time, she became very familiar with the 'technology assessment world' by her own account. Being the old hand that she was at investigative medicine and MTA, Borst-Eilers was a logical candidate for the post of extraordinary professor in the field of evaluation research. Her appointment may be considered to be a confirmation of the increasing interest in this type of research and recognition of its importance by the Board of Directors of the AMC.⁵⁶

Borst-Eilers was appointed extraordinary professor within the department of Clinical Epidemiology and Biostatistics. It was her task to become one of the driving forces of the incentive programme 'guidelines for clinical practice' there, which the Board of Directors launched to coincide with her appointment in 1992. Each year, hospital departments were given the opportunity to apply for support in the form of a maximum of 100,000 guilders and assistance, by Borst-Eilers and other staff members of the department of Clinical Epidemiology and Biostatistics, in the development of clinical guidelines. This had to involve small projects that could be completed within one year. 5 to 8 applications were accepted every year. These were selected by a committee of which, in addition to Borst-Eilers, Urbanus, Dunning, Van der Helm – the then head of the department of Clinical Epidemiology and Biostatistics – and Van Crevel were members as well.⁵⁷

The ultimate objective of the projects that were carried out within this programme was the creation of guidelines, but this often required conducting research. As a rule, this started with literature research, but in many cases this produced too little to be able to arrive at sufficiently substantiated guidelines. This is why small-scale evaluation studies were carried out which – as was stressed in AMC circles – led to publications in prominent journals virtually without exception. Sometimes it became apparent during such a project that there was a need for research that was more large-scale and long-term than was possible within the 'guidelines for clinical practice' programme. In these cases, the Investigative Medicine Fund was sometimes also – successfully – called on.⁵⁸

56. Interview with Borst-Eilers; Bossuyt and Semin-Goossens, 'Verantwoording Afleggen', p. 59; Mooij, *Polsslag*, p. 447.

57. Interviews with Bossuyt and Borst-Eilers; Bossuyt and Semin-Goossens, 'Verantwoording Afleggen', pp. 60-6. Van Crevel's neurology department also had its own, active, guideline programme, which was, already in 1994, explicitly associated with evidence-based medicine. See: W. Westrate, P. Portegies & H. van Crevel, 'Het Gebruik van Protocollen op een Neurologische Afdeling', *Nederlands Tijdschrift voor Geneeskunde* 138 (1994), pp. 1579-83, on p. 1582.

58. See n. 56 and 57 above.

The aforementioned committee consisting of Urbanus, Borst-Eilers and others also organised a monthly lecture series. Every second Wednesday of the month, two lectures were held on a wide range of subjects. In addition, plenary debates were organised between professors – and subsequently assistants – from various departments, who were to cross swords with each other on practical, clinical issues. All these meetings were visited by hundred to two hundred staff members of the AMC. The people who were present there experienced these Wednesday evenings as ‘true happenings’.⁵⁹

All these elements combined – ‘the professor appointments, the guidelines programme, the small ‘seeding’ subsidies for collecting evidence for the guidelines and this lecture series’ – ‘activated the house across the board’ according to Bossuyt. Using several examples, he was able to demonstrate that, within several years, publications by ‘all manner of departments’ appeared in ‘*New England*’ and other top journals.⁶⁰ In 2001, Bossuyt and a fellow clinical epidemiologist typified this AMC-wide success in the scientific field as ‘the result of conscious policy and targeted support, in which a vision on research was accompanied by targeted recruitment of suitable professors in key positions.’⁶¹

The dynamics attained by clinical research within the AMC – of which (the department of) clinical epidemiology was the epicentre – thus seem to have resulted from specific personal and local factors, varying from the almost ‘religious’ zeal with which Harry Büller returned from McMaster to the lectures and debates on Wednesday evenings. Bossuyt thinks that Urbanus’s visionary policy was perhaps the most decisive. At the same time, he repeatedly states – as do many other researchers (from the AMC or elsewhere in the Netherlands) – that one external factor played a crucial role: the Investigative Medicine Fund.⁶² According to Bossuyt, the Investigative Medicine Fund and (to a lesser extent) the subsidy programme Efficiency Studies (Dutch: DoelmatigheidsOnderzoek), which was placed with ZonMW (The Netherlands Organisation for Health Research and Development) and replaced the Investigative Medicine Fund in 1999, was highly exceptional from an international perspective as well. He provides the following explanation for this:

59. The quote is from: I. van Elzakker, ‘Bloedverlies bij Open Hartoperaties: de Verborgene Schatten van Oud Onderzoek’, in P. Bossuyt & J. Kortenray (eds.) *Schaatsen op Dik Ijs: Evidence Based Medicine in Praktijk* (Amsterdam: Boom, 2001), pp. 97-100, on p. 100. But see also n. 56 and 57 above.

60. See notes 40, 55 and 56 above. Bossuyt’s statement is also confirmed by a ‘check’ on PubMed.

61. Bossuyt & Semin-Goossens, ‘Verantwoording Afleggen’, p. 66.

62. Interviews with Algra, Assendelft, Borst-Eilers, Bossuyt, Van Gijn and Van der Graaf. See also: Banta, Oortwijn & Van Beekum, *Organization of Health Care Technology Assessment*, pp. 79-92; Boer, *Onderzoek op Maat*, pp. 75-92; Raad voor Gezondheidsonderzoek, *Advies HTA*, pp. 18-21; R. van der Sande, S. W. J. Lamberts & H. G. M. Rooijmans, ‘Kennis op de plank? Het Nuttig Effect van Onderzoeken uit het Programma van het Fonds Ontwikkelingsgeneeskunde’, *Nederlands Tijdschrift voor Geneeskunde* 147 (2003), pp. 2390-3.

'An important subsidising body for patient-related research has existed for 25 years now in the Netherlands, although it has always been connected to policy problems. In all universities and all university medical centres, proposals have been submitted for this programme. This means that a tradition of already 25 years of patient-related research exists in the Netherlands, which is practice-relevant. In all manner of disciplines, there have been people who have participated in this type of research and in many cases – in some fields more so than in others – have witnessed the translation of the results in practice. Well, this is unique in the world!'⁶³

The Utrecht 'Three Stage Rocket'

Looking back, it may be established that, at the end of the 1970s, Rotterdam already had the *first* 'sub-department' of clinical epidemiology in the Netherlands and as of 1986, also had the first extraordinary professor in this discipline, Koos Lubsen. The Leiden medical faculty subsequently acquired the first *full* professor of clinical epidemiology in 1987, in the person of Vandenbroucke, who became the head of a brand new department of clinical epidemiology, which replaced the fully dismantled Institute for Social Medicine (see chapter 4). According to those involved, the first 'real' (academic) *hospital department* of clinical epidemiology of the Netherlands was founded in the Amsterdam AMC in 1990. Thus, Utrecht was not particularly a leader in this field, yet the *largest* department of clinical epidemiology of the Netherlands eventually blossomed there. This did not seem likely for a long time, incidentally, but the situation changed due to three remarkable events.⁶⁴

The first of these three events occurred in 1987. Up until then, doors had remained largely closed for clinical epidemiology in Utrecht. The medical faculty did have a department of General Healthcare and Epidemiology, to which initially Frits de Waard – who had a good reputation as a researcher in the field of breast cancer screening – and subsequently (also) Bertine Collette as professors of epidemiology were affiliated. Yet they had scant contact with the 'clinic', partly because their interest mainly lay with prevention at the level of the 'population.'

This created resentment with three clinical professors in Utrecht, the neurologist Van Gijn, the cardiologist Robles de Medina and the professor of general practice De Melker. They were of the opinion that patient-related research in Utrecht needed to be strengthened. They were moreover convinced that more input from (clinical) epidemiology was an important prerequisite for this. Yet to their displeasure, they found that the coopera-

63. Interview with Bossuyt.

64. Unless specified otherwise, this reconstruction of events in Utrecht is based on the interviews with Algra, Van der Graaf, Van Gijn and Grobbee.

tion with De Waard's department did not take root. This is why, in 1987, they went to the dean of the medical faculty to plead for the appointment of a *clinical* epidemiologist, who was to support clinical research in Utrecht. This request was honoured: in the same year, Yolanda van der Graaf, an epidemiologist who had recently obtained her PhD, landed the post of clinical epidemiologist. She came to work at De Waard's department, though he had not asked for her appointment at all, and she had to be paid from his department's budget.

The three aforementioned professors may be regarded as representatives of the movement for patient-related research. Van Gijn in particular belonged to the most prominent and public representatives of this movement.⁶⁵ According to those in the know, Van Gijn's voice carried a great deal of weight within the University Hospital Utrecht (Dutch abbreviation: AZU). His influence as an advocate for clinical epidemiology in Utrecht is estimated to be very significant by quite a few people.⁶⁶

Van Gijn was always very clear about his source of inspiration. He repeatedly presented himself as a follower of the Danish gastroenterologist Wulff. Not long after his final medical examination in 1980, he came across the Dutch translation of Wulff's famous book *Rational Diagnosis and Treatment* by Lubsen and Querido. This book made a deep and lasting impression on him. Thirty years on, he is still able to vividly talk about this:

'I can point out the chair for you which I sat in when I read it: this was in a hotel on Vlieland [one of the West Frisian Islands or 'Wadden Islands' – TB]. It was as though you had always lived in Rotterdam and then suddenly were standing on the Euromast and thus could see the overall picture. It was a revelation!'

One of the reasons why Wulff's book was so appealing was that it seemed to provide an answer to a rather vague intellectual uneasiness that Van Gijn felt to an increasing extent during his training as a physician: 'I had the idea that I missed something, that something was lacking. I have swallowed a great many easily digestible chunks of knowledge which I can reproduce, but there has got to be something more. It is a science after all, so where are the instruments?' He followed a course in medical statistics at the time, during which he thought: 'this is getting close, but it's not what I actually miss. Shortly afterwards, he discovered Wulff's book and immediately knew: "This is it!"

Wulff's book focused on decision analysis, but it inspired Van Gijn to start organising clinical trials himself. Rational medical practice was only possible when knowledge

65. A good illustration of this is that Van Gijn, together with, among others, Lubsen and Dunning was a member of the NWO committee that was to assess the scientific quality of the applications submitted to the Investigative Medicine Fund. See: Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies 1990*, p. 7.

66. Interviews with Algra, Van der Graaf and Grobbee. See also: Algra, *Hoofdzaken*, pp. 13-14.

for the scientific substantiation of diagnostic and treatment methods was collected as well, he reasoned. His discontent with medical practice was prompted in part because he had the feeling that countless procedures were performed without a (sufficient) scientific foundation. After he had seen 'the light' through reading Wulff's book, it was an obvious step for him to organise his first clinical trial shortly afterwards, which was on a medical intervention for the treatment of a ruptured brain aneurysm.

Van Gijn remembers well how many mistakes he and his co-workers made in the beginning. Even the clinical professors who were involved did not have a clue about how such a research needed to be tackled. Van Gijn very quickly realised they required assistance from outside. All this took place in Rotterdam, where he still worked at the time, but there was no contact with Valkenburg's department of Epidemiology or with Lubsen's sub-department. Instead, Van Gijn sought methodological support via the contacts the Rotterdam departments of neurology and neurosurgery had maintained for several years with researchers from Scotland. Van Gijn learnt from the Scottish epidemiologist, Gordon Murray, and several of his fellow countrymen how randomised trials ought to be set up. Crucial here, according to him, was that 'these Scotsmen' asked him what they actually chose as an outcome event in this first trial. This seemed fairly self-evident to Van Gijn: the question was whether the intervention that was the subject of study ensured that the blood vessel, which had already ruptured once in this condition, would not rupture again. To his great surprise, the Scots said that it was not about this at all but about 'whether the patient can go home again, and how he is doing!' This appeared to be the 'pivotal point' of the study, Van Gijn says:

'What is the eventual result of this trial? That this procedure prevents a great many of these recurrent bleedings, but that this is actually of no use at all, because the patients all get *other* complications! So if we had not listened to those Scots and had counted how often a recurrent bleeding occurred, we would have thought this was a fantastic remedy, but this would have been an incorrect conclusion!

Thus, 'the Scots' had saved Van Gijn from completely missing the point. Ever since this experience, Van Gijn has always been involved in the organisation of trials with great enthusiasm. By his own account, he also became a 'missionary' for the so-called 'pragmatic' set-up of RCTs, as the approach he had been taught by the Scots was called. In another respect too, this first trial was a milestone in his career, as it (eventually) led to a publication in the *New England Journal of Medicine* – the first of many publications by Van Gijn in renowned journals which were to follow.⁶⁷

67. M. Vermeulen et al., 'Antifibrinolytic treatment in subarachnoid hemorrhage', *New England Journal of Medicine* 311 (1984), pp. 432-7. See also PubMed. Van Gijn's PhD student, M. Vermeulen, who was

In view of this prehistory, it is not surprising that Van Gijn, after coming to Utrecht as professor of neurology in 1983, worked hard there for the acceptance of patient-related research, in particular in the form of randomised clinical trials and the methodological input of a (clinical) epidemiologist. He was a fervent supporter of Wulff's approach to medicine, was convinced clinical research was required for better substantiation of medical practice, and had himself experienced how important the methodological input of epidemiologists could be in such research. Furthermore, it was essential, precisely in this period, that this should ultimately result in publications in high impact journals as well.

The latter will undoubtedly have contributed to the dean's decision to honour the plea by Van Gijn, Robles de Medina and De Melker for the appointment of a clinical epidemiologist. It moreover fitted in with the policy of both the university hospital and the medical faculty in Utrecht. Under pressure from the cutbacks in the 1980s, they were 'driven into each other's arms'. The faculty in particular had suffered heavy blows and therefore sought support from the hospital, which was financially much stronger. The cooperation between both institutions was additionally facilitated by the good relationship between Cerfontaine, the director of the AZU, and Kramer, the dean of the medical faculty in Utrecht. They initiated 'double appointments' of professors, who would be employed by the faculty for one or two days and by the hospital for the rest of the week. This way, Kramer was able to achieve a situation where, despite the financial constraints, fine professors could be kept on and talented researchers could be attracted, for the simple reason that the 'rich' hospital bore a large part of the salary costs. This did mean that, for the first time, professors were also employed by the hospital, which, as a result, also gained significant influence regarding the appointment of new professors. As was the case in the AMC, the strategy of increasing interconnectedness of faculty and hospital was perfectly compatible with the increasing interest in patient-related research. This became evident, for example, from a memorandum from the Utrecht medical faculty from 1986, in which the intention to strengthen this type of research was expressed as follows:

the first author of this *New England* paper, became a professor of neurology at the AMC in 1991. In his inaugural lecture he explicitly mentioned the same trial and also vigorously pleaded for *pragmatic* trials. See: M. Vermeulen, *Orlogische Redelijkheid*. Van Crevel (who was assistant professor in Rotterdam until 1981, and professor of neurology at the AMC in Amsterdam between 1981 and 1992 and one of the strongest proponents of the clinical epidemiology and EBM movement there was also involved in this trial and one of the authors of this *New England* paper. In a book devoted to the contributions of the then lately deceased Van Crevel to the field of neurology, both Vermeulen and Van Gijn referred to this trial and the lessons they (including Van Crevel) learned from their Scottish advisors about *pragmatic* trials. Apparently, this was an experience of 'life-changing', 'paradigmatic' significance to three of the most important supporters of clinical epidemiology and EBM in the field of neurology in the Netherlands! See: Hijdra et al., *Vernieuwingen in de Neurologie*, pp. 19-24, 30, 48-9.

'Patient-related research [...] belongs – as in a practical sense, it cannot occur otherwise than *in the interconnectedness of medical faculties and university hospitals* – to one of the essential tasks of the faculty [...]. The creation of conditions for the improvement of this research in the field of financing, programming and assessment is an important task for the faculty and the hospitals [i.e. the AZU, the Wilhelmina Children's Hospital and the Ooglijdersgasthuis (the name of a former eye hospital), the three precursors of the current UMC-Utrecht – TB].'⁶⁸

A more immediate reason for honouring the request of the three professors seems to have been the arrival of the Investigative Medicine Fund. In 1987, it was already known that the Health Insurance Fund intended to adopt the subsidy programme and to raise the budget considerably. Apparently the people involved in Utrecht soon realised that this not only offered unique opportunities to obtain considerable subsidies for patient-related research, but also that clinical departments required the help of a clinical epidemiologist for this. The main task of the clinical epidemiologist appointed, Yolanda Van der Graaf, became to support clinicians who wished to submit a project proposal to the Investigative Medicine Fund.

According to Van der Graaf, she initially barely knew what clinical epidemiology was. She had obtained her PhD in Nijmegen with epidemiological research into cervical cancer screening. In the beginning, she almost daily phoned her old department in Nijmegen or other people with methodological knowledge throughout the Netherlands, asking all manner of questions on setting up patient-related (evaluation) research. She duly learned the profession by doing so. This was also specifically reflected in the honouring of submitted applications for research subsidy in which she had participated.⁶⁹

Because her input thus proved very useful, clinical researchers were increasingly interested in working with Van der Graaf. For this reason, she was no longer able to do the work alone after several years. At the recommendation of Van Gijn, she received assistance in the person of the clinical epidemiologist, Ale Algra – a former student of Lubsen who had already working for a couple of years at Van Gijn's neurology department, being primarily engaged with the organisation of trials there. Algra would remain affiliated to the department of neurology for 50% of the time, and for the other 50% he would work as a clinical epidemiologist alongside Van der Graaf at the (faculty) department of epidemiology.

68. Cited in: Klijn, *Verlangen naar Verbetering*, p. 282. TB's italics. See also: Adviesgroep SGO, *Stimulering*, p. 36.

69. See interviews with Algra, Van der Graaf, and Van Gijn. See for examples of accepted research proposals from Utrecht: Commissie Ontwikkelingsgeneeskunde van de Ziekenfondsraad, *Advies Ontwikkelingsgeneeskunde 1994* (Amstelveen: Ziekenfondsraad, 1993); Idem, *Advies Ontwikkelingsgeneeskunde 1992* (Amstelveen: Ziekenfondsraad 1991); Idem, *Advies 1990*.

Algra's arrival led to the second remarkable event in the history of clinical epidemiology in Utrecht. Algra and Van der Graaf knew each other well. They had met in 1983 during a course by Miettinen and had kept in touch ever since.⁷⁰ When they became close colleagues around 1990, they decide to 'desert' together, as Van der Graaf phrased it. They thought they had not really found their place at the faculty and among the population epidemiologists, and were of the opinion that, as clinical epidemiologists, they should be in the clinic. The University Hospital had just moved to the new building at the Uithof, the new campus of the Utrecht University located outside the city's boundaries, which was still a building site in many respects. Van der Graaf and Algra found a 'portacabin' there which they rather liked, and which appeared to be 'free'. They decided to settle there and placed a sign reading 'clinical epidemiology' on the door. From then on, they would operate as an independent unit *within the AZU*, which was entirely separate from the *faculty department* of De Waard and Collette.

Thus, the first clinical epidemiology unit in Utrecht was actually a 'clandestine' one. This situation could only exist by virtue of the backing Van der Graaf and Algra received from higher up. In the preceding years, Van der Graaf had already noticed that she and her work were greatly appreciated by the Board of Directors of the AZU and in particular by Cerfontaine, its chairman. So it was no surprise to her that the new clinical epidemiology unit was immediately 'adopted' by Cerfontaine, who ensured there was financial support coming directly from the Board of Directors of the AZU.

This was followed by several years upon which Van der Graaf and Algra would look back with great pleasure. They described how much fun they had together and how many visitors they received. They would sit by their portacabin in the sun and 'then these professors swung by and they would sometimes briefly join them and have a chat.' Van der Graaf enjoyed 'being a bit of service in her work'. Clinicians soon knew how to find her with all manner of questions on clinical research and she enjoyed thinking about these kinds of questions. She moreover noticed she influenced 'these physicians' in favour of clinical epidemiology by writing research proposals together, which were subsequently honoured as well.⁷¹ This went quite far at times: 'we would sometimes literally grab the pen from people, as if to say: let us write this down.' Such was the success of this small unit that within several years a secretary and two more clinical epidemiologists could be appointed. There was also space to set up individual research, in addition to the supporting activities.⁷² 'We actually became more and more important', as Van der Graaf experienced.

70. Interviews with Algra and Van der Graaf; Algra, *Hoofdzaken*, p. 14.

71. For example: in the '1994 round', 17 (out of 56) research proposals to the 'Fonds Ontwikkelingsgeneeskunde' (Investigative Medicine Fund) were accepted. Clinical researchers from Utrecht were involved in 7 out of those 17 research projects. See n. 69 above.

72. This was the SMART-study. See on this: http://www.umcutrecht.nl/subsite/Vasculair-Preventie-Programma/Onderzoek/SMART_Study_Group.htm

This prosperous state of affairs generated the necessary tensions with Collette, who had been professor of epidemiology since 1989. This would eventually lead to the third 'event'. Van der Graaf and Algra were 'pushing considerably for clinical epidemiology to become more significant'. This was not welcomed by Collette, who noticed her position coming under increasing pressure. Various clinical researchers, including the professors Van Gijn, Robles de Medina, De Melker and the internist and oncologist Blijham, who had come from Maastricht in 1992, championed the further development of *clinical*-epidemiological support for clinical research. In their view, it was high time that Utrecht would see the advent of a 'fully-fledged' department of clinical epidemiology, as was now the case in several other places in the Netherlands, and they regarded Collette as an obstacle here. This viewpoint was wholeheartedly shared by Cerfontaine, who was quite charmed by the small group of clinical epidemiologists in Utrecht. The situation had eventually become so 'unpleasant' that Collette was requested or decided to go on early retirement. In the spring of 1995 her departure was a fact.

This paved the way for the appointment of a new professor whose teaching and research was to focus on 'clinical epidemiology' rather than on 'general epidemiology'. 1996 saw the appointment of Rick Grobbee, who came over from Rotterdam. In Rotterdam, where he had been extraordinary professor of clinical epidemiology for some years, Grobbee was no longer entirely satisfied for, in his view, attempts to launch the 'clinical branch' of epidemiology there were less than successful. Although the department of epidemiology in Rotterdam was 'incredibly good', it was, according to Grobbee, also very 'remote' and even 'slightly threatening' to the hospital there. One of his motivations for his transfer to Utrecht was that the 'logical connection between the department of epidemiology and the hospital', which he missed in Rotterdam, was handed to him on a silver platter there. He moreover noticed that 'they were very keen and willing in Utrecht and anything was possible there'. Grobbee could bring many people from Rotterdam to Utrecht, where, by his own account, he 'blithely' invested in postdocs and not in PhD students. Already immediately upon his appointment as professor, he was accompanied by an 'escort' of five staff members from the port city and, within several years, approximately ten more researchers would make the same switch. According to Grobbee, this was 'quite an *event*' causing him to be 'less popular for years' in Rotterdam.

Not only did Grobbee bring staff members from Rotterdam, but also the business-like approach to research which had developed there and had, among others, led to a 'whole machinery for PhD research, with good training and education, with a solid infrastructure in which data could be collected and with a considerable scientific production'. In order to be able to launch such a scientific 'business' in Utrecht as well, his first priority was to 'put affairs in order internally'. Already before his arrival, Grobbee had negotiated that the old department of General Healthcare and Epidemiology of the medical faculty in Utrecht, where he ended up as successor to Collette, and the Clinical Epidemiology unit of the AZU would merge. This led to the foundation of the Julius Centre for Patient-

Related Research in December 1996. With the foundation of this new centre and with this new name, Grobbee expressed that his arrival brought a ‘new start’, where he directly ‘outlined the way’. According to him, this was ‘very confrontational’ to some people from the ‘old public health group’ – which, in Grobbee’s view, ‘amounted to nothing: no scientific production, very much inward-looking and so on’. The result was that some staff members from this group left (whether or not voluntarily). The invasion from Rotterdam was initially indeed overwhelming to the people from the old clinical-epidemiology unit, but soon both sides noticed that they clicked well together.

In 15 years’ time, the Julius Centre, which employed approximately 20 people in the beginning, developed into a division of the UMC Utrecht, with approximately 500 staff – and is now operating under the name of Julius Centre for Health Sciences and Primary Care. Very important was the merger in 1999 with the Department of General Practice. One of the main arguments for this merger was the intricate link it established between epidemiology and a clinical discipline. According to Grobbee, this was the key to the blossoming of patient-related research in the field of general practice in Utrecht like nowhere else in the Netherlands and which is internationally recognised. The *glossy* that was published in 2012 on the occasion of the fifteenth anniversary amply praised the continuously increasing scientific production and the high ‘quotation score’ of the researchers of the Julius Centre, the growing ‘maturity’ of training and education within the division and the blossoming of the autonomous trial company Julius Clinical, which was founded in 2008. The development experienced by the Julius Centre in a relatively short time – in which clinical epidemiology and clinical epidemiologists always occupied a prominent place – may be called remarkable.⁷³

In the *glossy*, Grobbee ascribes this success to four factors. Firstly, he mentions the ‘very good’ staff he was able to appoint and preserve, partly because he was able to bring experienced researchers from Rotterdam. He furthermore points to the central organisation and business strategy he implemented from the very beginning. However, he would never have been able to bring his ‘escort’, set up his organisation and carry out his strategy if he had not consistently received a great deal of support for this within the AZU and subsequently the UMC Utrecht, in particular from the Board of Directors. This is the third factor he mentions. He finally argues that a self-reinforcing process of sorts was set in motion: as the Julius Centre could do more research projects, the ‘output’ became bigger, as a result of which the ‘track record’ improved, which made the Julius Centre more competitive, which made it easier to attract more projects, and so on.

It could be argued that this ‘self-reinforcing process’ was set in motion a long time before Grobbee’s arrival in Utrecht. The previous section discussed the enthusiasm of

73. Interview with Grobbee; *Julius 15 jaar* (Utrecht: Julius Centrum, 2012). Retrieved from: <http://portal.juliuscentrum.nl/nl-nl/organization.aspx>, d.d. 28 January 2015.

clinical researchers such as Van Gijn, about their experience that high-impact publications were possible precisely at a time in which, due to changes in the climate and the financing of academic medical research, this was more important than ever, and in which there was a growing interest in patient-related research and clinical epidemiology. In addition, issues were addressed such as the closer cooperation between and eventual merging of faculty and university hospital, the personal views and preferences of directors and the successful acquisition of subsidies from the Investigative Medicine Fund by the 'clandestine' unit of Van der Graaf and Algra. The combination of all these elements from the 'prehistory' of the Julius Centre caused a situation in the course of the 1980s and 1990s in which the way was paved for Grobbee, and clinical epidemiology in Utrecht could rise to great heights.⁷⁴

'McMaastricht'⁷⁵

Nowhere in the Netherlands is the connection between academic medicine and the medical school of McMaster University as strong as in Maastricht. Immediately upon the foundation of the eighth and youngest medical faculty of the Netherlands in the capital city of the province of Limburg, in 1974, an educational system was introduced which was entirely based on the famous 'problem-based learning' as applied in Hamilton. As a result, the nickname 'McMaastricht' soon became popular.⁷⁶

This did not mean, however, that the youngest faculty in the Netherlands also directly copied Hamilton's clinical epidemiology. A department of epidemiology did come into being in 1980, but the emphasis was more on public health here and on matters such as policy and management than on the clinic. In this and in several other respects, there were great similarities between this department and the department of epidemiology in Rotterdam. In both places, epidemiology was not placed with social medicine, as was usual elsewhere, but it enjoyed an independent status. Furthermore, the epidemiologists in Maastricht were engaged in the new educational programme, Social Health Science (subsequently renamed General Health Sciences), which was very similar to the General

74. See also Cerfontaine statements about the reasons why the Julius Centre was founded, in: *Julius 15 jaar*, p. 24.

75. The description of the emergence and development of clinical epidemiology in Maastricht is, among others, based on the interviews with Assendelft and Knottnerus. Where literature references are lacking, quotes and descriptions are derived from these interviews.

76. Among others: interview with Van Gijn. The educational innovation that was applied in Maastricht was an important part of the self-legitimation and establishment strategy of the youngest medical faculty in the Netherlands (of which the foundation in respect of the number of required training places in the Netherlands, other than at the time of the foundation of the medical faculty in Rotterdam, was not required. See on all this: Knegtmans, *Medische Faculteit Maastricht*, pp. 52-64, 85-90.

Healthcare training programme that launched approximately at the same time in Rotterdam, and in which Valkenburg's department was closely involved. Partly due to these research programmes, Rotterdam and Maastricht had the largest and strongest epidemiology groups in the Netherlands, as was also regularly noted in reports from authorities such as the RAWB and KNAW.⁷⁷ The term 'largest' should be understood in a relative sense here, for that matter. Indeed, those involved from both places emphasise that it concerned small departments where something beautiful blossomed from the great synergy between the staff members. André Knottnerus who, as an Amsterdam GP, left for Maastricht in 1982 'in order to really master epidemiology', says about this: 'We had a hotbed of young, enthusiastic people in Maastricht in the 1980s.'

Knottnerus obtained his PhD in Maastricht under the supervision of the professor of epidemiology, Sturmans, who had come over from Nijmegen in 1982 and Paul Knipschild, who also became professor of epidemiology in 1985. Several people describe them as men who inspired an enthusiastic group of young epidemiologists including, among others, Lex Bouter, Jos Kleijnen and a little later Pim Assendelft and Riekje de Vet. These people subsequently spread across the Netherlands, where they would all acquire important positions within clinical epidemiology and the EBM movement. Bouter became professor of epidemiology at VU University in Amsterdam in 1992, where he went on to be the first manager of the Institute for Health and Care Research (Dutch term: EMGO-instituut) two years later.⁷⁸ The EMGO developed into a research institute somewhat equivalent to the Julius Centre in Utrecht.⁷⁹ Between 2006 and 2013, Bouter was also rector and a member of the University Board of VU University. Kleinen left for the AMC in 1994, ending up in the department for Clinical Epidemiology and Biostatistics to become the first manager of the Dutch Cochrane Centre (DCC) there.⁸⁰ Several years later, he was succeeded by (among others) Assendelft there, who left in 2002 to be head of guideline development of the Dutch College of General Practitioners (Dutch abbreviation: NHG) and in 2004 became professor of general practice in Leiden and as of 2013 in Nijmegen. De Vet, finally, left Maastricht in 1999 to join the Institute for Health and Care Research of VU University, where she was also appointed professor of clinimetrics three years later – a 'discipline' that may be interpreted as 'Feinsteinian' clinical epidemiology.⁸¹

77. Koninklijke Nederlandse Akademie van Wetenschappen, *Advies voor het Deelplan Onderzoek*, p. 73; Raad van Advies voor het Wetenschapsbeleid, *Advies inzake de Prioriteiten*.

78. By the way, Miettinen was (shortly) director of EMGO in the late 1980s and Bart Dekker, the former medical director of the Dutch Heart Foundation, was affiliated with EMGO as advisor. See Miettinen, *Theory of medicine*. This was also mentioned by Dekker in the interview by TB.

79. See: www.emgo.nl

80. J. Kleijnen et al., 'De Cochrane Collaboration: Systematische Overzichten van Kennis uit Gerandomiseerd Onderzoek', *Nederlands Tijdschrift voor Geneeskunde* 139 (1995), pp. 1478-82; see also the website of the Dutch Cochrane Centre: dcc.cochrane.org.

81. One of Feinstein's most influential works was the book *Clinimetrics* from 1982.

This 'spreading out' of persons was not unique to Maastricht. It was previously discussed how clinical epidemiology in Leiden, Amsterdam (AMC) and Utrecht developed due to import from (in particular) Rotterdam. But from these places too, people would move elsewhere. Knottnerus emphasises that this 'circulation' of people is a very important phenomenon in the Netherlands. In his view, this was a major factor in the emergence and spreading of clinical epidemiology – and also of other 'frameworks' in this country:

'There is a fairly good and intense mobility between centres. So this also means that developments occurring at centre A can quite easily be passed on to centre B – and this is two-way traffic. So we have competition, yes, but there is enormous interaction as well which, in turn, produces collaborations.'

This exchange of ideas and people also extended abroad, among others to the department of clinical epidemiology of McMaster. In the early 1980s, the Maastricht rheumatologist Sjef van der Linden had spent a year there and upon his return he was as enthusiastic as the Amsterdammer Büller shortly before. Just as Büller had done in the AMC, Van der Linden immediately started organising courses in clinical epidemiology in Maastricht which had been copied one-on-one from the courses of McMaster. Since then, regular contacts have remained between the Canadian clinical epidemiologists and Maastricht, where Sackett sometimes visited as well.

As a result, the staff members of the department of epidemiology, who initially mainly focused on the 'population' and health services research, also started becoming interested in *clinical* epidemiology already fairly early in the 1980s. Knottnerus's interest in this, for example, was definitely awakened when he read the articles translated by Büller on 'How to read a clinical journal', which were an 'eye-opener' to him. Furthermore, the inaugural speech held by Knipschild in 1985 as professor of ('ordinary') epidemiology, for example, largely dealt with the clinical variant, for which he predicted 'a great future' and of which he announced it would be the focus of his own research programme.⁸² In the same year, Sturmans, who had always particularly emphasised the role of (population) epidemiology as a signpost for healthcare policy at the macro-level, explicitly pleaded for *clinical epidemiology* in the journal *Medisch Contact*. In an article entitled 'Is Healthcare Manageable?', he argued that 'evaluation research in the context of decision analysis, resulting in the establishment of protocols' was an important tool to better contain the costs of healthcare. The conclusion of the article was that there was a 'need for specialists who will

82. Knipschild, *Epidemiologie in de Contraceptie*, see in particular: pp. 11, 18.

apply the evaluation procedures outlined above within their discipline; a need for *clinical epidemiologists* in other words'.⁸³

As was evident from Sturmans's plea, the interest of the Maastricht epidemiologists extended way beyond clinical epidemiology in accordance with the McMaster model alone. Knottnerus sums up a whole range of foreign influences and contacts which were also there in Maastricht. He mentions the names of Feinstein, Miettinen, Guyatt, Sackett and Wulff, but, for example, also those of founders of clinical decision analysis, such as Finenberg, Weinstein and Elstein and the 'more classic' epidemiologists Kleinbaum and Cochrane, several of whom also visited Maastricht. According to Knottnerus, the people in Maastricht were very open to all the new frameworks which emerged in medicine between the late 1960s and late 1980s, including not only decision analysis and (clinical) epidemiology, but also clinimetrics, technology assessment, and (a little later), especially in the department of general practice, quality of care research.⁸⁴ In his view, this was not unique to Maastricht (although 'Maastricht' was at the forefront in this respect), but a typically Dutch phenomenon:

'I also think that these foreign top-ranking scientists I mentioned enjoyed coming to the Netherlands. We were a rather popular country, in the sense that we are open-minded, internationally-oriented; the people speak good English, there was no language barrier. In this early period, we did not yet play an important role in the competition between the two great Anglo-Saxon research populations – England and the United States [...]. And of course we were a country where the North-American top-ranking scientists could achieve quite a bit in terms of sowing things within Europe. Naturally, we were also focused on the events across the pond, much more so than Germany and France – let alone Italy, Spain or countries even farther afield in Southern and Eastern Europe'.⁸⁵

So the epidemiologists in Maastricht were preoccupied with all manner of matters: clinical epidemiology, decision analysis, technology assessment as well as policy and management in healthcare at the meso-level and macro-level. Also interesting is that, already fairly early in the 1980s, they commenced work on matters that would now be referred to as systematic reviews, meta-analysis and guideline development and are generally associated with evidence-based medicine – which, however, was not introduced until the 1990s.⁸⁶

83. Sturmans, 'Is de Gezondheidszorg Beheersbaar?' Original italics. See also the editorial in the same issue of *Medisch Contact*: Van Es, 'Rekenaars en Protocollen'.

84. Interview with Knottnerus; These various 'influences' from abroad are also apparent in: Knottnerus, *Dialectiek van het Onderzoek*.

85. Interview with Knottnerus.

86. See for an example of these 'systematic reviews' from Maastricht: B. W. Koes et al., 'Effectiviteit van Manuele Technieken bij Nekklachten', *Medisch Contact* 44: 37 (1989), pp. 1181-4. See for an example of guideline development: Knottnerus, *Dialectiek van het Onderzoek*, pp. 11-12.

The breadth of all these activities and rather eclectic handling of all these various frameworks also featured in an article Knottnerus wrote in *Medisch Contact* in 1987 in which he tried to create some order. He started by stating: 'In the past twenty years, various approaches were developed which aim to support and rationalise medical practice.' He subsequently grouped these 'various approaches' into four categories: descriptive research, consensus building, decision analysis and clinical epidemiological research. By this, he indicated (among others) that clinical epidemiology mainly revolved around the production of *new* scientific data – while the other frameworks were concerned with the collection or application of already existing knowledge.⁸⁷

Virtually simultaneously with Knottnerus and in a very similar way, Vandenbroucke also attempted to create clarity. Both in his inaugural speech as professor of clinical epidemiology from 1987 and in an article that appeared in *Nederlands Tijdschrift voor Geneeskunde* a year later, he sharply demarcated his own discipline in respect of related approaches by strongly emphasising the *scientific focus* as a distinguishing characteristic of clinical epidemiology.⁸⁸ In his oration he said about this:

'This scientific focus clearly differs from the one in decision analysis and the one in the cost-benefit analysis, often jointly referred to under the heading 'technology assessment', and it also differs from the one in quality assessment or in 'medical audit'. Decision analysis aims to outline decision-making rules for the future on the basis of the best scientific knowledge. Quality assessment intends to verify if the existing practice is in line with the most commonly known scientific knowledge. *Neither leads to numerical, scientific facts as aimed for by Clinical Epidemiology.*⁸⁹

A year later, Hofman, in his inaugural speech as professor of (general) epidemiology in Rotterdam, similarly tried to clarify the 'unique character' of epidemiology, emphasising, among others, that 'his' discipline focused on disease and not immediately or primarily on healthcare. He subsequently stated:

'However important decision analysis, health services research and technology assessment may be, it is not epidemiology. Epidemiology may provide data for decision analysis – whether it concerns decisions for the individual patient or for the entire population – but the object of epidemiology is disease and not healthcare.'⁹⁰

87. J. Knottnerus, 'Bouwstenen voor een Rationele Medische Besluitvorming', *Medisch Contact* 42: 16 (1987), pp. 501-4.

88. J. P. Vandenbroucke, 'Kwantitatieve Nieuwlichterij in de Geneeskunde: een Poging tot Ordening', *Nederlands Tijdschrift voor Geneeskunde* 132 (1988), pp. 337-40.

89. Vandenbroucke, *Klinische Epidemiologie en de Geest der Hygiënisten*, p. 20. TB's italics.

90. Hofman's inaugural lecture is included in: A. Hofman, *Veertig Jaar* and in: Valkenburg & Hofman, *Een Kwart Eeuw*. See p. 130 and p. 32, respectively.

It seems anything but a coincidence that these three researchers felt compelled to highlight the importance of these characteristics of (clinical) epidemiology – a *scientific* focus on generating new knowledge pertaining to *disease*. There are good arguments for the thesis that, due to these two characteristics, clinical epidemiology was able to conquer a place within Dutch academic medicine, while decision analysis, medical technology assessment and health services research did not succeed in this, or only to a far lesser extent. At a time of increasing competition for and scarcity of available research funds, the expertise of clinical epidemiologists in the field of research and research methodology was a ‘unique selling point’. Because clinical epidemiologists were additionally primarily focused on disease, they were the first and foremost attractive partners for academic clinical departments in setting up and carrying out patient-related research.

In view of this, the previous section discussed that clinical departments and professors in Amsterdam and Utrecht developed an interest in clinical epidemiology, for they recognised it as an instrument to improve the quality of this type of research in their departments when the circumstances required this more than ever. In Maastricht – where, just as at McMaster, there was a strong focus on primary care – something similar occurred with general practice. Knottnerus was personally involved in this.

General practice had been an academic discipline in the Netherlands for a relatively short time – it was not until the end of the 1960s that the first chairs and university institutes were founded there. As a result, a tradition of research was lacking. It was for this reason that in the 1970s, the Dutch institutes for general practice sought the help of social scientists who were far more skilled in methodology, and who had the wind in their sails in this decade as well. This led to a great deal of attention for issues such as the physician-patient relationship, iatrogenesis and medicalisation, which were then high on the agenda from a social perspective. While, as Knottnerus stresses, these were major and relevant issues, the highly social-scientific orientation of academic general medicine soon came under attack. Critics argued that there should be much more attention for issues focusing on medical content. In addition, general practice, as well as social medicine for that matter, was struggling with a reputation for performing very poorly in the field of research. When, in the 1980s, specific attention was paid to the quality of medical research in the Netherlands in various advisory reports such as that of the RAWB from 1983, as well as in the execution of austerity measures, general practice did not come off lightly. The department of general practice in Maastricht was hit hard as well. This was the reason for seeking help from Knottnerus, who was given the task of rebuilding research there from the ground up.⁹¹

91. See the section about the ‘reorientation of research policy’ in Maastricht in the period 1983-1984: Kneegtmans, *Medische Faculteit Maastricht*, pp. 204-9. See also: Knottnerus, *Dialectiek van het Onderzoek*, pp. 4-6.

Around 1985, Knottnerus thus made the switch to the department of general practice. In his old workplace at the department of epidemiology he had become used to a culture in which the publication of research was considered to be very important. This was regarded as the principal way for researchers to fulfil their duty of being accountable to society, engaging in international scientific debate and adding to the general 'body of knowledge'. Only later, according to Knottnerus, did the consideration that publishing was good for careers come into play. In general practice, however, the opinion on publishing differed entirely:

'There was a culture of: "Well, all this writing down! Why the need to put your name under a piece? The research has been carried out, hasn't it? We already know the results now, don't we? This publishing business only serves to get yourself in the picture". So the image people had of publishing was very negative and international publishing was not even considered at all, for the Netherlands was specific; our country had different problems to other countries.'

Knottnerus set up a completely new research programme, which was entirely based on clinical epidemiology and was thus a departure from the previously existing social-scientific orientation within general practice. Needless to say, this did create some resistance, but not too much. Not for nothing had Knottnerus been asked to come and help out in what was experienced as an emergency. His approach made an impact in a remarkably short time span. Knottnerus remembers that the publication culture within the department of general medicine 'was entirely reversed within two to three years'.

This success resulted in Knottnerus's appointment of professor of general practice in Maastricht in 1988 – yet he would still remain partly affiliated to the (clinical) epidemiology department there. He also made critical comments in his inaugural lecture on the increasing practice of exclusively measuring the scientific quality of departments by the 'international hit parade' of numbers of publications and impact factors.⁹² Yet this did not stop him from continuing on the chosen course. Shortly after his appointment as professor, he founded a research school, the Netherlands School of Primary Care Research, 'for I felt we had to join this momentum'. Young researchers were trained within this research school and, in Grobbee's terminology, a 'machinery for promotional research' got off the ground. Excellent scores were achieved here for all the usual indicators, such as publications, quotation indexes and research funds obtained.⁹³

Vandenbroucke and several (emeritus) professors of general medicine argue that academic general practice in the Netherlands, which was 'effectively moribund' in the 1980s,

92. Knottnerus, *Dialectiek van het Onderzoek*, p. 24-5.

93. Interview with Knottnerus. See also PubMed and n. 94. below.

was saved from an imminent demise and flourished internationally thanks to Knottnerus and to clinical epidemiology.⁹⁴ It resulted in a great reputation for Knottnerus, not only within general practice, but also within clinical epidemiology. This undoubtedly contributed to his appointment as co-editor of the *Journal of Clinical Epidemiology* in 1998 at the request of Feinstein – as successor to Vandenbroucke.

Conclusion

The honourable positions of Vandenbroucke and Knottnerus as co-editors of the *Journal of Clinical Epidemiology* are illustrative of the rather special position of Dutch clinical epidemiology. While it should not be forgotten that it concerns a rather minor discipline within the domain of biomedical sciences which, as far as status is concerned, has to compete with countless other disciplines, clinical epidemiology in the Netherlands has gained a relatively strong position within academic medicine in comparison with other countries.

The explanation for this should not be sought in one or several causes, but in a combination of many factors at all manner of levels. On the personal level, the capacities of leading researchers, the enthusiasm and the missionary zeal of advocates, good and sometimes accidental contacts between individuals, and the sometimes non-conformist policy choices by directors such as Urbanus and Cerfontaine played an important role. On the local level in addition, as is evident from the foregoing ‘cases’, all manner of specific circumstances in faculties and university hospitals influenced the way in which the introduction of clinical epidemiology unfolded in various places.

With respect to the national level, one can point, among others, to the movement for patient-related research, to the sharp budget cuts the universities faced in the 1980s and which led to a major change in medical research, to the role of the Investigative Medicine Fund and to the relative equality, short distances and exchange of persons and ideas between the various academic medical centres. It is striking here to see how the same names reappear in various places and in various roles every time. The past chapters paid a great deal of attention to, among others, Querido, not because he was so much more important than others, but because he was very suitable as an example of this phenomenon of a relatively small world in which everyone knew each other well, there were many mutual contacts and in which, invariably in several capacities, people were involved in important developments.

94. Interviews with Assendelft, Thomas and Vandenbroucke; in these interviews, it was a.o. emphasized that the shift from a social-scientific orientation to clinical research/clinical epidemiology orientation, in which Knottnerus took the lead, was soon followed by other academic departments of general practice in The Netherlands, with similar consequences with regard to the quantity and quality of research output. See also on this: C. Spreeuwenberg, ‘Patiëntgebonden Onderzoek in de Huisartspraktijk’, *Medisch Contact* 47: 9 (1992), p. 259; Idem., ‘Universitaire Huisartsgeneeskunde 25 jaar’, *Medisch Contact* 47: 37 (1992), p. 1051. Interviews with Assendelft, Thomas and Vandenbroucke.

At the international level, the changes in the university research climate in the Netherlands cannot be viewed separately from the worldwide transition from 'little science' to 'big science'.⁹⁵ Moreover, specifically with regard to the rise of patient related research and clinical epidemiology in this country, the impact of developments, ideas and people from abroad was considerable. Here, figures such as Miettinen, Wulff and Sackett were almost religious-style personal sources of inspiration to some Dutch advocates of clinical epidemiology and evidence-based medicine – which is also slightly ironic in light of the anti-authoritarian profile the EBM movement has always propagated. As Querido would have put it, these international figures provided, from within, the 'discipline of medicine's' 'own methodology'.⁹⁶ Or, as Vandenbroucke has argued, by stressing the primacy of the clinic, people like Feinstein and Sackett appeared to offer Dutch clinicians 'a new distinctiveness' and the opportunity to 'become leaders of healthcare'.⁹⁷

This summary of factors may undoubtedly be supplemented with countless issues that have not even been addressed yet in this chapter. Bossuyt mentions the weakness of biostatistics in the Netherlands, for example. According to him, this paved the way for clinical epidemiologists to act as the main supporters of patient-related research – as biostatisticians did in several other countries.

With the 'serving' role of clinical epidemiology that Bossuyt points out here, the main recurrent theme in this chapter has been mentioned. It has been repeatedly stressed how successful this role was, measured by matters such as publications and the honouring of subsidy applications. The great development experienced by patient-related research in the Netherlands as of the latter half of the 1980s, partly due to the 'input' of clinical epidemiology, therefore did not go unnoticed in the Netherlands and abroad. In 1991, for example, the Amsterdam internist, Wieling, wrote in *Nederlands Tijdschrift voor Geneeskunde* that the incentive measures for the benefit of clinical research seemed to make an impact:

'Research from the Netherlands contributes substantially to major medical journals: in the period 1989-1990 I counted 24 original articles from the Netherlands in *The Lancet* and 16 in *The New England Journal of Medicine*; in the period 1979-1980 these numbers were 16 and 3. 10 out of 16 articles deal with typically clinical epidemiological research in my opinion.'⁹⁸

95. De Solla Price, *Little Science, Big Science*; Galison & Hevly, *Big Science*; Heilbron, Van Bottenburg & Geesink, *Wetenschappelijk Onderzoek*; Mooij, *Polsslag*, pp. 440-2; Miedema, *Science 3.0*; Ravetz, *Scientific Knowledge*.

96. See chapter 5.

97. See chapter 5.

98. Wieling, 'Spectrum', pp. 643-5.

In 1996, a ‘country profile’ of the Netherlands appeared in *The Lancet*, consisting of seven articles. The reason for this was described as follows: ‘The Dutch have taken a hard look at medical research and transformed it’. Later on, this was further adapted to: ‘there was a big swing towards clinical research.’⁹⁹ Many of the ‘usual suspects’ from the Netherlands contributed to this profile, for that matter, including Vandenbroucke, Van Gijn, Knottnerus and Visser, the former member of the SGO advisory group.

In the *Lancet* articles, in the paper by Wieling and in countless other sources,¹⁰⁰ the image repeatedly emerges of how the climate of patient-related research in the Netherlands experienced an about-turn in a short period of time. Departments which, up to the 1980s, were often barely interested in research, were transformed into research and publishing machines. According to those in the know, this was not so much the result of focused government policy, but first and foremost a side effect of the harsh austerity measures taken by the Minister of Education & Science. Various interviewees argue that the government only made one – admittedly very important – positive contribution to clinical research in the Netherlands in the form of the Investigative Medicine Fund.

There is a broad consensus on the crucial role clinical epidemiology played in the blossoming of clinical research in the Netherlands. Wieling notes about this in 1991:

‘In the past 10 years, the focus in patient-related research has shifted to clinical epidemiology to such an extent that, in my opinion, patient-related research is often equated with it, and wrongly so in my view.’¹⁰¹

This raises the question of what exactly is the difference between clinical epidemiology and clinical research, but there are many different opinions about this. Some people call themselves clinical epidemiologists *because* they conduct clinical research; others regard clinical epidemiology primarily as a methodological discipline, which is concerned with methodological research – which may eventually benefit patient-related research. There are also significant differences in the ‘kind’ of clinical epidemiological research that is performed in different centres in the Netherlands. Diagnostic research is carried out in one place, for example, and aetiological research in another, while in other places, in turn, people are mainly concerned with prognostic or intervention research. Some departments exclusively focus on the clinic, and others are also explicitly involved in primary care or public health.¹⁰²

99. ‘The Netherlands’, *Lancet* 347 (1996), pp. 1229-39.

100. See a.o.: Adviesgroep SGO, *Stimulering*, pp. 12-13, 40; Schuurman, ‘Medisch-Wetenschappelijk Onderzoek’; Verhoef, ‘Financiering’; Verhoef & Kramer, ‘Is het Einde?’

101. Wieling, ‘Spectrum’, p. 644.

102. These differences were (a.o.) discussed in the interviews (by TB) with Algra, Bossuyt, Van der Graaf, Grobbee and Vandenbroucke.

With a view to the introduction of evidence-based medicine in the Netherlands, however, these 'internal' differences are a great deal less interesting than the question of what distinguishes clinical epidemiology from the other frameworks that emerged in the 1970s and 1980s, such as medical audit, peer review, clinical decision analysis, protocol medicine, technology assessment and health services research. All these approaches and concepts have, to a greater or lesser extent, enjoyed their fair share of attention in the Netherlands, but none of them have acquired an academic position that is even remotely comparable to that of clinical epidemiology. There may be all sorts of reasons for this, but one seems to stand out above the rest. People such as Bossuyt, Vandenbroucke and Knottnerus have repeatedly argued that of all these frameworks, *only* clinical epidemiology is primarily a *science*, and, as a result, is the only framework capable of properly contributing to the production of new knowledge and the improvement of research methodologies. Not only is this an adequate analysis, but they needed to emphasise this as they tried to manifest themselves as clinical epidemiologists at a time in which, more than ever, scientific performance was the *condition sine qua non* for a successful entry into the 'academy'.

Thus, the key to the success of clinical epidemiology in the Netherlands seems to have primarily been: performing in the field of (the assistance of) *scientific (patient-related) research* in the context of scarcity and increasing competition in science. This begs the question of what consequences this had for the introduction and development of evidence-based medicine in the Netherlands. EBM is concerned with the practical *application* of scientific knowledge in training and education, in practice and in policy. At the same time, EBM originated from clinical epidemiology and, in terms of organisation, is often placed with clinical epidemiology. In the AMC, for example, the programme for the development of clinical guidelines, as well as the Dutch Cochrane Centre (DCC), were accommodated with the department of Clinical Epidemiology and Biostatistics. In 2011, the then manager of the DCC, Rob Scholten, was appointed professor with the teaching and research remit 'clinical epidemiology, in particular evidence-based medicine'.¹⁰³

Yet clinical epidemiologists are above all scientists and, as a result, their interests, concerns and objectives differ from those of practitioners or policymakers. They acquired their academic position by 'scoring' in the form of publications and research funds obtained and need to continue to do so in order to preserve or develop this position. The fact that evidence-based medicine developed from, and is often embedded in, clinical epidemiology therefore does not seem to make bridging the gap between science and practice – which is often identified as one of the main objectives of EBM – any easier. That clinical epidemiology is an almost exclusively *academic* discipline, additionally raises questions

103. See Scholten's inaugural lecture: R. J. P. M. Scholten, *Hoe Sterk is het Eenzame Bewijs?* (Amsterdam: AMC, 2011).

about the way in which EBM relates to another gap in medicine that is often mentioned: that between university centres and ‘periphery’.

In order to obtain more insight into these and other issues, the next, third and last part of this book will no longer focus on science – the *production* of evidence – but on the *application* of scientific evidence in practice and policy, at the micro-level and macro-level.



Part III.

**EBM in the Netherlands:
the Rise (and Fall?) of a
Mechanism of Control**

Introduction to Part III:

‘Medical practice is at a ‘crossroads.’ It is up to the profession: it either has to put its affairs in order now, or it has to tolerate that the government, the insurers or hospitals take over the initiative.’¹

In the 1991 report entitled ‘Medical Practice at a Crossroads’, the Standing Committee on Medicine of the Health Council sounded the alarm. With the statement above regarding the ‘crossroads’ at which medical practice found itself, the message was propagated that something was thoroughly wrong in medicine, and that something had to change urgently. The committee pleaded for a radical change of course within medicine, which not only involved a reorganization of professional activity, but also a change of attitude. This was worked out in recommendations such as: ‘accountability for medical practice on the basis of systematic evaluation should become part of the routine of the physician’, ‘it is the task of the profession to formulate protocols on the basis of effectiveness studies’, ‘when introducing new procedures, proven effectiveness can be the only criterion’, and ‘the clinical-epidemiological way of thinking should be part of medical training from the very start.’² Because of the content of ‘Medical Practice at a Crossroads’, and the authority the Health Council enjoys in the Netherlands, this report is often regarded as the starting point of evidence-based medicine in the Netherlands.³

Freely translated, the Health Council argued that medicine was in a crisis, and that evidence-based medicine offered a possible way out. Interestingly, the authors of ‘Medical Practice at a Crossroads’ also gave a historical explanation for the precarious situation in which medicine had ended up. Around the middle of the twentieth century, physicians were still held in high regard, enjoyed a high income, were considered authorities, and could work in isolation without any hindrance.⁴ This situation had changed completely within several decades, as was stated in the report:

‘The growth of medical possibilities and greater patient assertiveness present physicians with new choices all the time. They are expected to make efficient decisions, in that they are expected to treat as many patients as possible, to the best of their abilities, within a limited budget, in a given period of time. Craftsmanship alone will not suffice; they are expected to cooperate and confer with colleagues, present themselves in a gaugeable way,

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1. Gezondheidsraad, *Medisch Handelen op een Tweesprong* (Den Haag, [1991]), both on p. 12 and p. 51.
 2. *Ibid*, pp. 13-14, 52-5.
 3. See a.o.: Bal, Bijker & Hendriks, *Paradox*, pp. 100-1, 203-5, 287-9; Bossuyt & Offringa, ‘Wortels van Evidence Based Medicine’, pp. 43-5. This report was also discussed in this sense in the interviews with Borst-Eilers, Bossuyt, Van Gijn, Knottnerus and Rigter.
 4. Gezondheidsraad, *Medisch Handelen op een Tweesprong*, pp. 9, 27-8.

have an eye for quality, and, not least, treat patients and members of family in a pleasant and forbearing way. The modern physician should be prepared to continuously account for their actions: to the patient, to the insurer and to hospital management.⁵

This sketch of the changes in the ‘image of the physician’ between approximately 1950 and 1990 and the subsequent call for a reorganization of medical professional activity fit in remarkably well with the ideas of Theodore Porter – as discussed in the general introduction – on a shift from disciplinary to mechanical objectivity, or from trust in the expertise and intersubjective knowledge of ‘experts’ to trust in figures and impersonal, transparent procedures.⁶ ‘Medical practice at a crossroads’ described how the medical professional came under increasing pressure in the latter half of the twentieth century – precisely, or so it seems, as the result of processes of democratisation and bureaucratisation, as emphasised by Porter. The subsequent recommendations by the Health Council can be regarded as a shift from disciplinary to mechanical objectivity. The authors of the report distanced themselves from a ‘traditional’, individual way of working, where every physician trusted their own clinical judgement and pathophysiological reasoning. Instead, they pleaded for a more quantitative foundation of medical practice, in the form of ‘proven effectiveness’ and the ‘clinical-epidemiological mind set’. In addition, they advocated the application of protocols and guidelines in medicine to meet the social demand for transparency and accountability. To a considerable extent, this is in line with Porter’s argument that representatives of scientific disciplines often tried to compensate for the lack in trust in their (personal) expertise by showing that their statements are based on (impersonal) procedures and numbers.

In this third part of this book, the link between EBM and Porter’s theoretical insights with respect to the shift from disciplinary to mechanical objectivity will be critically reviewed. Where the previous part mainly concerned the developments in medical research, in this part, the significance of EBM for medical practice and medicine as a profession will be scrutinized. The Porter thesis and the hypothesis derived from it that EBM was embraced by many stakeholders as a mechanism of control – as an instrument to get a grip on the internal and external challenges with which medicine was faced in the late twentieth century – will be assessed with the help of empirical historical data. The main historical source that will be used here is the weekly journal *Medisch Contact*, the official publication of the KNMG (Royal Dutch Medical Association) that was characterised in the general introduction as the ‘barometer of the medical profession’ in the Netherlands.

This third part consists of three chapters. In chapter 7, first of all, the debates within and outside the medical profession in the 1970s and 1980s, so the ones *preceding* the in-

5. Ibid., pp. 9-10.

6. Porter, *Trust in Numbers*, in particular pp. vii-xii, 3-8.

roduction of evidence-based medicine in the Netherlands, will be mapped out. The ways in which medicine and healthcare were under pressure in these decades, and how the medical profession reacted to that, will be discussed. A few important points for consideration will be provided when it comes to the Porter thesis, but nevertheless, the view that EBM emerged in the Netherlands in a period when there was a need for a mechanism of control, both with the profession and with 'third parties', remains essentially unchanged.

In chapter 8 the rise of EBM in the Netherlands in the 1990s and early 2000s will be analysed. The rather remarkable 'success' of EBM in the Netherlands will be explained by showing the linkages between events and factors on the macro and the micro level. In particular, the Dutch policies on 'rational rationing' of health care will be related to the rise of evidence-based clinical guidelines in The Netherlands. In this context, the role and impact of the report 'Medical Practice at a Crossroads' by the Dutch Health Council and the role of Minister of Health, Els Borst-Eilers, will be discussed in more detail.

In Chapter 9, a tentatively attempt will be made to provide insight into the significance and impact of EBM in the Netherlands. What has become of the policies of Borst-Eilers and the ambitions of the Dutch guideline movement? In answering this question, three 'detours' will be taken. Firstly, the effects of the rise of evidence-based clinical guidelines on the *clinical autonomy* of physicians, both at the individual and the collective level, will be discussed. Secondly, the (shifting views on) the issue of *implementation* – or the lack thereof – will be addressed. And finally, the current debate on the *opportunities* for and *threats* to a positive role for EBM in (Dutch) healthcare in the 21st century will be mapped out.

Chapter 7.

The Need for a Mechanism of Control (1970s-1980s)

During the 1977 member conference of the KNMG, the then chairman, Dr. H.W.A. Sanders, delivered a speech entitled 'Changing View of Medicine and the Medical Profession'.¹ He began by observing that medicine and the medical profession had 'lately' been much more critically regarded by 'citizens and society' than had hitherto been the case. An increasing number of government officials and politicians, legal experts and economists, sociologists and philosophers had begun to take an interest in health and medicine. Along with 'several physicians not involved in patient care', they had managed to influence public opinion by 'prominently' bringing their viewpoints to the fore. Due to the mass media as well as the medical literature, the ideas of authors such as Zola, Illich and McKeown could no longer be avoided. All levels of society were permeated by the message that the medicalisation of society had gone too far; that the significance of curative care for healthcare and well-being was very limited; that, in some respects, the medical 'establishment' *itself* had become a threat to health; and that medical practice went hand in hand with unnecessarily high costs and inefficient use of the available means. According to Sanders, the result was that the position and autonomy of the medical profession came under pressure:

'Thus, the people are made to understand the urgency of more power for the government to structure and regulate, of more possibilities for external supervision of the organisation as well as for the monitoring of healthcare practices, and of reducing and limiting the scope and autonomy of the professionals working in this sector.'

Sanders argued that it would be ill-advised to give in to the temptation to react emotionally to all the criticisms. In his view, not only were physicians obliged to continuously check whether their performance was up to scratch in a medical-scientific, medical-technical or medical-ethical sense, but also if their professional performance was sufficiently

1. H.W.A. Sanders, 'Veranderend Oordeel over Geneeskunde en Medische Professie', *Medisch Contact* 32: 40 (1977), pp. 1246-9. All quotes and paraphrases in the discussion of Sander's speech are derived from this article.

aligned with the expectations of society. With regard to the latter, Sanders stressed that societal circumstances required physicians to simultaneously provide 'humane care' as well as 'the most effective and efficient care possible'. In addition, when 'necessary and useful', physicians had to 'provide clarity and question their own performance'.

This 'broader perception of responsibilities' was elaborated upon by Sanders by delving more deeply into 'four essential elements' on which 'greater emphasis should be placed'. The first was 'involving the patient more actively' in medical practice. Sanders spoke about a 'shift in emphasis in the physician-patient relationship from paternalism to participation'.

The second element was 'the significance of "care" alongside and sometimes above "cure"'. The limited curative possibilities of medicine with respect to cardiovascular diseases, chronic degenerative diseases, mental disorders and certain forms of cancer, made it necessary to devote more time and attention to 'care aspects'.

The third element was 'keeping up to date with, applying and contributing to knowledge'. Sanders maintained that it had gradually become generally accepted that every physician should make a considerable effort to stay up to date, and was also constantly in need of further training. The difficulty, however, lay in the 'enormous number' of general and specialised medical journals and books and the 'plethora of courses, symposia and conferences'. In addition, the absorption of knowledge did not automatically lead to its integration in medical practice. As knowledge increased, and physicians had more options available to them, there was a growing danger, that they would apply these in an 'unselected and unfocused manner'. In the event of atypical symptoms, many physicians were inclined to assume the presence of disease, until through exhaustive and often prolonged diagnostic examination the contrary was proved. The result was 'a progressive increase in the number of citizens that appear to be suffering from a 'non-disease''.

In respect to the *contribution* to knowledge, Sanders established 'with concern' that, in the Netherlands, in the field of applied medical research few initiatives were developed and few clinical trials were successfully completed. In medicine, but in countless other fields as well, there was 'an increasing overestimation [...] of the significance of opinions based on authority, reputation and charisma, and a distinct underestimation of the concept of "experiment"'. Yet, Sanders argued, even the most carefully formulated diagnostic, prognostic or therapeutic hypothesis that was based on all available knowledge, could not become 'clinically applicable knowledge without first passing the laborious and time-consuming phase of being tested by means of a well-designed and well-conducted "trial"'. Therefore, in his view, every physician should feel the duty to contribute to applied clinical research to the best of their ability.

As fourth and last element, Sanders mentioned 'the evaluation of medical practice'. In his view, the cost-benefit analyses and cost-effectiveness analyses, that were conducted in order to assess the quality of healthcare provisions at the meso and macro levels, had a distorted one-sided emphasis on curative care. Furthermore, the results and conclusions

appeared to be largely determined by the methods used and the value judgments and perspectives of the researchers involved. With regard to the evaluation of medical practice at the micro level he focused on the ‘assessment of personal performance against the opinion of colleagues’. He more than welcomed the fact that this activity, which had been given shape in a more systematic and structural way for several years, with the introduction of the concept of ‘Intercollegiale Toetsing’ – a specific form of peer review in which physicians evaluated each other’s professional activities.

Sanders subsequently concluded his speech with the following summary of his argument:

As a response to the changing view and the criticism of medicine and the medical profession [...as well as] to the rigorous plans for a revision of health care [...], I plead for: a reassessment of our responsibilities and tasks, as group and as individuals [...].²

Thus, Porter’s theoretical ideas about a shift from disciplinary to mechanical objectivity as a *professional response to external pressures* almost literally seem to have manifested themselves in historical reality. Sanders’s speech began with an explanation of these external pressures, and subsequently largely consisted of an argument about the way in which the medical profession should respond to them. Several elements of his speech are in line with Porter’s thesis, such as a greater emphasis on transparency, a more ‘democratic’ relationship with the patient, a more important role for quantitative knowledge as a foundation for medical decision making and systematic evaluation of medical practice. Moreover, what seemed to be important above all to Sanders in the end was restoration of *trust* – the central notion with Porter. At the end of his speech, he emphasised that for a physician, it is first and foremost the interests of his patients that should be paramount. To this end, a physician had to shape his performance to the best of his knowledge and ability ‘on a par with the state of science and the demands of the time, with respect for their lives and their personal dignity’. For this was, as Sanders stated in the final sentence of his speech, ‘the basis on which the *trust* of the patient in their physician is founded’.

In this chapter, the relevance of the Porter thesis for a historical understanding of the introduction of evidence-based medicine in the Netherlands will be further explored. The initial discussion will be centred on why Porter’s ideas, by and large, offer a useful framework for an interpretation of the developments within medicine and healthcare in the second half of the twentieth century. However, some reservations regarding this will be presented. In short, it will be argued that the Porter thesis is too general and too schematic to arrive at a satisfactory historical explanation for the emergence of EBM.

2. Sanders, ‘Veranderend Oordeel’, p. 1249. TB’s italics.

Therefore, more specific developments within the domains of medicine, healthcare and public health, which all contributed to a growing need for a ‘control mechanism’, will be discussed in the second part of this chapter. It will be argued, that the specific circumstances of the 1970s did not particularly suit the successful introduction of ‘something like EBM’, but that this changed due to a number of shifts in the 1980s. There will be a particular focus on the gradual change in thinking about, and the specific efforts with regard to, both the *quality* and the *efficiency* of medical practice. Attention will be paid to the role of several frameworks that emerged in the 1970s and 1980s and enjoyed some popularity, such as peer review, protocol medicine and clinical decision analysis. As the transition between these frameworks and the introduction of evidence-based medicine in the 1990s will appear to be a fluent one, it could be argued that, all and all, this chapter sketches the historical background in which the Dutch case of EBM should be placed.

1970s: External Pressure and Professional Response

The above-mentioned speech by Sanders was exemplary for the discussions held within the profession since the late 1960s, and during the 1970s in particular. That ‘the changing view of medicine and the medical profession’ had been a concern in the medical world for some time may be illustrated with several of the many available examples from *Medisch Contact*.

In 1970, an editorial was published with the title ‘Infringement on Authority’. It featured a discussion of two recent news reports on physicians who were purported to have been in the wrong. These articles and the accompanying tendentious headlines were depicted as ‘symptomatic of the inclination of newspapers [...] to manifest, when it comes to medical care, mistrust of anyone that is considered an authority’.³ In the same year, *Medisch Contact* published the annual speech of the then president of the National Association of Specialists (Dutch abbreviation: LSV), J. van Mansvelt, who stated in it: ‘Over the past years, there has been increasing criticism of our medical community, and I feel partly guilty of the fact that we have not succeeded in lending the Dutch specialist a better “image” [...]’.⁴ In the same year, an article appeared in the same journal with ‘The Demythologisation of the Medical Professional’ in the title and the remark that the physician had become the object of ‘fierce and often well-organised attacks by the frustrated under-achievers’.⁵ In 1974, *Medisch Contact* gave ample attention twice to the inaugural speech

3. J. J. van Mechelen, ‘Aantasting van Autoriteit’, *Medisch Contact* 25: 11 (1970), pp. 249-50.

4. ‘Voordracht van LSV-Voorzitter Dr. J. van Mansvelt ter Inleiding van de Tweede Ledenvergadering 1970’, *Medisch Contact* 25: 44 (1970), pp. 1173-80, on p. 1179.

5. A. J. M. van Beusekom-Kits van Heijningen, ‘De Ontmythologisering van de Medicus en de Rol van de Maatschappij Geneeskunst’, *Medisch Contact* 25: 50 (1970), 1353-4.

of professor C.L.C. van den Nieuwenhuizen, extraordinary professor of international aspects of the practice of medicine, entitled: ‘The Physician: Dethroning or Abdication?’⁶

Such articles and the terms used in them, such as demythologisation, dethroning and abdication make it clear that the medical professionals had all but failed to notice that they were no longer self-evidently put on a pedestal. There was a clear awareness, moreover, that besides social status, issues such as professional position and autonomy were under pressure as well. It was also realised that this criticism and pressure came from several sides at the same time. In the 1970s, the pages of *Medisch Contact* repeatedly featured complaints about the way ‘publicity media’ published critical reports on physicians and healthcare as a whole. These complaints pointed to the (malicious) influence of ‘left-wing intellectuals’ who attacked the medical profession. In addition, it was often stated that ‘the patient’ had changed. It was considered that, due to an increased assertiveness and higher expectations, patients had become more critical and more demanding. In conclusion, it was noticed that the government had started to explicitly interfere with healthcare.⁷

The latter was regarded as the greatest threat to the professional autonomy of the physician. For a long time, the government had confined itself to a ‘back-seat’, supervisory role, but at the end of the sixties, politics ‘came to the conclusion that the state should expressly play a role in the planning and organization of healthcare.’⁸ This resulted, amongst others, in the issuing of the Health Care Memorandum by Minister Veldkamp in 1966. It was not until the middle of the 1970s, however, during the Den Uyl cabinet (1973-1977) that the government attempted to pursue a ‘comprehensive policy’ in this field. In 1974, state secretary J.P.M. Hendriks presented the Structure Memorandum, in which he addressed all healthcare provisions and aspects, which widely varied in size,

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6. “‘De Arts: Onttroning of Abdicatie?’” Prof. Dr. C.L.C. Van Nieuwenhuizen Haalt Heel Wat Overhoop’, *Medisch Contact* 29: 11 (1974), 325-31.
 7. See, apart from the references in the notes above and below, the following articles (in chronological order): F. A. Bol, ‘De Plaats van de Arts in de Moderne Samenleving’, *Medisch Contact* 25: 8 (1970), pp. 175-6; Idem., ‘Volksgezondheid in een Snel Veranderende Wereld’, *Medisch Contact* 25: 40 (1970), pp. 1045-6; L. van der Drift, ‘Arts, Mens, Maatschappij’, *Medisch Contact* 25: 42 (1970), pp. 1129-33; ‘De Patiënt Wordt Mondig’, *Medisch Contact* 27: 51 (1972), pp. 1375-6; F. A. Bol, ‘1972’, *Medisch Contact* 27: 52 (1972), pp. 1397-8; M. J. van Trommel, ‘De Nederlandse Gezondheidszorg in Beweging’, *Medisch Contact* 28: 22 (1973), pp. 672-5; ‘Prioriteiten en Actualiteiten in de Gezondheidszorg: Voorjaarscyclus 1973 Studium Generale Erasmus Universiteit Rotterdam’, *Medisch Contact* 28: 23 (1973), pp. 689 et seq.; A. E. Leuftink, ‘Problemen Waarmee de K.N.M.G. Vandaag bezig is en Morgen te Doen zal Krijgen’, *Medisch Contact* 29: 41 (1974), pp. 1321-6; P. Gros, ‘Dagbladpers en Gezondheidszorg’, *Medisch Contact* 30: 29 (1975), pp. 713-14; J. Ridderikhoff, ‘Quo Vadis Aesculapis?’, *Medisch Contact* 31: 26 (1976), pp. 836-8; A. J. van Loon & H. G. Schmidt, ‘Opnieuw de Arts-Patiënt Relatie’, *Medisch Contact* 32: 9 (1977), pp. 274-6; F. A. Bol, ‘Medische Wereld en Media’, *Medisch Contact* 32: 47 (1977), p. 1455; J. J. H. Vossen, ‘De Patiënt-Arts Relatie in de Huidige Kentering der Tijden’, *Medisch Contact* 35: 6 (1980), pp. 195-6. See also the account of the criticisms of medicine since the 1960s in: F. Schwarz, ‘Het Beeld en de Identiteit van de Dokter’, *Medisch Contact* 41: 26 (1986), 833-5.
 8. J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), p. 7.

organisation and financing, but also issues such as education, training and information technology. As such, the Structure Memorandum is a milestone in the history of Dutch healthcare policy.⁹

Medisch Contact paid a great deal of attention to this break in the trend in government policy. It was established clearly that there was no doubt as to what the main reason was for the increased need to provide 'guidance' on the part of the government: the explosive cost development in healthcare. From the latter half of the 1960s, there is hardly an edition of *Medisch Contact* to be found in which this issue was not addressed (indirectly) in one or more articles. The sharply increasing cost of healthcare was mainly attributed to the medical-technical progress that had occurred, particularly in hospitals.¹⁰

Although the subject had been foremost for a long time already, the preoccupation with the cost issue noticeably increased around the middle of the 1970s. The first signs that there was going to be an end to decades of economic prosperity were responsible for this, but also alarming figures on the cost increases in healthcare, which were accompanied by ominous forecasts for the future. In 1975, for example, the Council for Public Health (Dutch abbreviation: RVZ) established that the costs of healthcare had increased by 50 per cent between 1963 and 1972 – so in barely a decade. Expressed as the

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9. Gerritsen & Van Linschoten, *Gezondheidszorgbeleid*, pp. 7-10, 16-17, 23-7, 57-62, 67-9. See also (a.o.): G. H. Okma, 'Studies on Dutch Health Politics, Policies and Law' (PhD thesis, University Utrecht, 1997).
 10. This does not mean that this was the correct explanation for the rising healthcare costs. C.A. Grünwald concludes, in her 1987 dissertation *Beheersing van de gezondheidszorg (Controlling healthcare)*, that other factors were far more important. She mentions, among others, (general) inflation, demographic factors, and the salary expenses in health care. See: C. A. Grünwald, *Beheersing van de Gezondheidszorg (Controlling Health Care)* ('s Gravenhage: VUGA, 1987), pp. 34-5. However, from a historian's point of view, the 'correct explanation' of the rising health care costs is less relevant than the dominant views (and actions) at the time, regardless of whether they were true or false. See for the dominant views at the time (in chronological order): 'Werkgroep Effectiviteit en Efficiency Overheidsziekenhuizen', *Medisch Contact* 25: 35 (1970), p. 925; L.P. de Jong, 'Een Proefschrift over Structuur en Doelmatigheid van Voorzieningen tegen Ziektekosten', *Medisch Contact* 25: 43 (1970), pp. 1150-2; 'Ministerie Steunt Kostenanalyse Gezondheidszorg door Middel van Macro-Rekenmodel', *Medisch Contact* 27: 40 (1972), pp. 1051-2; Trommel, 'Nederlandse Gezondheidszorg'; 'Beheersbaarheid van de Gezondheidszorg: Eindrapport van een "Feasibility Study" Uitgevoerd door de Samenwerkende Organisatie Adviseurs voor de Gezondheidszorg', *Medisch Contact* 28: 51 (1973), pp. 1413-14; J. J. M. de Leeuw, 'Kritische Bespreking Onderzoek Beheersbaarheid Gezondheidszorg', *Medisch Contact* 28: 51 (1973), pp. 1415-20; 'Kosten Gezondheidszorg tot 1980 Voorspeld', *Medisch Contact* 29: 7 (1974), pp. 211-12; H. G. van Gemert, 'Hoe Hard Stijgen Nu Eigenlijk de Kosten van Onze Gezondheidszorg?', *Medisch Contact* 29: 36 (1974), 1146-8; 'Hoge Kosten Gezondheidszorg Nopen tot Heroriëntatie', *Medisch Contact* 30: 25 (1975), p. 762; 'Kosten, Financiering en Doelmatigheid in de Gezondheidszorg', *Medisch Contact* 30: 50 (1975), pp. 1631-2; F. A. Bol, 'Stijgende Kosten', *Medisch Contact* 31: 12 (1976), p. 347; 'Stijgende Kosten Gezondheidszorg: 7,5% van het Bruto Nationaal Produkt', *Medisch Contact* 31: 16 (1976), p. 492; 'L.S.V.-Symposion: Medische Specialisten en Kostenbeheersing', *Medisch Contact* 31: 52 (1976), pp. 1630-1; Ch J. Maats, 'De Uitoefening van het Medisch Beroep en het Dilemma van de Schaarste', *Medisch Contact* 33: 40 (1978), pp. 1231-5; 'Kosten Gezondheidszorg: Tweede Financieel Overzicht van de Gezondheidszorg Waarin Opgenomen een Raming van de Kosten tot 1983', *Medisch Contact* 33: 42 (1978), p. 1318; J. M. Greep, 'Nederlandse Gezondheidszorg in Ernstige Problemen', *Medisch Contact* 35: 51/52 (1980), pp. 1604-8.

percentage of national income that was spent on healthcare, this meant an increase from 4.5 to 7.2 per cent. It was established, moreover, that there was an 'accelerated increase' in expenditure on healthcare. If this trend were to continue, no less than 9.3 per cent of the national income would have to be spent on healthcare in 1980. In absolute figures, this would entail an estimated amount of 34.6 billion guilders.¹¹ By comparison: in 1970, the total cost of Dutch healthcare did not even amount to a quarter of this amount, namely almost 7.4 billion guilders – which, for that matter, was almost ten times as much as the almost 800 million (0.8 billion) guilders spent in 1953.¹² In 1976, the Netherlands Bureau for Economic Policy Analysis (Dutch abbreviation: CPB) stressed the unsustainability of this 'accelerated increase' in expenditure on healthcare by presenting an 'absurd' extrapolation: in the event of an unchanging trend, healthcare would devour the full 100 per cent of the Gross National Product in 1994.¹³

This kind of information was regularly reported in *Medisch Contact*, where a considerable degree of serious concern was manifested. In 1975, for example, an article appeared in this journal entitled: 'Pulling the Emergency Brake. Structural Revision of Dutch Healthcare, to Be Embarked on in the Hours in which there are Signs of a *Serious Emergency*'.¹⁴ The author of the article spoke of an 'appalling cost increase' and of a system that 'threatens to collapse'. This high degree of concern was shared by State Secretary Hendriks, who said during the Parliamentary debate on the budget of Health for 1975: 'I predict literally sleepless nights for Parliament and myself when we need to come up with methods that enable us to live up to the task of delivering healthcare, taking into account our limited resources.'¹⁵

Needless to say, medical professionals responded in a variety of ways to the widely felt need for cost control, the increasing government interference and growing external criticism. It is striking, nevertheless, that (self-)reflection and adaptation to the changing circumstances were predominant in the vast majority of the articles and reviews in *Medisch Contact*. In the articles in which the 'demythologisation' and 'dethroning' of the physician was discussed, virtually all authors took the view that this development had many good

11. 'Kosten Gezondheidszorg tussen 1963 en 1972 Gestegen met Ongeveer 450%', *Medisch Contact* 30: 22 (1975), p. 683.

12. 'Kosten Gezondheidszorg tot 1980'.

13. Quoted in: Grünwald, *Beheersing*, p. 1.

14. P. C. J. van Loon, 'Aan de Noodrem. Structurele Ombuiging van de Nederlandse Gezondheidszorg aan te Vangen in de Uren Waarin een Ernstige Noodtoestand Zich Aftekent', *Medisch Contact* 31: 12 (1976), pp. 349-55. TB's italics. See also the even more pessimistic reaction to his article: L. P. de Jong, 'De Betekenis van de Noodrem als Instrument voor Kostenbeheersing', *Medisch Contact* 31: 20 (1976), pp. 622-3. See also for example: 'Minister Stuyt Zou Controle op Ziekenfondsverstrekkingen Willen Bevorderen', *Medisch Contact* 27: 46 (1972), p. 1224. In addition, see n. 10 above.

15. Quoted in: Ph. A. Idenburg et al., *Gezondheidszorg onder Druk: Besluitvorming in een Tijd van Kostenbeheersing* (Aphen aan den Rijn/Brussel: Samsom, 1982), p. 7.

sides to it.¹⁶ Typical is the way in which Van Mansvelt, as president of the LSV, interpreted the ‘growing criticism [...] of our medical community’ in 1970. He spoke of ‘a developing sense of reality that we may rejoice in’. He argued that in the past, people often had an image of the medical professional that was ‘far from realistic’. Therefore, it was ‘perhaps only to be encouraged, that both within and outside the circle of professionals, a more critical attitude with regard to this is developed’.¹⁷

It is not surprising that board members and directors of organisations such as the LSV and the KNMG took the lead with such ‘professional responses’ to external pressures. In this context, the annual speech delivered by KNMG president Sanders in 1977 fitted in a long-standing pattern.¹⁸ In editorials and the most relevant articles in *Medisch Contact* too, the dominant view was that the changing circumstances required adaptations in professional practice, both at an individual and a collective level. A strong emphasis was placed on issues such as educational reform, continued training, ‘medical audit’ and peer review, but nor were issues avoided at a macro level regarding the desired structure and design of healthcare.¹⁹

In all this, it is striking how explicit was reflection on the position, content and significance of the medical profession, and on the individual physician as a professional in modern society.²⁰ This is illustrated in particular by the annual speech of KNMG president Boelen from 1975, in which he referred to ‘the doubts the physician is sometimes overcome with in this time, when he or she contemplates the content of the profession’, and in which he pointed to the necessity for the physician to reflect on ‘future developments’. He counselled his audience:

16. See also notes 9-13 above.

17. ‘Voordracht van LSV-Voorzitter Dr. J. van Mansvelt’, p. 1179. See also, for example: ‘Voorzitter Commissie Ziekenhuisstaven L.S.V.: Zelfkritiek Nodig’, *Medisch Contact* 28: 9 (1973), p. 262.

18. See, for example, several lectures held at the yearly member conference of the KNMG in 1970 on the theme: ‘Healthcare in a rapidly changing world’: Bol, ‘Volksgezondheid in een Snel Veranderende Wereld’; Van der Drift, ‘Arts, Mens, Maatschappij’; R.J.H. Kruisinga, ‘Volksgezondheid en Maatschappij’, *Medisch Contact* 25: 41 (1970), pp. 1085-90; A. Querido, ‘Perspectief in de Klinische Geneeskunde’, *Medisch Contact* 25: 41 (1970), pp. 1098-1101. Also typical was the open letter published by the president and vice-president of the KNMG in *Medisch Contact* in 1974, in which they called upon ‘all physicians in the Netherlands’ to lend their participation to a more effective use of the available resources, to the regionalisation plans of the government and to a solution for the ‘the expected inflow of physicians by voluntarily limiting the size of the practices’. See: ‘Open Brief van Maatschappijvoorzitter en -ondervoorzitter aan Alle Artsen in Nederland’, *Medisch Contact* 29: 3 (1974), p. 73.

19. See almost all references in this section of this chapter. The ‘solutions’ to these problems, that were proposed in the 1970s, will be addressed later in this chapter.

20. In this context, the work of the sociologist Freidson, who had published *Profession of Medicine* in 1972, was regularly addressed in *Medisch Contact*. See a.o.: F. A. Bol, ‘De Medicus als Professional’, *Medisch Contact* 31: 32 (1976), p. 1019; Idem., ‘Wettelijk Regelen: tot Hoever?’, *Medisch Contact* 32: 16 (1977), p. 487; R. Giel, ‘Het Dilemma van de Medische Beroepsuitoefening’, *Medisch Contact* 31: 32 (1976), pp. 1021-6; P. M. Verbeek-Heida, ‘De Medicus als Professioneel: een Studie over Toegepaste Wetenschap’, *Medisch Contact* 27: 26 (1972), pp. 717-20.

'Retreatment into the already known means an impoverishment of physicianship, and is to the detriment of the patient. *New insight into the content and the boundaries of the medical profession* will have to take shape.'²¹

It very much remains to be seen, however, whether this highly 'professional' response to external criticism was representative for the profession as a whole. Those who shift their focus from the articles to the letters to the editor in *Medisch Contact*, will notice that physicians regularly expressed feelings of defensiveness, hurt and anger with respect to the 'external pressures' on medicine and on medical professionals. The best example was perhaps the letter from S. Bouwer, an orthopaedic surgeon from the 'peripheral' city of Amersfoort, which was published in the journal in 1974 under the headline 'This is Well Out of Order...!' Responding to critical comments from the state secretary and in the media on the specialists' fees, Bouwer wrote that he was filled with 'nausea' because of the 'anti-campaign' that was waged against physicians, 'the almost daily attacks in the publicity media from politicians and others', the 'unfair trial that was brought against us for political reasons with the aim to bring us to our knees', where, 'literally, on every occasion, time and again, official bodies, politicians and other groups mention the "exorbitant" physicians' salaries in one breath with the devaluation of our healthcare'. Because, in his view, the medical professional organisations did far too little to counter these 'relentless attacks on our profession, on us as individuals, on our integrity', he felt compelled to bring 'a few matters' to the attention of the Dutch people. This was followed by an argument of approximately 2,500 words in which no less than 35 'truths' were summed up with the aim of making it clear that all the criticism of medicine and the salaries of physicians was unjustified.²²

The board of the LSV responded in a later issue of *Medisch Contact* with the dry comment that Bouwer engaged in 'a certain degree of "overshooting"'.²³ In addition, several letters appeared in the journal from physicians who distanced themselves from Bouwer by arguing it was simply true that medical specialists enjoyed generous incomes, or by raising the question: 'What do you fear and why are you angry?'²⁴ Much larger in number, however, were the statements of support addressed to Bouwer. For sixteen issues long, the letters section of *Medisch Contact* was filled to the brim with letters from specialists, sometimes signed by an entire list of staff members of hospitals, with the text:

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21. J. L. A. Boelen, 'Naar een Nieuw Inzicht in de Inhoud en de Grenzen van het Artsenberoep', *Medisch Contact* 30: 41 (1975), pp. 1265-7, the quotes are on pp. 1265 and 1266. TB's italics.
 22. S. Bouwer, "'Dit Gaat Te Ver...!'", *Medisch Contact* 29: 8 (1974), pp. 222-4.
 23. Centraal Bestuur der L.S.V., 'Naschrift van het Centraal Bestuur der L.S.V. bij de Twee Open Brieven van S. Bouwer', *Medisch Contact* 29: 18 (1974) p. 554.
 24. W. Schuurmans Stekhoven, 'Waarvoor Bang en Waarom Boos?', *Medisch Contact* 29: 24 (1974), pp. 760-1.

‘The undersigned wish to express their explicit assent to the content of the piece submitted by colleague S. Bouwer.’²⁵

This is rather in contrast with the vast majority of the articles in *Medisch Contact* during the 1970s, in which the tone and attitude were much more formal and a considerable amount of self-criticism was manifested too. It is perfectly reasonable to assume that these more ‘professional’ responses came from a certain segment of the medical profession, comprising opinion leaders, academics and directors of professional organisations, while the defensive, emotional response from Bouwer and the many statements of support possibly show a glimpse of the views and feelings of the overwhelming majority of medical professionals in the country. It is, however, extraordinarily difficult to prove the veracity of these kinds of assumptions. It is therefore better to stick to the conclusion that the content of *Medisch Contact* does not necessarily represent the views of the entire medical profession. What is more: it is important to ensure that the profession is not seen as one whole. In addition to a possible dividing line between ‘vanguard’ and greater mass, consideration must be given to the differences between (academic) centre and periphery, independent professionals and medical professionals in employment, specialists and GPs, older and younger generations, and, of course, differences in personality, temperament, political preference, et cetera.

This does not mean, however, that the notion of the professional response to external pressures should be dismissed. Figures such as KNMG president Sanders explicitly thought in these terms themselves. Moreover, it may be derived from the consecutive volumes of *Medisch Contact*, but also from other sources that, under the influence of the changing circumstances of the 1970s, actually quite a lot has been going on with respect to the (views about the) societal position of the medical profession and the adaptation of professional practices to the demands of the time. The fact that there were great differences between individual medical professionals or between segments within the profession does not undermine this general image.

On the basis of Porter’s thesis, it would be expected that the professional response to external pressures would entail a shift from disciplinary to mechanical objectivity. Indeed, there were proposals in this direction. For example, there was some attention to ‘medical audit’, which approached Porter’s idea of mechanical objectivity, as it reflected aspects such as ongoing and systematic quality control, accountability, transparency, collective agreements, the use of standards and adherence to procedures. In practice, however,

25. See the ‘letters to the editor’-section of issues 9 to 24 of volume 29 (1974) of *Medisch Contact*. See also two later letters from Bouwer, in which he claimed that he had received ‘hundreds of oral, written, and telephone statements of adhesion’: S. Bouwer, ‘Dit gaat te ver...! (I). Tweede Open Brief aan de Landelijke Specialisten Vereniging’, *Medisch Contact* 29: 18 (1974), p. 554; Idem., “‘Dit gaat te ver...!’ (II)”, *Medisch Contact* 29: 24 (1974), pp. 758-60.

medical audit, as applied in the United States, barely got off the ground in the Netherlands. The emphasis was mainly on one element of it, namely ‘Intercollegiale Toetsing’, a form of peer review. Typical in this context is the way in which the then president of the National Association of General Practitioners (Dutch abbreviation: LHV) distanced himself in 1973 from medical audit, described by him as a ‘medical accountancy service’, and simultaneously pleaded for ‘Intercollegiale Toetsing’ (in English: ‘Peer Review’) as a ‘system for assistance and support’ for GPs.²⁶ The specialists, rather than the GP’s, took this up energetically. As early as 1973, the National Association of Specialists (Dutch abbreviation: LSV) established the Peer Review Taskforce followed, in 1979, by the establishment of a Central Supervisory Body for Peer Review (Dutch abbreviation: CBO). As becomes clear from the name, the CBO (initially) concerned itself with the promotion and supervision of peer review in Dutch hospitals.²⁷ Due to the fact that in the Netherlands, peer review and not ‘auditing’ prevailed in a broader sense, there was only ‘internal supervision’ within circles of close colleagues, while virtually nothing came of ‘external supervision’ through, for example, accrediting agencies, introduction of standards of procedure, by-laws, rules and regulations, and publication of the results of ‘audit’.²⁸

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26. F. N. M. Bierens, ‘Onderlinge Toetsing: een Stimulus in de Huisartsenpraktijk’, *Medisch Contact* 28: 22 (1973), pp. 679-80.
 27. The objective of the CBO was formulated in somewhat broader terms as: ‘the encouragement and guidance of all quality control and quality improvement activities in Dutch hospitals’. See: ‘Centraal Begeleidings Orgaan voor de Intercollegiale Toetsing: Stichtingsakte Gepasseerd’, *Medisch Contact*: 34: 9 (1979), p. 282.
 28. See: *Ibid.* See, in addition, for (just!) a selection of relevant articles from *Medisch Contact*: J. Bazelmans, ‘Intercollegiale Toetsing: een Psychologische Benadering’, *Medisch Contact* 32:15 (1977), pp. 469-73; Bierens, ‘Onderlinge Toetsing’; J. de Boer, ‘Een Zinvol Voorbeeld van Intercollegiale Toetsing’, *Medisch Contact* 35: 14 (1980), pp. 421-3; F. A. Bol, ‘Toetsing in Algemene Ziekenhuizen’, *Medisch Contact* 35: 14 (1980), p. 415; *Idem.*, ‘Visioen of Fictie’, *Medisch Contact* 33: 42 (1978), p. 1311; *Idem.*, ‘Nieuw en Oud Blauw’, *Medisch Contact* 32: 31 (1977), p. 971; *Idem.*, ‘Toetsing’, *Medisch Contact* 31: 35 (1976), p. 1103; A. Chr. J. Brand, ‘Samenwerken in de Gezondheidszorg: Fasen en Facetten Nader Belicht’, *Medisch Contact* 33:11 (1978), pp. 343-9; M. Buijze-den Hollander & A. Knottnerus, ‘Nogmaals Praktijkverkleining: Wat is Er tegen de Kleine Praktijk?’, *Medisch Contact* 35:19 (1980), pp. 575-8; J. C. J. Burkens, ‘Medical Audit: Extern of Intern?’, *Medisch Contact* 30: 14 (1975), pp. 401-4; A. F. Casparie, ‘Medical Audit, een Nationale Zaak’, *Medisch Contact* 28: 17 (1973), pp. 507-9; W. R. Casparie, A. F. Disse & A. F. Casparie, ‘Kwaliteit en Doelmatigheid van het Medisch Werk in Ziekenhuizen (I)’, *Medisch Contact* 29: 6 (1974), pp. 161-5; *Idem.*, ‘Kwaliteit en Doelmatigheid van het Medisch Werk in Ziekenhuizen (II)’, *Medisch Contact* 29: 7 (1974), pp. 203-7; ‘Congres Nederlands Huisartsen Genootschap: “Van Zelfbeoordeling naar Verbetering”’, *Medisch Contact* 33: 57 (1978), pp. 1470-1; H. F. J. Crebolder & J. A. E. van der Feen, ‘Nascholing en Toetsing Van Huisartsen: Scheiding of Integratie?’, *Medisch Contact* 40: 33 (1985), pp. 997-8; F. Engel, ‘Medical Audit of Intercollegiale Toetsing’, *Medisch Contact* 33: 10 (1978), pp. 321-4; J. C. van Es, ‘Intercollegiale Toetsing’, *Medisch Contact* 41: 7 (1986), p. 191; A. M. Gründemann & H. J. Overbeek, ‘Enkele Beschouwingen over het Begrip “Normering van het Medisch Handelen”’, *Medisch Contact* 31: 16 (1976), pp. 480-5; R. Grol et al., ‘Onderlinge Toetsing Huisartsen: Beknopt Overzicht Toetsingsprojecten’, *Medisch Contact* 39: 30 (1984), pp. 945-9; G. C. J. M. Hamilton-van Hest, ‘Intercollegiale Toetsing in Algemene Ziekenhuizen’, *Medisch Contact* 41:7 (1986), pp. 197-200; Interimrapport van de Taakgroep Intercollegiale Toetsing, *Medisch Contact* 29: 29 (1974), pp. 948-51; ‘De Kwaliteit van

Perhaps even more than on peer review, the discussions within the medical profession in the 1970s focused on the necessity for innovating medical education, and of continuous training for physicians in particular.²⁹ Judging by what took off specifically – peer review and all manner of initiatives in the field of training – it may be argued that the efforts medical professionals made in response to the ‘pressure’ of the 1970s mainly focused on inter-subjectivity and on the training and socialisation of individual professionals within the discipline. In the many reflections on this in *Medisch Contact*, there was a constant emphasis on the preservation of professional autonomy and on self-regulation by and within the profession.³⁰ All this points to a trend of reinforcement of *disciplinary objectivity* rather than to a shift towards mechanical objectivity.

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- de Medische Beroepsuitoefening: Rapport van het KNMG-Hoofdbestuur’, *Medisch Contact* 35: 51/52 (1980), pp. 1624-36; ‘Kwaliteitsbewaking bij het Medisch Handelen’, *Medisch Contact* 31: 9 (1976), p. 268; ‘L.S.V.-Ledenvergadering Kreeg Rapport Intercollegiale Toetsing Gepresenteerd’, *Medisch Contact* 31: 26 (1976), pp. 833-35; ‘L.S.V.-“Workshop” Intercollegiale Toetsing’, *Medisch Contact* 33: 20 (1978), pp. 613-14; ‘Medical Audit: Hoe te Operationaliseren? Najaarsvergadering 1974 Medisch Directeuren Algemene Ziekenhuizen’, *Medisch Contact* 30: 15 (1975), pp. 431-4; H. J. Nijhuis, ‘Intercollegiale Toetsing’, *Medisch Contact* 36: 29 (1981), pp. 875-7; ‘Onderlinge Toetsing Huisartsen’, *Medisch Contact* 36: 41 (1981), p. 1286; H. Raat & G. Goudriaan, ‘Kwaliteitssystemen en Professionele Autonomie: Intercollegiale Toetsing, Protocollaire Geneeskunde en Evaluatieonderzoek’, *Medisch Contact* 40: 27 (1985), pp. 806-8; ‘Rede L.H.V.-Voorzitter F.N.M. Bierens’, *Medisch Contact* 28: 48 (1973), 1339-42; ‘Regionale Bijeenkomsten over Blauwdruk Beleid Landelijke Huisartsen Vereniging’, *Medisch Contact* 30: 37 (1975), pp. 1139-43; C. Spreuwenberg, ‘Toetsing van Medisch Handelen’, *Medisch Contact* 43: 17 (1988), p. 515; ‘Studiedag over het Onderwerp Medical Audit’, *Medisch Contact* 28: 15 (1973), pp. 439-40.
29. This was discussed so frequently in *Medisch Contact* that it would be unfeasible to refer to all relevant articles. This theme was raised in almost all articles referred to in this and the preceding section of this chapter. See for an additional small selection of relevant articles (in chronological order): ‘Gezondheidszorg én Medische Opleiding: Een Rapport Uit de Faculteit der Geneeskunde aan de R.U. Utrecht’, *Medisch Contact* 30: 26 (1975), pp. 789-91; W. G. Petersen, ‘Gezondheidszorg én Opleiding’, *Medisch Contact* 30: 10 (1975), pp. 285-7; ‘Medisch Onderwijs is Niet Meer Wat het Geweest is’, *Medisch Contact* 31: 4 (1976), pp. 109-111; R. A. de Melker, ‘Weten is Nog Niet Toepassen. Over de Nascholing van Huisartsen’, *Medisch Contact* 31: 3 (1976), pp. 69-74; H. Roelink, ‘De Rol van het Academisch Ziekenhuis in de Ontwikkeling van de Relatie tussen Gezondheidszorg en Medische Opleidingen’, *Medisch Contact* 33: 18 (1978), pp. 555-8; R. Voorneman-Hammelburg, S. A. Duursma & H. Roelink, ‘Post-Academisch Onderwijs Geneeskunde. I: Recente Ontwikkelingen’, *Medisch Contact* 33: 41 (1978), pp. 1295-9; ‘De Kwaliteit van de Medische Beroepsuitoefening’; E. Schadé, ‘Nascholing Huisartsen: een Verslag uit de Periferie’, *Medisch Contact* 38: 35 (1983), pp. 1096-8; ‘“Over Nascholing Gesproken”: Tien Jaar Stichting Nascholing Huisartsen’, *Medisch Contact* 38: 47 (1983), pp. 1479-80; J. C. van Es, ‘Nascholing’, *Medisch Contact* 38: 47 (1983), p. 1475; Crebolder & Van der Feen, ‘Nascholing en Toetsing’.
30. See for example: Bol, ‘De Medicus als Professional’; Idem., ‘Wettelijk Regelen’; H. J. J. Leenen, ‘De Rol van de Wetgever bij het Regelen van het Medisch Handelen’, *Medisch Contact* 32: 16 (1977), pp. 489-92. The apprehension that the professional autonomy of physicians was under threat was one of the major reasons for interest in peer review. This came explicitly to the fore, for example in the report ‘Huisartsen waarheen?’ (‘GP: whither?’) from 1976, in which was stated: ‘a timely and thorough approach to peer review will not only ensure that the quality of medical practice is protected or even improved, but also that demands for external control will decrease’. See: ‘Huisarts Waarheen? De Plaats van de Medicus in het Eerste Echelon. Discussienota van de Commissie Eerste Echelon’, *Medisch Contact* 31: 5 (1976), pp. 141-64, on p. 152.

These findings imply that the Porter thesis needs to be amended. On the one hand the 'schema' of a professional response to external pressures is certainly broadly applicable to the circumstances and internal debates of the medical profession of the 1970s. On the other hand, this schema does not appear to be sufficiently precise and specific to be able to interpret particular developments in that decade, nor (eventually) the introduction of evidence-based medicine in the Netherlands in the 1990s. If, with Porter's ideas, the emergence of EBM was adequately explained, then it would not be possible to understand why (something like) EBM only came into being in the 1990s, and not in the 1970s. After all, many of the challenges that were identified in 1991 in 'Medical Practice at a Crossroads' had already been addressed in the 1970s. The urgent appeal to the medical profession, in the report by the Health Council, to put its affairs in order 'now', or else other actors would take over the initiative, was not new or unique at all. In the late 1970s and early 1980s, such statements were issued so frequently that they almost became a mantra. In 1981, for example, the GPs in the journal *Huisarts en Wetenschap* (*GP and Science*) were led to believe that they were at 'a crossroads' and that their 'profession had to put its affairs in order internally'. They were also warned that it was important to prevent the government and other parties from taking control.³¹ There are numerous other examples of 'precursors' to the main message of 'Medical Practice at a Crossroads', in which sometimes virtually the same wording was used, including examples from as early as 1970.³² Yet, in the 1970s no marked shift toward mechanical objectivity occurred, let alone the successful introduction of 'something like EBM'.

From this, it follows that it is not very elucidating to speak only of pressure on the medical profession and the 'professional response' to it. It is also necessary to define more clearly of what this 'pressure' and professional response exactly consisted. What order had to be put in what affairs? And did this apply to the same affairs all the time, or did this change over the course of time? In order to be able to answer these questions, in the following paragraphs, we will look into the discussions in *Medisch Contact* and other sources from the 1970s and subsequently in the 1980s in greater depth.

31. See on this (and for the quotes in the text) the dissertation of Johanna Dwarswaard, who systematically analysed dozens of subsequent volumes of (a.o.) the journal *Huisarts en Wetenschap* (*GP and Science*): J. Dwarswaard, *Dokter en Tijdgeest*, pp. 108-17, 206.

32. See for only a small selection of relevant examples: J. L. A. Boelen, 'Perspectief voor de Gezondheidszorg: Zelf Orde op Zaken Stellen', *Medisch Contact* 45: 8 (1990), pp. 262-3; Bol, 'Wettelijk Regelen'; W. H. Cense, 'Uitdagend Perspectief', *Medisch Contact* 42: 41 (1987), pp. 1292-5; A. Kastelein, 'Bestuurscrisis en Doelmatigheid', *Medisch Contact* 42: 35 (1987), pp. 1081-2; Van Loon, 'Aan de Noodrem'; F. L. Meijler, 'Zekerheden en Onzekerheden in de Geneeskunde', *Medisch Contact* 37: 7 (1982), pp. 189-90; 'De Plaats van de Arts in de Moderne Samenleving', *Medisch Contact* 25: 8 (1970), pp. 175-6; Sturmans & Van Arkel, 'Epidemiologie en Planning. 1', p. 551; C. Spreeuwenberg, "'Verandering Verzekerd" (3)', *Medisch Contact* 43: 14 (1988), p. 419.

Medicine and (Public) Health in Rapid and Accelerated Change

As mentioned before, in the 1970s, *Medisch Contact* repeatedly discussed the ‘changing circumstances’ that necessitated reflection and adaptation. This did not only and not particularly refer to external pressures, the more interfering government and (threatening) cutbacks. Much more frequently, it involved the tumultuous developments within medicine itself. All new (technological) opportunities were first of all welcomed as commendable progress. At the same time, there was an awareness that the new ‘medical power’ also brought with it fresh problems, dilemmas and undesirable side-effects. The question of whether everything that was medically possible was also justified was frequently raised. People pointed to medical-ethical questions with respect to the beginning and end of life, and matters such as organ transplantation. It was also mentioned that patients did not always benefit from the use of all that was technically possible. It was noted several times that there was a lack of a balanced application of all new scientific knowledge and technological opportunities. Medical specialists in particular, seemed to be carried away in the ‘whirlpool’ of fast, technological developments and super-specialisation.³³ This led LSV president Van Mansvelt to argue in 1970: ‘In our fields, too, the art of applying our knowledge has lagged behind the development of knowledge itself.’³⁴

How difficult it was for individual physicians to keep up with the rapid developments in their discipline was accurately expressed by K.C. Winkler, a Utrecht professor in the study of infection and contamination. In his farewell lecture in 1978, he argued that the explosion of knowledge and ability in medicine had led to an explosion of *inability* on the part of the individual professional.³⁵ Another paradox that was identified was that the increase of knowledge, diagnostic options and effective therapies actually increased *uncertainty* among physicians. The number of choices they had to make from an increasing number of alternatives, when deciding on the care of individual patients, increased dramatically, while there was always a margin of uncertainty in the data on the basis of which decisions had to be taken.³⁶

33. Paraphrase from: ‘De Medische Professie in het Ziekenhuis’, *Medisch Contact* 25: 11 (1970), pp. 251-3.

34. ‘Voordracht van L.S.V.-voorzitter Van Mansevelt’, p. 1179.

35. Cited in: Borst-Eilers, *Geneeskunde op Recept?*, p. 10; H. J. Sluiter, ‘De (On)macht van het Getal’, *Nederlands Tijdschrift voor Geneeskunde* 123 (1979), pp. 601-3, on p. 603.

36. All these aspect of the rapid technological advances in medicine were repeatedly discussed in *Medisch Contact*. See for a small selection of relevant articles: Boelen, ‘Naar een Nieuw Inzicht’, Bol, ‘1972’; Idem, ‘Plaats van de Arts’; J. J. H. M. Daniëls, ‘Plaats en Functie van de Arts in de Gezondheidszorg’, *Medisch Contact* 37: 39 (1982), pp. 1217-21; H. J. J. Leenen, ‘Grenzen aan de Medische Hulpverlening’, *Medisch Contact* 32:17 (1977), pp. 547-8; Leuftink, ‘Problemen’; Van Loon, ‘Aan de Noodrem’; Maats, ‘Uitoefening’; J. van Mansvelt, ‘Doelstelling in de Gezondheidszorg’, *Medisch Contact* 27: 31 (1972), pp. 835-6; Querido, ‘Perspectief’; Sluiter, ‘(On)Macht’; M. J. van Trommel, ‘Bezinning Nopens de Huisarts in de Nabije Toekomst’, *Medisch Contact* 26: 20 (1971), pp. 561-7; Idem, ‘Nederlandse Gezondheidszorg’; R. Vermeer, ‘Over “Macht” en “Verontrusting”’, *Medisch Contact* 27: 42 (1972), pp. 1105-7.

Apart from the fact that the work had not become easier for physicians in medical terms, they also had to deal with the consequences of all technological developments for the physician-patient relationship. During the 1970s, medical professionals regularly used *Medisch Contact* to express their apprehension regarding the ‘dehumanisation’ of medical practice. KNMG president Van der Drift, for example, wondered aloud at the 1970 members’ conference if the application of all scientific and technological options in medicine would perhaps negatively affect the patient-physician relationship, ‘with the result that the human languishes, while their organs thrive.’³⁷

In addition, it was discussed that, as a result of increased medical possibilities, patients had come to expect more and often *too much* from medicine. It was observed that, in the Dutch society, the idea arose that ‘people no longer need to suffer pain nor have fear, and that abnormalities or defects can be mended at all times.’³⁸ The changes in the expectation of patients were often related to more general social developments and to the sharp increase in material prosperity in particular. The steady economic growth of the post-war era had made possible the huge expansion of the welfare state, with major consequences for the view of healthcare in society. For example, in 1970, KNMG president, Van der Drift stated that the *demand for* healthcare had evolved into *entitlement to* healthcare for every citizen – a right that was also explicitly mentioned in the Public Health Memorandum of 1966.³⁹

At the same time, an extension of the meaning of the notion of ‘health’ had occurred. Van der Drift and various others pointed to the famed ‘positive’ definition of the World Health Organization from 1946 in which health was described as ‘a state of complete physical, mental and social well-being; and not merely the absence of disease or defect’. They argued that a trend from ‘cure model’ to ‘health model’ was *actually* taking shape. In line with this, it was established that the notion of health had increasingly begun to overlap with the notion of *well-being*. Several commentators thought that this was also the fault of increased prosperity. On the one hand, people barely needed to worry any longer about their primary needs and, as a result, they could focus on ‘higher’ things. On

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37. Van der Drift, ‘Arts, Mens, Maatschappij’. See for more references: n. 43 below. And see also: F. A. Bol, “‘Humanistic Medicine’”, *Medisch Contact* 31: 46 (1976), p. 1443; H. J. Dokter, “‘Heel de Mens’: de Mens als Middelpunt in de Gezondheidszorg”, *Medisch Contact* 33: 21 (1978), pp. 652-4; J. C. van Es & R. A. de Melker, ‘Wat voor Gezondheidszorg Willen Wij?’, *Medisch Contact* 33: 31 (1978), pp. 961-5; D. Garell et al., ‘Het Geneeskundig Gesprek met de Zieke Mens’, *Medisch Contact* 32: 22 (1977), pp. 705-9; ‘Huisarts-geneeskunde: een Hulpverleningsmodel. Oratie Van Prof. Dr. H.J. Van Aalderen’, *Medisch Contact* 29: 17 (1974), pp. 530-4; ‘Prioriteiten en Actualiteiten’.
38. The quote is from the (then) KNMG-president Bierens, and was cited in: J. van Mansvelt, ‘Verantwoorde Gezondheidszorg’, *Medisch Contact* 40: 51/52 (1985), p. 1584. See also: Schwarz, ‘Beeld en Identiteit’. See for more relevant references: n. 43 below.
39. The paraphrases and quotes are derived from: Van der Drift, ‘Arts, Mens, Maatschappij’; “‘De Arts: Onttroning of Abdicatie?’”. See for more relevant references: n. 43 below.

the other hand, it was frequently noted that material prosperity had not led to greater well-being, and, in many cases, had come at the expense of it.

This issue of 'abundance and discontent' was commented upon roughly along two strands. In the first place, there were commentators who pointed to the immediate harmful consequences for public health of the technologically driven economic growth. In particular, traffic casualties, pollution of the living environment and the spread of unhealthy habits such as smoking were recurrent themes. Commentators explicitly related this to the increase of chronic 'lifestyle diseases' such as cancer and cardiovascular diseases. Secondly, there was a striking amount of attention for the psychological and social impact of the economic-technological developments. Van der Drift, for example, spoke of an increase in 'psychosocial deregulation', evidenced by the requests for help from GPs, of which the focus was increasingly less 'purely somatic'. He established a relationship with the labour conditions in a time of upscaling, mechanisation and automation of production processes, quoting an insurance medicine expert who had wondered if it was medically and ethically right to declare someone fit for 'the grey mass of labour in employment, which is experienced as pointless, unattractive, monotonous, frustrating, mindless and degrading'.⁴⁰

This debate was mainly held by social medicine professionals and others who were specifically interested in these issues. It is very doubtful whether, for example, the majority of medical specialists working in hospitals went along with this. However, the above-mentioned themes certainly affected 'mainstream' medicine, as becomes clear, among others, from the interest of successive KNMG boards in these matters. It may be derived from *Medisch Contact* and other sources that, in the 1970s, there was a widespread feeling within the medical profession of a tension between, on the one hand, the hi-tech direction medicine developed in, and, on the other hand, the societal changes described above. It was repeatedly claimed that medicine had become rather strongly aimed at cure, while the needs of patients and society increasingly manifested themselves in other fields as a result of the shifting disease pattern among the population and the broadening of the concept of health.

In many of these contemplations on the relationship between cure, care and prevention, a link was established with the cost issue. More than once, it was argued that the effectiveness of the increasingly large amounts spent on healthcare was sharply decreasing.⁴¹ An often mentioned cause for this was that a great deal of time, energy and (financial) resources were spent on super-specialist and hi-tech curative care from which only few people benefited.⁴² The spectacular successes and large investments in this area

40. Van der Drift, 'Arts, Mens, Maatschappij', p. 1130.

41. In this context, the work of McKeown was frequently mentioned. See on McKeown: chapter 3.

42. Paraphrase derived from: 'Prioriteiten en Actualiteiten'.

were in contrast, it was argued, with a relative inability to have a positive influence on the health status of the population as a whole.⁴³

The sketch provided above of the more substantive debates among medicals in the 1970s makes it plausible that the initiatives for change and innovation in medicine were not primarily the result of the more general processes of modernisation, democratisation and bureaucratisation on which Porter particularly focuses. The more specific developments *within* medicine and in the field of (public) health seem to have been much more important. Physicians were faced with accelerated scientific-technological developments in their discipline, with which they could barely keep up and which, besides bringing undisputed progress, also led to new questions and problems. In addition, the direction in which medicine was moving was slightly at odds with the changes in the social demand for healthcare.

Physicians were continually confronted with these developments and their consequences in daily practice. It is therefore not surprising that medical professionals them-

43. See on all this: “Arts: Onttroning of Abdicatie?”; Boelen, ‘Naar een Nieuw Inzicht’; F. A. Bol, ‘Volksgezondheid en Milieuhygiëne’, *Medisch Contact* 32: 20 (1977), p. 623; Idem, ‘Taken Huisarts’, *Medisch Contact* 32: 24 (1977), p. 759; Idem, ‘Nieuw en Oud Blauw’; Idem, “Humanistic Medicine”; Buijze-den Hollander & Knottnerus, ‘Nogmaals Praktijkverkleining’; Dokter, “Heel De Mens”; ‘Dr. J. L. A. Boelen, K.N.M.G.-Voorzitter 1975: Visie op Relatie tot de Samenleving Nodig’, *Medisch Contact* 30: 1 (1975), pp. 5-7; Van der Drift, ‘Arts, Mens, Maatschappij’; J. C. van Es, ‘Mogelijkheden en Onmogelijkheden van de Huisarts als Gezondheidsbevorderaar’, *Medisch Contact* 31: 43 (1976), pp. 1357-63; Van Es & De Melker, ‘Wat voor Gezondheidszorg?’; Garell et al., ‘Het Geneeskundig Gesprek’; ‘De Geneeskunde van de Industriële Mens: op Zoek naar een Theorie’, *Medisch Contact* 28: 51 (1973), pp. 1427-8; E. C. D. van Gils, ‘Arts-Milieuhygiëne’, *Medisch Contact* 25: 43 (1970), pp. 1145-6; ‘Huisartsgeneeskunde: een Hulpverleningsmodel’; Kruisinga, ‘Volksgezondheid en Maatschappij’; B. J. Huygen, ‘Een Definitie van Gezondheidszorg’, *Medisch Contact* 32: 22 (1977), pp. 710-12; L. R. Kooij, ‘Het Functioneren van de Huisarts: Aanzet tot een Takenpakket’, *Medisch Contact* 35: 27 (1980), pp. 819-20; J. P. Kuiper, ‘De Betrekkelijke Waarde van Gezondheid en Gezondheidszorg’, *Medisch Contact* 33: 33 (1978), pp. 1019-25; Idem, ‘Een Voorkomende Gezondheidszorg’, *Medisch Contact* 31: 42 (1976), pp. 1323-30; Idem, ‘Doelstelling van de Gezondheidszorg’, *Medisch Contact* 26: 23 (1971), pp. 631-6; Leuftink, ‘Problemen’; Van Loon & Schmidt, ‘Opnieuw de Arts-Patiënt Relatie’; P. C. J. van Loon, ‘Op Weg naar een Gezondheids-professie? Gezondheidsbeleid met Steun door Onderwijs- en Volkshuisvestingsbeleid’, *Medisch Contact* 30: 48 (1975), pp. 1551-5; Idem, ‘Aan de Noodrem’; Maats, ‘Uitoefening’; Van Mansvelt, ‘Verantwoorde Gezondheidszorg’; Idem, ‘Doelstelling’; M. Plooi, ‘Geneeskunde en Gezondheidszorg in de Komende Decennia’, *Medisch Contact* 26: 50 (1971), pp. 1323-6; ‘Politisering van de Medische Beroepsuitoefening’, *Medisch Contact* 27: 7 (1972), pp. 181-2; ‘Prioriteiten en Actualiteiten’; ‘Rede L.H.V.-Voorzitter’; F. E. Reitsma, ‘Generalisatie en Individuele in het Geneeskundig Denken’, *Medisch Contact* 32: 22 (1977), pp. 703-4; Ridderikhoff, ‘Quo Vadis?’; F. van Soeren, ‘Tragedie der Zeventiger Jaren’, *Medisch Contact* 32: 20 (1977), pp. 639-40; Van Trommel, ‘Bezinning’; Idem, ‘Nederlandse Gezondheidszorg’; Vermeer, ‘Over “Macht”’; Vossen, ‘Patiënt-Arts Relatie’. The trends as described in the last few pages correspond well with the findings of Dwarswaard’s analysis of successive volumes of the journal *Huisarts en Wetenschap*, see: Dwarswaard, *Dokter en Tijdgeest*, in particular pp. 56-63, 73-74. See also: Van Lieburg, *Vijf Eeuwen*, p. 125.

selves had ‘doubts and worries’ as well,⁴⁴ and that some of them were among the leading critical voices, expressing concerns about medicalisation, iatrogenesis and technological progress. The latter applied, for example, to the psychiatrist J.H. van den Berg, who published the book, *Medische Macht en Medische Ethiek (Medical Power and Medical Ethics)* in 1969 which, in subsequent years, was regularly and welcomingly quoted from in *Medisch Contact*.⁴⁵

All this puts the ‘Porterian’ action/reaction schema of a professional response to external pressures into perspective. Firstly, ‘internal’ pressures appear to have been at least as important as ‘external’ pressures. Secondly, there were individuals and segments within the profession that did not just *respond* to these pressures, as they had a ‘pro-active’ attitude rather than just a ‘reactive’ one.⁴⁶ The image of a professional response out of necessity is difficult to reconcile with the way in which some, with genuine conviction, set to work with new ideas and new initiatives – comparable to the aforementioned enthusiasm of medical professionals and researchers for the ideas of figures such as Miettinen, Wulff and Sackett.⁴⁷ Thirdly, at a more fundamental level, it seems difficult to maintain a clear distinction between the medical profession and the ‘outside world’, between those who ‘acted’ and those who ‘reacted’, and between internal and external pressures.

Nevertheless, it could be argued that an increasing ‘external pressure’ on medicine and medical professionals played a significant role. That the cost increase in healthcare would sooner or later force the government to take measures that would immediately hurt the pockets of medical professionals, was more than clear by the middle of the 1970s. Yet it is remarkable here that the attention of the government was not merely or primarily focused on the implementation of cutbacks, and medical professionals were not just concerned with safeguarding their income. One of the reasons seems to be that both for the government and for the medical profession, the necessity for some degree of cost control was part of a much broader discussion on the structure, objectives, planning and organization of healthcare. Besides financial motives, the tendency of the government to interfere more in health care, had clear substantive motives as well – including the perceived need to shift the accent from cure to prevention and care. In other words, there was a strong emphasis on the streamlining of the rapid flow of developments in this area, which is to say: on ‘direction’ rather than on ‘cutbacks.’⁴⁸

44. See a.o.: Bol, ‘1972’; A. W. Herwijer, ‘Onrustige Dokters’, *Medisch Contact* 29: 46 (1974), pp. 1503-5.

45. J. H. van den Berg, *Medische Macht en Medische Ethiek* (Nijkerk: Callenbach, 1969).

46. See also, in this context and with regard to general medical practice: Dwarswaard, *Dokter en Tijdgeest*, pp. 108-17.

47. See part 2 (chapters 4-6). And see almost all references in this and the previous sections of this chapter.

48. See on this, apart from many of the references in n. 43 above: C. Blankestijn, ‘Structureel Hoogtij. Een Vergelijking van de Knelpuntennota, de Structuurnota Gezondheidszorg en de Startnota Jeugdwelzijnsbeleid’, *Medisch Contact* 30: 23 (1975), pp. 695-700; Bol, ‘Visioen of Fictie’; H. J. Dokter, ‘Ordering, Systematisering en Aansluiting tussen Intra- en Extramuraal Gezondheidszorg’, *Medisch Contact* 30:

Needless to say, there was a great deal of resistance within the profession to the government plans. Yet it cannot be argued that the government and the medical profession were diametrically opposed to each other during the 1970s. To a certain extent, the profession agreed with government policy, for the need for planning, regulation and structuring was felt among medical professionals as well. This was very much evident in the series of articles that appeared in *Medisch Contact* in 1970 and 1971 on the 'future structure' and the 'objectives' of healthcare, which were both published in book format too.⁴⁹ Another good example is the speech made on this issue by KNMG president, Van der Drift, during the 1970 members' conference. He discussed 'three important reasons why we should involve ourselves not only in the study of the future, but also in the *controlling* of future developments'. These three reasons were: upscaling, acceleration and revolutionary developments in science, technology and society.⁵⁰

The strong emphasis that was placed on 'direction', planning and structuring fit in with the political and social climate of the 1970s.⁵¹ The same may be said of several solutions pleaded for in the 1970s as an answer to the problems in medicine and healthcare. This may be illustrated with the help of the above-mentioned speech by Van der Drift which, in many respects, is representative of what was argued in the course of this decade by opinion leaders in medicine. Van der Drift mentioned three policy areas in which 'creative, stimulating and anticipatory policy formation' would have to occur, one of which was the careful examination of structures of healthcare to determine their efficiency. A second area he pointed to was medical education. The way in which he wished to innovate education fit in with the widespread demand in society for the democratisation of higher

48 (1975), pp. 1541-5; 'Hoge Kosten Gezondheidszorg'; M. C. de Haan, 'Gezondheidszorgbeleid Vraagt Blauwdruk voor de Toekomst', *Medisch Contact* 31: 27 (1976), pp. 873-4; H. Oeges, 'Herstructurering Gezondheidszorg: een Revolutionair of een Evolutionair Proces?', *Medisch Contact* 32: 19 (1977), pp. 595-8; 'Het Wetsontwerp Voorzieningen Gezondheidszorg: Resumé van het Commentaar van de KNMG', *Medisch Contact* 32: 6 (1977), pp. 170-2; See also the summaries of the lectures at a 1976 LSV-symposium on 'Cost Control and Quality': 'Kostenbeheersing vanuit het Medisch Functioneren onder Handhaving van Kwaliteit: Eerste Serie Samenvattingen van de Voordrachten Gehouden op het L.S.V.-Symposium te Utrecht d.d. 10 December 1976', *Medisch Contact* 32: 1 (1977), pp. 11-16. See for the 'Tweede, Derde en Vierde Serie Samenvattingen' (second, third and fourth series of summaries): *Medisch Contact* 32: 3 (1977), pp. 66-76; *Medisch Contact* 32: 4 (1977), pp. 110-16; *Medisch Contact* 32: 5 (1977), pp. 146-150. See for other sources than *Medisch Contact*: n. 60 below.

49. This 13-part series started with an article in issue 2 and was finalised with an article in issue 14 of volume 26 (1970). The series on the 'objectives of healthcare' was initiated by an article in issue 23 of volume 26 (1971). A year later, this theme was picked up again by J. van Mansvelt in issue 31 of volume 27 (1972), and subsequently the editors decided to devote a series to his thema. Articles that were part of this series were published in the issues 35, 38, 45, 46, 49, 50, and 52 of volume 27 (1972) and in the issues 1,3,5,7,11, and 14 of volume 28 (1973).

50. Van der Drift, 'Arts, Mens, Maatschappij'. TB's italics.

51. See on the political and social climate of the 1970s : n. 60 below.

education and a better alignment of it with societal needs. He spoke of ‘the mobilisation of expertise that is present in society’ and the ‘putting into practice of co-responsibility’.

The last policy area to which Van der Drift drew attention pertained to ‘the issues of environmental healthcare and the promotion of well-being’.⁵² These issues were very much the focus of attention in the (first half of the) 1970s. The importance of environmental and mental health was constantly repeated in *Medisch Contact*. An often-heard sentiment at that time was that there was a need for the ‘socialisation’, and, perhaps, even politicisation of medicine – where physicians identified the pathogenic factors in society, and pointed the way towards the decontamination of society. All the attention to ‘well-being’ also had its effect on the discussions at the micro level of the consultation room. It was regularly argued that the attitude of physicians towards their patients not only had to be less paternalistic and more democratic, but also ‘more humane’. In general practice in particular, there was a great deal of interest in the psychosocial aspects of the health complaints of patients as well in the physician-patient relationship itself.⁵³ At this time when sociology was a popular mass study, a strong interest emerged among medical professionals – and GP’s in particular – into what insights and perspectives the social sciences could contribute to medicine and healthcare.⁵⁴

Thus, the medical professionals of the 1970s were children of their time, who embraced the ideas and approaches that suited their era. From this perspective, it is not a surprise that, as discussed in part II, Dutch epidemiologists in the 1970s were above all interested in public health, health services research and ‘policy and management’, while clinical epidemiology was hardly accepted at that time.⁵⁵ Moreover, it appears that the time was not yet ripe for a shift from disciplinary objectivity to mechanical objectivity in the form of something such as evidence-based medicine. This underlines the earlier remark that a historical explanation of the rise of EBM takes more than just the notion of a professional response to external pressure. It is also necessary to zoom in on the specific time and circumstances in which this happened. Especially interesting here is the question as to what *changed* in the course of the 1980s compared to the 1970s, and to

52. See n. 43 above.

53. See n. 43 above.

54. H. J. van Aalderen, ‘De Gedragwetenschappen in de Medische Opleiding’, *Medisch Contact* 27: 31 (1972), pp. 831-3; F. A. Bol, ‘Sociale Wetenschappen en Geneeskunde’, *Medisch Contact* 31: 24 (1976), p. 767; N. H. Groenman, ‘Gedragwetenschappen in het Medisch Onderwijsprogramma’, *Medisch Contact* 29: 36 (1974), pp. 1137-41; H. ten Kroode & S. K. Kwee, ‘Sociale Wetenschappen en Geneeskunde (II). Resultaat Van Drie Conferenties’, *Medisch Contact* 31: 25 (1976), pp. 806-12; H. ten Kroode & S. K. Kwee, ‘Sociale Wetenschappen en Geneeskunde (Slot). Proeve van een Opzet. Van Sociaal-Wetenschappelijk Onderwijs in het Medisch Curriculum’, *Medisch Contact* 31: 26 (1976), pp. 839-44; N. van Oosterzee, ‘Sociale Wetenschappen en Geneeskunde (I). Terugblik op Drie Conferenties’, *Medisch Contact* 31: 24 (1976), pp. 769-73.

55. See chapters 4, 5, and 6. See also, for example: Landheer, ‘Gezondheidszorgonderzoek’.

what extent these changes paved the way for the introduction of EBM in the Netherlands during the 1990s.

Shifts in the 1980s: 'From Healthcare Model to Management Model'

In many ways, the debates in the 1980s on medicine and healthcare were a continuation of those held in the previous decade. The most important issues essentially remained unchanged. The cost increase in the field continued unabated, medicine kept developing rapidly in terms of technology, the profession was still regularly confronted with criticism in the mass media, and the general impression was that patients were becoming increasingly emancipated. As a result many of the same concerns, varying from the struggle of individual physicians to stay 'up to date' to the necessity of establishing legal, and financial boundaries for healthcare,⁵⁶ continued to fill the pages of *Medisch Contact*.

Yet from the late 1970s, and increasingly manifestly so in the course of the 1980s, a number of shifts occurred in the discussions that were held on these kinds of issues. First of all, it is striking that interest in issues such as well-being, environmental health and psychosocial aspects in medical practice was clearly on the wane. The trend towards the 'socialisation' of healthcare slowly turned into a movement in which physicians seemed to increasingly limit themselves to their 'core business'. The post-war developments in which the concept of 'health' acquired an ever broader meaning, also seem to have regressed to a more limited focus on the prevention or treatment of illness. In reflections on the future of (general) medical practice or the position of the physician in society, arguments could increasingly be heard that may be summarised with the proverb 'every man to his own trade'. Since they could not or should not want to solve the problems of society anyway, physicians needed to stick to 'what they were good at' again.⁵⁷

56. See chapter 8 for more on the discussions on the boundaries of/for healthcare.

57. See for example the lecture by KNMG-president Daniëls from 1982 and Knottnerus' nuanced comments to his lecture: Daniëls, 'Plaats en Functie'; J. A. Knottnerus, 'Over Medicalisering en de "Leest van de Dokter"', *Medisch Contact* 38: 12 (1983), pp. 337-40. N.B.: see also the references in Knottnerus' article. See also, for example: F. N. M. Bierens, 'Verantwoorde Gezondheidszorg en Verantwoordelijkheid', *Medisch Contact* 40, no. 40 (1985), 1223-6; J. C. van Es, 'Verwachtingen', *Medisch Contact* 41: 5 (1986), p. 127; W. L. J. M. Laane, 'De Ziekte van Onze Gezondheidszorg. Goede en Betaalbare Gezondheidszorg: een Onbereikbaar Ideaal?', *Medisch Contact* 36: 51 (1981), pp. 1571-3; W. B. van der Mijn, 'Hoe Nu Verder?', *Medisch Contact* 37: 49 (1982), pp. 1583-4; A. W. Musschenga & E. Borst-Eilers, 'Prioriteiten in de Gezondheidszorg: Rechtvaardig Verdelen, Maar Hoe?', *Medisch Contact* 42: 1 (1987), pp. 13-19; D. Post, 'Heffen we de Eerste Lijn op? Huisarts en Specialist in een Nieuwe "Orde"', *Medisch Contact* 43: 19 (1988), pp. 591-3; C. Spreeuwenberg, 'De Toekomst van de Huisartsgeneeskunde', *Medisch Contact* 33: 39 (1978), pp. 1205-8; Idem., 'Universitaire Huisartsgeneeskunde'; A. Vrij, 'Bezinning op Gezondheidszorg', *Medisch Contact* 40: 41 (1985), pp. 1281-2. Furthermore, see the KNMG-report *Gezondheidszorg*

Another shift was that the strong focus on planning, organisation and structuring of healthcare slowly decreased. Stated in somewhat stereotypical terms: the ideal of malleability of the 1970s made way for the 'no nonsense' era of the 1980s. Partly as a result of this, the debates became 'more barren' as well. Due to declining interest in the question of how healthcare should be designed, it increasingly seemed as if it was about only one issue: the curbing of the cost of healthcare. During the study of successive volumes of *Medisch Contact*, for example, it became evident that, during both decades, there was frequent mention of a 'crisis' in healthcare. In the 1970s, a whole range of factors and developments was subsequently involved in the analysis, while in the 1980s, attention was increasingly focused on the uncontrollability of the costs. In other words: while, in the 1970s, *planning and structuring* seemed to be the key concepts, in the 1980s, *cost containment* was the order of the day.⁵⁸

This trend was summarised very well in 1982 in the headline above an editorial in *Medisch Contact*: 'From Healthcare Model to Management Model'.⁵⁹ Gone was the time,

bij Beperkte Middelen (Healthcare with Limited Resources) from 1986 and the commentary on that report by Van Es, the editor-in-chief of *Medisch Contact*: 'Gezondheidszorg bij Beperkte Middelen: KNMG-Commissie Rapporteer', *Medisch Contact* 41: 12 (1986), pp. 357-73; J. C. van Es, 'Gezondheidszorg in Proportie', *Medisch Contact* 41: 12 (1986), p. 351. The same trends in the 1980s were observed by Dwarswaard too, in her analysis of the journal *Huisarts en Wetenschap*, see: Dwarswaard, *Dokter en Tijdgeest*, p. 79.

58. Compare the reference in the previous sections of this chapter (for example n. 43 above) with (a.o.) the following editorials and articles from *Medisch Contact*: Ament, Van Arkel & Sturmans, 'Epidemiologie en Planning. 3'; J. L. A. Boelen, 'Kwaliteit Medisch Handelen: Naar een Maatstaf in het Zicht van de Budgettering', *Medisch Contact* 38: 32 (1983), pp. 991-4; Daniëls, 'Plaats en Functie'; J. C. van Es, 'Crux Medicorum', *Medisch Contact* 42: 4 (1987), p. 99; Idem, 'Kiezen of Delen', *Medisch Contact* 42, no. 1 (1987), p. 3; Idem, 'Carrot en Stick', *Medisch Contact* 38: 50 (1983), p. 1559; J. C. van Es & S. E. M. Everwijn, 'Wikken en Wegen in de Geneeskunde. Evaluatie: Context, Doelen, Consequenties', *Medisch Contact* 39: 8 (1984), pp. 237-40; Greep, 'Nederlandse Gezondheidszorg'; J. M. Greep & M. N. van der Heyde, 'Op Weg naar een Protocollaire Geneeskunde?', *Medisch Contact* 35: 18 (1980), pp. 551-2; L. M. J. Groot, 'Geneeskunde en Economie', *Medisch Contact* 37: 49 (1982), pp. 1570-4; F. J. A. Huygen, 'Kostenbeheersing in de Gezondheidszorg: de Rol van de Huisarts', *Medisch Contact* 39: 10 (1984), pp. 320-1; Laane, 'Ziekte'; Musschenga & Borst-Eilers, 'Prioriteiten'. See also the letters to the editor, published under the heading 'Overheid, KNMG en Matiging' in *Medisch Contact* 37: 11 (1982), pp. 307-10. See for other sources/literature than *Medisch Contact* in which the same trend is explicitly addressed: Grünwald, *Beheersing*; Idenburg et al., *Gezondheidszorg onder Druk*; C. A. de Kam, 'De Zorgen van Morgen', *Tijdschrift voor Sociale Gezondheidszorg* 62 (1984), pp. 951-4; H. J. J. Leenen, 'Grenzen van de Gezondheidszorg', *Tijdschrift voor Sociale Gezondheidszorg* 61 (1983), pp. 370-3; R. Naaborg, 'Kosten en Beleid in de Nederlandse Gezondheidszorg: Periode 1963-1983', *Acta Hospitalia* 24: 3 (1984), pp. 5-20. See also the reports of several governmental agencies on the theme of 'the boundaries of healthcare' (which will be discussed in detail in chapter 8), including: Gezondheidsraad, *Grenzen van de Gezondheidszorg*.
59. F. A. Bol, 'Van Zorgmodel naar Beheersmodel', *Medisch Contact* 37: 29 (1982), p. 851. A similar distinction – between a 'professional system' and 'a management system' – was suggested in: H. J. van der Steeg & F. C. A. Jaspers, 'Management en Professie: Blok of Blokkade?', *Medisch Contact* 41: 35 (1986), pp. 1105-6. In 1987, the then KNMG-president Cense also wrote about a shift from 'zorgmodel' (healthcare model) to 'beheersmodel' (management model), literally using these exact terms; see: W. H. Cense, 'Pre-Dekker-Syndroom', *Medisch Contact* 42: 10 (1987), p. 292.

it was contended, when the physician could exclusively work in accordance with the 'healthcare model', which meant that they only dealt with the individual patient and their healthcare needs. In the meantime, however, the era of the 'management model' had definitely begun, characterised by concepts such as bed reduction, strengthening of first-line support and budgeting in hospitals.

That the chief editor summed up these government measures, fits in with his conviction (shared by many other physicians at the time) that the emergence of the management model had been caused by the increasing influence of politics and legislation in healthcare. Therefore, a short sketch will follow below of the most significant developments and subsequent changes here during the 1970s and 1980s, followed by a characterisation of the way in which the medical profession responded to this.⁶⁰

In the 1970s, government policy was mainly aimed at the creation of 'system and coherence' in healthcare. Over time, a patchwork of provisions and regulations had originated, creating a strong need for 'organisation'. The Den Uyl cabinet (1973-1977), moreover, aimed to 'harmonise' the entire sphere of well-being – healthcare was considered one of its components. The aim was, not least, to keep cost increases under control by channeling the rapid developments in this area in a better way. This also fit in 'with the predominant vision at the time, that it was the task of the government to provide regulations in a welfare state', as was argued by the then director-general of health when reflecting on this many years later.⁶¹ With trial and error, a policy was established, which may be typified as planning and management of the supply. Legislation was created or prepared, which facilitated fairly detailed regulation of (mainly) the supply of hospital provisions.⁶²

The Den Uyl cabinet was succeeded by the first Van Agt cabinet (1977-1981), which had a different political stance. The new government believed much less in the benefits of state guidance. Even more important were the persistent economic headwinds, as a

60. The sketch, in the next few pages, of developments in Dutch healthcare policies is based on: K. P. Companje (ed.), *Tussen Volksverzekering en Vrije Markt. Verzekering van Zorg op het Snijvlak van Sociale Verzekering en Gezondheidszorg 1880-2006* (Amsterdam: Aksant, 2008), pp. 581-91, 684-8, 749-83; Gerritsen & Linschoten, *Gezondheidszorgbeleid*; Grünwald, *Beheersing*; H. E. G. M. Hermans, *Zorg en Markt in Historisch en Huidig Perspectief* (Deventer: Kluwer, 1991); H. C. van der Hoeven & E. W. van der Hoeven, *Om Welzijn of Winst: 100 Jaar Ziekenfondsen en Sociale Zekerheid* (Deventer: Kluwer, 1993), pp. 265-371; Idenburg et al., *Gezondheidszorg onder Druk*; Mooij, *Polsslag*, pp. 396-405; Musschenga & Borst-Eilers, 'Prioriteiten'; Naaborg, 'Kosten en Beleid'; Okma, 'Studies', pp. 90-102; 'Prof. Drs. J. Van Londen Wordt Voorzitter van de Nationale Raad voor de Volksgezondheid: "Het is Belangrijk dat de Eerste Aanvoerder van het Directoraat-Generaal een Arts is', *Medisch Contact* 46: 13 (1991), pp. 391-4; R. A. A. Vonk, *Recht of Schade: een Geschiedenis van Particuliere Zorgverzekeraars en hun Positie in het Nederlandse Zorgverzekeringsbestel, 1900-2006* (Amsterdam: Amsterdam University Press, 2013), pp. 193-300.

61. 'Prof. Drs. J. Van Londen'.

62. A.o.: 'Wet Ziekenhuis Voorzieningen' (Hospital Provisions Act) from 1971 and Wet Voorzieningen Gezondheidszorg (Health Care Provisions Act) which was established in 1982, but was never (entirely) implemented.

result of which major concerns arose about the sustainability of the welfare state. In these political and economic circumstances, the shift from 'healthcare model to management model' began to emerge. At the same time, it should be noted that a clear break in the trend in government policy with respect to healthcare did *not* occur in this period. The approach to government planning and supply management was broadly maintained. Only the roughest edges were removed.

The real turnaround in government policy with regard to healthcare took shape during the first Lubbers cabinet (1982-1986), which followed the short-lived second and third Van Agt cabinets (1981-1982). The policy of the first Lubbers cabinet had one clear main objective: putting government finances in order. During the previous years, public debts and budget deficits had sharply increased. Moreover, the Netherlands had plunged into an unprecedented structural economic crisis. In these circumstances, the government felt compelled to implement drastic cutbacks. As discussed in part II, the rigorous policies of the Ministry of Education and Science in this period contributed to a transformation of academic research. In the field of healthcare too, far reaching measures were taken. Immediately after accepting his post in 1982, the State Secretary of Health, Joop van der Reijden, announced his intentions to introduce budget financing for hospitals as of 1983, to press on with the reduction of the number of hospital beds, to create an arrangement for the establishment of independent professionals, and to fundamentally revise the system of healthcare insurance. In a first response, KNMG president Daniëls compared these policy intentions to 'heroic interventions' in surgery.⁶³ Van der Reijden himself subsequently spoke of 'major, forced changes'.⁶⁴

He was driven to do this because of the ambitious target set during the formation of the government: reducing the increase in the expenditure on healthcare to 0 per cent. Taking into account the explosive cost development that had been going on in this field for decades, this was a virtually impossible task.⁶⁵ However, Van der Reijden did succeed in realising the necessary 9 billion guilders' of budget costs (distributed across 1984, 1985 and 1986), save for 350 million guilders. This is not to say, however, that his policy was successful in all respects. The fundamental revision of the insurance system was not achieved, for example, although he did manage to implement a lesser reform of it. Yet there is no doubting the fact that the state secretary forcefully intervened in healthcare.

In the view of the then director-general of public health, J. van Londen, government policy had ended up in an entirely new 'developmental phase'. The thinking in terms of

63. 'KNMG-Voorzitter Dr. J.J.H.M. Daniëls: Nieuw Regeringsbeleid een Heroïsche Ingreep', *Medisch Contact* 37: 50 (1982), p. 1595.

64. J. P. van der Reijden, 'Terugblik op de Periode 1982-1986', in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidsbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 33-7.

65. See for example: 'De Nederlandse Volksgezondheid gedurende de Afgelopen Jaren in CBS-Cijfers', *Medisch Contact* 38: 52 (1983), p. 1628.

structure of the 1970s, which was still more or less present during the Van Agt cabinets, had made room for a new consideration, namely: 'how to *efficiently* use the available resources for healthcare'.⁶⁶ This shift was not only the result of the mounting tension between increasing cost and economic recession. The government, in addition to many other parties, including medical professionals themselves, was also of the opinion that the resources were not used efficiently enough. In the 1970s, there were already often explicit references to the McKeown thesis that expensive, curative healthcare only very marginally contributed to health gains and longer average life expectancy (at the population level). At the time, this mainly led to pleas for more attention for prevention as well as for a shift from secondary to primary healthcare. These views were clearly present in the 'Memorandum 2000', presented by Van der Reijden in 1985. Yet this could not conceal the fact that, under his administration, McKeown's 'lessons' were (probably in deviation from McKeown's own intentions) above all understood as legitimating the policy of cutting costs. This was based on the reasoning that healthcare had become increasingly expensive, without this being reflected in the 'yields'.⁶⁷ Therefore, in view of the economic circumstances, it could, and had to be demanded from healthcare institutions and healthcare workers that they started using the resources more efficiently. Budgeting was a particularly appropriate measure for this purpose, as it forced hospital administrators and, by extension, the healthcare professionals working in the hospitals too, to think about how they could use the available monies as well and, in particular, as efficiently as possible.

In retrospect, Van der Reijden himself regarded his administration as 'the closure of several decades in which the *planning* of welfare and health care was the first priority of political action in these policy areas'.⁶⁸ The motives for the cutbacks in public spending by the government of which he formed part were not only financial and economic, but also ideological. The first Lubbers cabinet was opposed to a welfare state that was strongly guided by state intervention, which manifested itself in a sharp focus on *deregulation*. Due to the legacy of previous cabinets, the policy of planning and structuring could not be entirely halted yet, but, according to Van der Reijden, the 'demise of planning' was finally there when the second Lubbers cabinet (1986-1989) took office.⁶⁹

During this second Lubbers cabinet, the sea change in the government's vision on healthcare policy was complete as *market mechanisms* were introduced in healthcare. A

66. 'Prof. Drs. J. Van Londen'.

67. The Scientific Council on Government Policy (Dutch abbreviation: WRR) too, (re-)interpreted the McKeown-thesis in this sense. In this context, the WRR also mentioned 'the law of diminishing returns'. See a.o.: J. M. Dekkers, 'Naar een Herwaardering van het Financieringsstelsel: de Wetenschappelijke Raad voor het Regeringsbeleid en het Kostenvraagstuk in de Somatische Gezondheidszorg', *Medisch Contact* 37: 50 (1982), pp. 1599-1602; Leenen, 'Grenzen'; De Kam, 'Zorgen'.

68. Van der Reijden, 'Terugblik'.

69. *Ibid.*

highly influential factor was the publication of the 1987 report, 'Bereidheid tot Verandering' ('Willingness to Change'), by the Committee on the Structure and Financing of Healthcare, better known as the Dekker-committee (which was chaired by Wisse Dekker, the former president of the Dutch multinational Philips). This committee pleaded for the introduction of a completely different and simpler insurance system. The distinction between public insurance funds and private insurers needed to be abolished. Instead, it was necessary to create a system with a compulsory basic health insurance for every citizen and optional additional insurances to be taken out voluntarily. On this last point, the market could do its work: insurers would have to compete with each other for the favour of the 'healthcare consumer'. Although the 'Dekker plan' was implemented with major adaptations and, moreover, not until 2006,⁷⁰ it formed a milestone because the 'market idea' had definitely arrived in Dutch healthcare.

This does not necessarily mean that this sector was entirely at the mercy of liberal market forces. Even the most outspoken proponents of 'free-market healthcare' realised that healthcare was not an 'ordinary' market, and that some degree of state regulation remained necessary. Nevertheless, the trend towards deregulation continued where, gradually, more and more room was made available for market incentives and market mechanisms. This 'transition from a centrally planned economy to a regulated market economy'⁷¹ was not considered a panacea by the then government, yet it was regarded as a prerequisite for 'cheaper' healthcare – among others things, because personal responsibilities could be enhanced this way, and cost-conscious action stimulated.⁷²

Quality and Efficiency

Against this political and economic background, a remarkable shift emerged in the way in which the issue of quality control and improvement in medical practice was approached. Very gradually, *efficiency* was increasingly being mentioned explicitly and emphatically as an essential (sub)component of the *quality* of medical practice. In 1983, E. Reerink, the then director of the aforementioned CBO (the Central Supervisory Body for Peer Review) wrote about this:

70. In 2006 the Health Insurance Act (Dutch: Zorgverzekeringswet) came into force, see chapter 9.

71. This is a quote from the former State Secretary for Health of the second Lubbers-cabinet, see: D. J. D. Dees, 'Terugblik op de Periode 1986-1989; in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidsbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 39-43.

72. This paragraph is partly a paraphrase from: Hermans, *Zorg en Markt*, pp. 14, 16. See also n. 60 above, and: J. C. van Es, 'Bereidheid Tot Verandering?', *Medisch Contact* 42: 15 (1987), p. 451; Idem, 'De Verzorgingsmaatschappij', *Medisch Contact* 38: 37 (1983), p. 1143; Idem, 'Budgettering een Strop', *Medisch Contact* 38: 6 (1983), p. 147; E. W. Roscam Abbing, 'Kwaliteit Medisch Handelen. Tussen Nu en 2000', *Medisch Contact* 38: 24 (1983), pp. 725-6.

‘The description of the concept of quality has evolved over the years. The following statement dates back to the thirties: “High-quality healthcare is healthcare for which all relevant knowledge and techniques are used that are at the disposal of healthcare.” From much more recently is the following description of the concept of quality: the degree of similarity between the objectives of healthcare and the healthcare actually provided. The economic concept of the scarcity of resources was recently introduced in healthcare, not only in the discussion on quality, but also in the description of it. The following phrase is from Williamson from the United States: “Quality is the degree of benefit achieved for the patient with a minimum of unnecessary use of resources and services”⁷³

It is not a coincidence that it was the director of CBO (Central Supervisory Body for Peer Review) who identified this development, as the link between quality and effectiveness was particularly emphasised in contemplations on peer review (in Dutch: ‘Intercollegiale Toetsing’). This happened in 1979, for example, when the four most prominent medical professional (umbrella) organisations in the Netherlands published a joint response to the government memorandum that had appeared a short time before, entitled ‘The Policy on Healthcare with regard to Cost Development’. In the comments from said organisations, it was stressed several times that their *own* initiatives in the field of peer review, which, admittedly, were primarily aimed at improving quality, ‘also proved effective on the point of cost containment’ in practice.⁷⁴ On behalf of the LSV, there was reference to the symposium on the theme of ‘Cost Containment in Medical practice with Preservation of Quality’, which this association had organised as far back as in 1976. It was also argued that the establishment in 1979 of CBO had resulted from this symposium.⁷⁵ A year later, the board of management of the KNMG published a report on ‘The Quality of Medical Professional Practice’.⁷⁶ In this report, peer review was discussed in depth as one of the most important quality-enhancing factors. It was also remarked that ‘increasing efficiency of medical practice, in particular’ is nowadays considered ‘a legitimate aim of peer review’.⁷⁷

In subsequent years, the link between the quality and efficiency of medical practice was established increasingly often, and with ever-growing self-evidence by medical professional organisations and individual medical professionals, but also by politicians and

73. E. Reerink, ‘De Kwaliteit van het Medisch Handelen in het Ziekenhuis’, *Medisch Contact* 38: 11 (1983), pp. 303-4.

74. ‘KNMG, LAD, LHV en LSV Reageren Samen op Regeringsnota Kostenontwikkeling’, *Medisch Contact* 34: 27 (1979), pp. 851-55, on p. 851.

75. *Ibid.*, p. 855. See on the LSV-symposium: ‘L.S.V.-Symposium’; ‘Kostenbeheersing. Eerste Serie’; ‘Kostenbeheersing. Tweede Serie’; ‘Kostenbeheersing. Derde Serie’; ‘Kostenbeheersing. Vierde Serie’.

76. ‘Kwaliteit van de Medische Beroepsuitoefening’.

77. *Ibid.*, p. 1633.

government agencies.⁷⁸ In 1982, for example, the Scientific Council for Government Policy (Dutch abbreviation: WRR) made a strong case for peer review as, among other things, a monitoring instrument of the efficiency of healthcare.⁷⁹ Similarly significant was the comprehensive attention paid to this issue in the 1986 report published by the KNMG Committee on Healthcare with Limited Resources. This committee was appointed in 1983 in response to the 'Healthcare with Limited Resources Memorandum' of the same year by State Secretary Van der Reijden, in which it was confirmed again that the healthcare policy of the first Lubbers cabinet would be dominated by considerable cut-

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78. See, for example (in chronological order); F. A. Bol, 'Gezondheidszorg en Politiek', *Medisch Contact* 34: 27 (1979), p. 847; Idem, 'Doelmatigheid of Bezuiniging', *Medisch Contact* 34: 41 (1979), p. 1307; 'Over Kostenbeheersing in de Klinische Geneeskunde. Afscheidsrede Prof. Dr. P.J. Donker', *Medisch Contact* 34: 45 (1979), pp. 1435-8; A. Kastelein & N. Willems, 'Diagnostische Verrichtingen en Algorithmen. Een Kostenbesparing?', *Medisch Contact* 35: 10 (1980), pp. 304-6; H. Reynders, 'Kostenbeheersing in de Klinische Geneeskunde', *Medisch Contact* 35: 10 (1980), pp. 311-12; Greep and Van der Heyde, 'Op Weg'; Greep, 'Nederlandse Gezondheidszorg'; Daniëls, 'Plaats en Functie'; Dekkers, 'Naar een Herwaardering'; R. J. M. Vandevelde, 'Intercollegiale Toetsing en Preoperatieve Screening', *Medisch Contact* 38, no. 5 (1983), pp. 134-6; Van Es, 'Budgettering een Strop'; 'Artsen Dienen Beter na te Denken alvorens tot Handelen over te Gaan', *Medisch Contact* 38: 10 (1983), p. 277; Reerink, 'Kwaliteit'; E. Reerink, 'Kwaliteitsbevordering van het Medisch Handelen: de Rol van het CBO', *Medisch Contact* 38: 11 (1983), pp. 304-6; A. F. Casparie, 'Maatstaven voor Goede Zorg. Consequenties voor de Medische Praktijk van Alledag', *Medisch Contact* 38: 12 (1983), pp. 349-50; O. Fokkens, 'De Grenzen van de Medische Beslisingsvrijheid', *Medisch Contact* 38: 15 (1983), pp. 440-2; M. N. van der Heyde, 'Protocollaire Geneeskunde: de Besluitboom in de Heelkunde', *Medisch Contact* 38: 21 (1983), pp. 621-2; T. C. G. M. Vissers, 'Protocollaire Geneeskunde', *Medisch Contact* 38: 23 (1983), pp. 685-8; J. J. F. M. de Man, 'Structurele Wijzigingen in de Nederlandse Specialistische Gezondheidszorg', *Medisch Contact* 38: 23 (1983), pp. 699-700; A. Kastelein, 'Kiezen of Delen. Over de Bruikbaarheid van de Diagnostiek', *Medisch Contact* 38: 24 (1983), pp. 721-4; Roscam Abbing, 'Kwaliteit'; Boelen, 'Kwaliteit'; L. M. J. Groot, 'Is het Veld Rijp voor Kostenbeheersing? Eerste Ervaringen met Budgettering van de Intramurale Instellingen van Gezondheidszorg', *Medisch Contact* 39: 2 (1984), pp. 39-40; J. C. M. Gerritsma & J. A. Smal, 'Besliskunde: een Nieuwe Loot aan de Boom van het Medisch Onderwijs', *Medisch Contact* 39: 6 (1984), pp. 179-82; Van Es & Everwijn, 'Wikken en Wegen'; Huygen, 'Kostenbeheersing'; Van Es, 'Rekenaars en Protocol-len'; Idem, 'Arts en Econoom', *Medisch Contact* 40: 48 (1985), p. 1483; Van Mansvelt, 'Verantwoorde Gezondheidszorg'; Idem, 'Verantwoorde Gezondheidszorg: Wie is voor Wat Verantwoordelijk?', *Medisch Contact* 41: 6 (1986), pp. 165-170; Van Es, 'Intercollegiale Toetsing'; A. J. B. I. Sips, 'Protocolen voor de Huisarts', *Medisch Contact* 41: 9 (1986), pp. 277-9; Van der Steeg & Jaspers, 'Management en Professie'; R. A. de Melker, 'Is de Huisarts tot Verandering Bereid? Het Rapport-Dekker en de Huisarts', *Medisch Contact* 42: 23 (1987), pp. 722-4; Cense, 'Uitdagend Perspectief'; Centraal Bestuur LSV, "'De Specialist van Morgen": Toekomstvisie in Nota Neergelegd', *Medisch Contact* 43: 11 (1988), pp. 327-8; KNMG, 'Commentaar op "Verandering Verzekerd"', *Medisch Contact* 43:17 (1988), pp. 539-43; W. Schellekens, "'Dekker" en Kwaliteit: Kwaliteit Gedekt?', *Medisch Contact* 44: 13 (1989), pp. 427-30; W. J. F. I. Nuijens, 'Kwaliteitsbewaking en Verzekeraars', *Medisch Contact* 44: 21 (1989), pp. 709-12. This tendency was also present in other sources than *Medisch Contact*. See for example: J. Lubsen & M. G. M. Hunink, 'Medische Besliskunde: een Oud Probleem in een Nieuwe Jas', *Nederlands Tijdschrift voor Geneeskunde* 128 (1984), pp. 249-57; L. M. J. Groot, *Budgettering: een Keerpunt* (Assen/Maastricht: Van Gorcum, 1985); Gezondheidsraad, *Grenzen van de Gezondheidszorg*, p. 48. See also: Dwarswaard, *Dokter en Tijdgeest*, pp. 79-81, 118, 123.
79. Cited in: Reerink, 'Kwaliteit'.

backs and enhancing *efficiency*. Three years later, the KNMG committee established that the efficiency of medical practice had been a 'subject of debate' for quite some time, and had, moreover, already led to significant initiatives on the part of the medical profession, as the 'principle of peer review' had been generally accepted 'a number of years ago'. While the quality of medical practice was most important, the CBO had nevertheless 'attempted to also gradually extend its field of action to an assessment of the resources used'.⁸⁰

In 1984, the Rotterdam professor of health economics, L.M.J. Groot, published a discussion on this development. He identified a 'to a certain extent, remarkable' phenomenon, namely that, recently, the efficiency of medical practice had become part of the concept of "quality". By 'remarkable', he did not necessarily mean that something odd or strange was going on, but rather something very special and praiseworthy, which made him optimistic about the future. He wrote about this:

When one has been involved in healthcare for quite some time, and when one compares the current circumstances to those of ten years ago, one finds that more has changed than deemed possible [...]. In particular, I would like to point to the shifts I notice in the profession. The taking of responsibility for the cost development and the willingness to put into perspective the professional element and the accompanying autonomy in the context of the limited resources, in particular, are issues that were certainly not open to discussion several years ago [...]. I am convinced that we, in the Netherlands, on the basis of the current willingness, will succeed in creating a reasonable solution to the problems surrounding cost control.⁸¹

This optimism was nowhere near shared by everybody. However, that something essential had changed in the mind set with regard to the quality and efficiency of medical practice within the medical profession, was noticed everywhere in the mid-1980s. In 1985, KNMG president Bierens provided a concise summary of this by speaking of 'the new quality concept in healthcare'.⁸²

This trend can be understood to a great extent from the perspective of the professional interests the KNMG and other professional medical organisations represented. An attempt was actually made to keep the government and other 'third parties' at bay by 'integrating' the issue of the cost of healthcare – summarised in the concept of effi-

80. 'Gezondheidszorg bij Beperkte Middelen', see in particular p. 367.

81. Groot, 'Is het Veld Rijp?'

82. Bierens, 'Verantwoorde Gezondheidszorg'. The notion that, 'in the last few years', a new quality concept had emerged within the medical profession was also stressed and elaborated on in (a.o.); Boelen, 'Kwaliteit', p. 993;; Van Es, 'Gezondheidszorg in Proportie'; K. J. L. Hoefnagels, 'Gezondheidszorg bij Beperkte Middelen: KNMG Bijt Spits af', *Medisch Contact* 41: 13 (1986), pp. 393-5; B. Leijnse, 'Economische Overwegingen bij de Toepassing van Medische Technologieën', *Medisch Contact* 41: 4 (1986), pp. 101-5; Spreeuwenberg, "'Verandering Verzekerd" (3)'. See also n. 78 above and n. 83 below.

ciency – in the quality of medical practice. As repeatedly stressed by these organisations, the quality of medical practice was very much an issue for the profession itself. At the same time, there was a clear awareness of the importance of accountability and a more efficient use of financial resources in a time of scarcity. Thus – and partly in answer to explicit demands by ‘third parties’ and at grass root level – the activities of professional organisations with regard to the quality (and thus also the efficiency) of medical practice intensified markedly as of the late 1970s, and particularly in the 1980s. This clearly may be considered to be a professional response to the changing political and economic circumstances.⁸³

Consensus Guidelines and Clinical Decision Analysis

As improvements in the quality and efficiency of medical practice were increasingly mentioned in the same context, the instrument that was to contribute to this came more and more under discussion. Peer review (‘Intercollegiale Toetsing’) as applied up to that time, was inadequate, according to a swelling chorus of voices. First of all, peer review should not take place on a voluntary basis alone, but it should be made compulsory, as argued, for example, by the WRR (the Scientific Council for Government Policy) in 1982.⁸⁴ In addition, there was a need for the formalisation and regulation of the method. Peer

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83. See a.o.: H. van Andel, ‘Medische Technologie Geëvalueerd: de “Consensus-Meeting”’, *Medisch Contact* 36: 45 (1981), pp. 1395-8; ‘De Arts als Toetsbare Professional: een Vervolggesprek met KNMG-Voorzitter W.H. Cense’, *Medisch Contact* 43: 1 (1988), pp. 9-10; H. G. Bessem, ‘Inhoud Geven aan de Kwaliteit van het Geneeskundig Handelen’, *Medisch Contact* 36: 52 (1981), pp. 1621-2; Casparie, ‘Maatstaven’; Cense, ‘Uitdagend Perspectief’; Centraal Bestuur LSV, “‘Specialist Van Morgen’”; Dekkers, ‘Naar een Herwaardering’; J. C. van Es, ‘Macht en Machteloosheid van de KNMG’, *Medisch Contact* 38: 28 (1983), p. 839; Idem, ‘Arts en Professie’, *Medisch Contact* 41: 45 (1986), p. 1443; ‘Gezondheidszorg bij Beperkte Middelen’; J. Heckman, ‘Kwaliteitsbewaking en Kostenbeheersing in Ziekenhuizen’, *Medisch Contact* 40: 15 (1985), pp. 454-6; D. B. Kagenaar, ‘Wetgevingsactiviteiten van Belang voor Medische Beroepsuitoefening’, *Medisch Contact* 36: 15 (1981), pp. 441-3; ‘KNMG, LAD, LHV en LSV Reageren’; S. van der Kooij, ‘Zilveren NHG-Jubileum. Vijftienvintig Jaar Nederlands Huisartsen Genootschap’, *Medisch Contact* 36: 47 (1981), pp. 1446-8; J. M. W. M. Merkus, ‘Oudste Wetenschappelijke Vereniging Bereid en in Staat tot Veranderen: Nederlandse Vereniging Voor Obstetrie en Gynaecologie 100 Jaar’, *Medisch Contact* 43: 20 (1988), pp. 627-8; Raat & Goudriaan, ‘Kwaliteitssystemen’; E. Reerink, ‘Kwaliteitsbewaking in het Ziekenhuis’, *Medisch Contact* 40: 41 (1985), pp. 1279-80; Idem, ‘Kwaliteit’; Idem, ‘Kwaliteitsbevordering’; Spreeuwenberg, “‘Verandering Verzekerd’ (3)”. See also: M. van den Burg & R. H. J. ter Meulen, ‘Prioriteiten binnen de Gezondheidszorg. Een Vergelijkende Studie naar Normatieve Overwegingen van Prioriteitenstelling in Zweden, Engeland en Nederland, in M. van den Burg et al., *Normatieve Aspecten van Richtlijnontwikkeling en Kosteneffectiviteitsstudies in de Cardiologie en Psychiatrie*. Deelrapport KNMG-Project Passende Medische Zorg (Utrecht: KNMG, 2000), appendix 3, on pp. 40-2; Dwarswaard, *Dokter en Tijdgeest*, pp. 108, 115-17.
84. See on this: Reerink, ‘Kwaliteit’. See also: F. A. Bol, ‘25 Jaar NHG’, *Medisch Contact* 36: 45 (1981), p. 1383.

review proved tricky when a 'benchmark' was not available.⁸⁵ The KNMG wrote in the 1986 report 'Healthcare with Limited Resources' that the initiatives of the CBO for the purpose of reviewing medical practice had been met with 'little support', 'also due to the lack of criteria, norms or standards necessary for such an assessment process. Therefore, according to the committee, 'further thought should be given to alternative assessment methods, such as protocolisation'.⁸⁶

'Protocol medicine', referred to in this quote, had arrived from the United States around 1980.⁸⁷ It initially involved protocols drafted during so-called 'consensus conferences'. During such conferences, leading representatives of the relevant disciplines would convene to ultimately agree on the correct practices and the procedures to be followed with respect to specific situations in medical practice. The resulting protocols could subsequently be used as a guidance tool for peer review. In the Netherlands, it was the CBO that took the lead when it came to the organisation of such consensus conferences. This started in 1982 with a first consensus meeting on blood transfusion policy, which led to the publication of the first CBO guidelines. In the ensuing years, many consensus meetings and guidelines would follow. In 1990, it could be reported that, in eight and a half years, 28 conferences were held (resulting in new guidelines) and three consensus texts were revised.⁸⁸

The CBO consisted of a director, a 'bureau' and a scientific council. There were three separate working groups for every guideline, which were managed and supported by the CBO. It was established in 1979 by the LSV and the Medical Association for the Promotion of the Hospital Sector with the aim of promoting the quality of medical practice in Dutch hospitals. It was financed via the tariffs for healthcare and stays in hospitals. The

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85. This is a paraphrase from the interview by TB with Siep Thomas, but this point was repeatedly made in *Medisch Contact* too, see n. 86 below.
86. 'Gezondheidszorg bij Bepaalde Middelen', p. 367 See also (in chronological order): Greep & Van der Heyde, 'Op Weg'; Greep, 'Nederlandse Gezondheidszorg'; Bol, '25 Jaar NHG'; M. de Haan & H. Hollenbeek Brouwer, 'Normen voor het Dokteren van de Huisarts: een Weinig Omschreven Vak', *Medisch Contact* 37: 51/52 (1982), pp. 1650-3; Reerink, 'Kwaliteitsbevordering'; Casparie, 'Maatstaven'; Vissers, 'Protocollaire Geneeskunde'; Boelen, 'Kwaliteit'; Van Es & Everwijn, 'Wikken en Wegen'; Grol et al., 'Onderlinge Toetsing'; Heckman, 'Kwaliteitsbewaking'; Raat & Goudriaan, 'Kwaliteitssystemen'; Bierens, 'Verantwoorde Gezondheidszorg'; F. Schwarz, 'Kwaliteitscontrole en Normering van het Medisch Handelen', *Medisch Contact* 40: 48 (1985), pp. 1489-91; Hamilton-van Hest, 'Intercollegiale Toetsing'; Sips, 'Protocollen'; Dwarswaard, *Dokter en Tijdgeest*, pp. 115-16.
87. See a.o.: Van Andel, 'Medische Technologie'; M. Evenblij, '25 Jaar CBO-Richtlijnen: een Blik in de Keuken van de Richtlijnenmakers', *Medisch Contact* 62: 45 (2007), pp. 1844-7.
88. R. P. T. M. Grol et al., 'Consensus over Consensus. Een Kritische Beschouwing van de Procedure van de CBO-Ontwikkeling', *Nederlands Tijdschrift voor Geneeskunde* 134 (1990), pp. 1186-9. See also: Van Andel, 'Medische Technologie'; Casparie, 'Maatstaven'; Van Es, 'Rekenaars en Protocollen'; Van Es & Everwijn, 'Wikken en Wegen'; R. Grol, W. Kistemaker & M. Hanrahan-Cahuzak, 'Invoering van Consensusrichtlijnen: Preventie van Ziekenhuisinfecties', *Medisch Contact* 45: 16 (1990), pp. 517-21; Knottnerus, 'Bouwstenen'; Reerink, 'Kwaliteitsbevordering'; Sips, 'Protocollen'.

guidelines that were developed over the years were therefore (mainly) intended for medical specialists and intramural healthcare in hospitals.⁸⁹

However, in general medical practice, too, protocol medicine became more widespread. In 1983, the first protocols on house visiting and examination of the newborn were drawn up. These and other 'early' guidelines in general medical practice concerned local or regional initiatives, which in no way always covered the entire country. This changed, when, in 1987, the Dutch Society of General Practitioners (Dutch abbreviation: NHG) commenced with the systematic development of national guidelines, the famed 'NHG standards', of which the first – on the treatment of Diabetes Mellitus type II – was published in 1989. The approach differed somewhat from that of the CBO, but, in essence, the NHG standards also (initially) came about with the help of the consensus method.⁹⁰

Virtually simultaneously with the consensus approach, there was a plea for a different approach to protocol medicine at the start of the 1980s, which was a great deal more scientific, according to proponents. Instead of guidelines on the basis of consensus, there should be protocols consisting of algorithms and decision trees. Put differently: the qualitative and subjective consensus method needed to make way for a more quantitative, 'objective' and controllable approach. The methodologies for this could be derived from clinical decision analysis (CDA), in which there was already a great deal of interest in the Netherlands in the 1980s. Halfway through this decade, advocates of such a formal type of medicine based on protocols also began to mention clinical epidemiology as supplier of scientific data and methods necessary for a proper foundation of decision trees and algorithms.⁹¹

89. 'Centraal Begeleidings Orgaan'; Evenblij, '25 Jaar'; Reerink, 'Kwaliteitsbevordering'.

90. P. V. M. Cromme et al., 'Diabetes Mellitus Type 2. NHG-Standaard', *Huisarts en Wetenschap* 32 (1989), pp. 509-12; Dwarswaard, *Dokter en Tijdgeest*, pp. 115-17; Evenblij, '25 Jaar'; K. Gill, 'Naar een Protocolaire Geneeskunde. Protocolaire Huisartsgeneeskunde, Schijn van Zekerheid?', *Huisarts en Wetenschap* 27 (1984), p. 32; Idem, 'Protocolaire Geneeskunde: Keurslijf of Aanwinst voor de Huisarts?', *Medisch Contact* 38: 34 (1983), pp. 1057-9; K. Gill & A. de Boer-Fleischer, 'Hoe Kijkt de Huisarts naar de Pasgeborene?', *Huisarts en Wetenschap* 26 (1983), pp. 386-7; R. Grol et al., 'Standaard en Consensus. Hoe Informeert de Huisarts Zijn Patiënten?', *Medisch Contact* 44: 13 (1989), pp. 435-7; V. C. L. Tielens, 'Het Nederlands Huisartsen Genootschap en Kwaliteitsbewaking in de Huisartsgeneeskunde', *Medisch Contact* 44: 22 (1989), pp. 748-50.

91. See (in chronological order): Greep & Van der Heyde, 'Op Weg'; Kastelein & Willems, 'Diagnostische Verrichtingen'; Greep, 'Nederlandse Gezondheidszorg'; Reerink, 'Kwaliteitsbevordering'; Casparie, 'Maatstaven'; Van der Heyde, 'Protocolaire Geneeskunde'; J. Roos, 'Protocol Toverkol?', *Medisch Contact* 38: 22 (1983), pp. 653-4; Vandeveldde, 'Intercollegiale Toetsing'; Gerritsma & Smal, 'Besliskunde'; Van Es & Everwijn, 'Wikken en Wegen'; Van Es, 'Medische Besliskunde'; A. J. Dunning, "'Medische Besliskunde": het Medisch Handelen als Proces', *Medisch Contact* 39: 9 (1984), pp. 269-71; T. C. G. M. Vissers & A. F. Casparie, 'Medische Besliskunde en de Kwaliteit van het Medisch Handelen', *Medisch Contact* 39: 9 (1984), p. 272; E. Zeppenfeldt, 'Protocolaire Geneeskunde', *Medisch Contact* 39: 44 (1984), pp. 1425-6; Van Es, 'Rekenaars en Protocollen'; Bierens, 'Verantwoorde Gezondheidszorg'; H. J. van der Helm & E. A. H. Hische, 'De Evaluatie van Diagnostische Technologieën: een Besliskundige Benadering', *Medisch Contact* 41: 9 (1986), pp. 273-6; J. C. van Es, 'Gouverner, C'est Prévoir', *Medisch Contact* 42: 3 (1987),

One of the first to highlight the combination of protocol, decision analysis and clinical epidemiology was the professor of epidemiology, Ferd Sturmans. He did so, among others, in an article in *Medisch Contact* in 1985, in which the controllability of healthcare costs was central.⁹² Large parts of this article were integrally incorporated a year later in the KNMG report 'Healthcare with Limited Resources', which Sturmans co-wrote himself as one of the committee members. Not only did the report plead for protocolisation, but it also explicitly asked how the diagnostic and therapeutic protocols should be created: according to the consensus method of the CBO or the 'more systematic form of decision analysis'? The latter option was subsequently explicitly selected. In addition, there was reference to the role the clinical epidemiologist could play here as methodologist.⁹³

In an appendix to the report, the committee and then KNMG president, Bierens, explicitly placed 'protocol medicine' in the context of cost containment and efficiency improvement. He wrote that 'efforts should be pursued to achieve greater efficiency'. A protocol, therefore, should not contain 'a sum of all the possibilities', but 'an optimal strategy'.⁹⁴ The message that the profession needed to take action itself, for else third parties would intervene, was not excluded either, as Bierens wrote:

'If the professional fails to develop protocols, it is inescapable that medical insurers will do this.'⁹⁵

Although various approaches often existed alongside one another, or were combined, the developments, as sketched above, may be placed in a chronological schema. Towards the end of the 1970s, peer review enjoyed the most interest, while at the beginning of the 1980s, this applied to protocol medicine according to the consensus method, and approximately halfway through this decade, the call for the application of decision analysis techniques in the establishment of guidelines, and for the acquisition of the data for this with the help of clinical-epidemiological research, prevailed.⁹⁶

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- p. 67; Knottnerus, 'Bouwstenen'. This trend was also visible in *Nederlands Tijdschrift voor Geneeskunde* (*Dutch Journal of Medicine*) as of 1984, see o.a.: Lubsen & Hunink, 'Medische Besliskunde'; H. J. G. H. Oosterhuis, 'Medische Besliskunde; vóór of tegen?', *Nederlands Tijdschrift voor Geneeskunde* 128 (1984), pp. 1948-51; J. D. F. Habbema, 'Beslissingsondersteunende Technieken voor de Kliniek, *Nederlands Tijdschrift voor Geneeskunde* 132 (1988), pp. 343-9. And see also: Groot, *Budgettering*, p. 18.
92. Sturmans, 'Is de Gezondheidszorg Beheersbaar?'. See also: Ament, Van Arkel & Sturmans, 'Epidemiologie en Planning. 3'; Sturmans & Van Arkel, 'Epidemiologie en Planning. 4'; Ament, Van Arkel & Sturmans, 'Epidemiologie en Planning. Slot'.
93. 'Gezondheidszorg bij Beperkte Middelen'.
94. *Ibid.*, pp. 372-3.
95. *Ibid.*, p. 372.
96. This is (a.o.) tentatively derived from the number of 'hits' in successive volumes of *Medisch Contact* and *Nederlands Tijdschrift voor Geneeskunde*, using keywords such as 'intercollegiale toetsing' ('peer review'), 'protocol', 'besliskunde' (decision analysis) en 'klinische epidemiologie' ('clinical epidemiology').

In the light of the Porter thesis, this trend may be interpreted as follows. Due to its internal, informal and voluntary nature, peer review as it was introduced in the 1970s, may be regarded as a strategy aimed at the consolidation of disciplinary objectivity. Over time, however, this instrument became increasingly encapsulated – or at least attempts were made to this effect – in a system of protocol medicine. In addition, within protocol medicine, there was increasing criticism of the consensus method of the CBO, and there was an increasingly explicit call for a more systematic, formalistic decision analysis approach based on numerical knowledge. This trend may be perceived as a shift in the direction of ‘mechanical objectivity’. In this context, it is worth noting that, in 1988, Vandenbroucke interpreted (and welcomed) the emergence of clinical decision analysis, clinical epidemiology and medical technology assessment⁹⁷ as ‘*quantitative modernism*’.⁹⁸

The above-mentioned developments were largely enforced by the economic recession and government policy. Nevertheless, it must also be noted that, above all, it was (some) medical professionals who enthusiastically set to work on peer review, protocolisation, consensus conferences and clinical decision analysis. In addition to strategic reasons and professional interests that could form an incentive here, medical considerations often gave rise to this. It was repeatedly stated in *Medisch Contact* that it was not only external critics or politicians who wanted to implement cutbacks or had doubts about quality, effectiveness and efficiency in healthcare. In this respect, the 1980s saw a continuation of the discussions held in the 1970s within the medical profession. This trend seems to have enhanced itself, as attention to the phenomenon (and problem) of the inter-physician and interregional variation clearly increased, partly because research into this did not properly start in the Netherlands until the 1980s. In addition, when studying the successive issues of *Medisch Contact*, the impression arises that the critical ideas on medicalisation and iatrogenesis, which emerged in the seventies, became increasingly internalised over time within the medical profession itself.⁹⁹

97. Medical technology assessment and its relation to EBM will be discussed in chapter 8.

98. Vandenbroucke, ‘Kwantitatieve Nieuwlichterij’.

99. The Dutch medical ethicist M. Christiaens even argued in 1983 that ‘all along the line’ an important shift in the thinking about health care had occurred. He exemplifies this by a change of attitude toward the criticism toward medical practice of the philosopher Illich. In the 1970s Illich ideas were generally rejected, but in 1983 they had ‘become commonplace well into the highest echelons of health care policy.’ See: M. Christiaens, ‘Arts, Patiënt, Gemeenschap: naar een Nieuwe Driehoeksverhouding’, *Medisch Contact* 38: 29 (1983), pp. 894-6. Indeed, in his 1982 lecture, the then KNMG-president argued that Illich had been ‘right on many points’. See: Daniëls, ‘Plaats en Functie’. See also, on this lecture: Knottnerus, ‘Over Medicalisering’. Furthermore, the ideas of McKeown served as source of inspiration and guidance for the KNMG-rapport ‘Healthcare with Limited Resources’. And see also the manner in which the issue of regional and inter-physician variation was addressed in this report: ‘Gezondheidszorg bij beperkte middelen’; Hoefnagels, ‘Gezondheidszorg bij Beperkte Middelen’; P. J. Thung, ‘KNMG-Rapport “Gezondheid bij Beperkte Middelen”. Doelstellingen: Gronden en Grenzen van de Gezondheidszorg’, *Medisch*

It was also increasingly and emphatically argued in this period that physicians should perhaps exercise more restraint when it came to all technological possibilities. Above all, there was a great deal of criticism of the way in which diagnostics were sometimes practiced in medical practice. In itself, this was nothing new. Already in 1961, the Amsterdam professor of internal medicine, J.C.G. Borst, had, in a speech during a KNMG conference, taken a stand against what he called ‘*médecine à la mitrailleuse*’: routine and often irresponsible and dangerous research methods used with diagnostics. Borst pleaded for fewer and selective diagnostics.¹⁰⁰ It seems that Borst’s message was more current than ever in the early 1980s. It was referred to several times, among others by Ad Dunning, the Amsterdam professor of cardiology, in his best-seller *Broeder Ezel* (*Brother Donkey*) from 1981. In it, Dunning used Borst’s concept of ‘*médecine à la mitrailleuse*’ to describe a medical practice ‘where the heavy artillery with which our diagnostic arsenal is equipped is tested on anything that moves in the medical field of fire’ and where ‘the link between head and hand is severed, for patient listening is replaced with the diagnostic mill that is to grind blood, urine or X-ray images in such a way, that it is not the physician but the mill of medical technology that separates the diagnostic chaff from the wheat’.¹⁰¹ Again, the concepts of ‘quality’ and ‘efficiency’ went hand in hand in these kinds of contemplations: the excessive use of diagnostic technologies was both expensive and unnecessarily burdensome and sometimes even downright harmful for the patient. Against this

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- Contact 41: 14 (1986), pp. 442-8. See also the lecture of KNMG-president Bierens from 1985: Bierens, ‘Verantwoorde Gezondheidszorg’. See for the attention for and research on inter-physician and regional variation the influential publications of J.P. Mackenbach as of 1988, a.o.: J. P. Mackenbach et al., ‘Regional Differences in Mortality from Conditions Amenable to Medical Intervention in the Netherlands: a Comparison of 4 Time-periods’, *Journal of Epidemiology and Community Health* 42 (1988), pp. 325-32; Idem, ‘Regional Differences in Decline of Mortality from Selected Conditions, The Netherlands, 1969-1984’, *International Journal of Epidemiology* 17 (1988), pp. 821-9. See for more publications of Mackenbach on this subject PubMed, or: <http://survey.erasmusmc.nl/intern/pwp/jpmackenbach&tab=4>. In addition, see for more relevant articles from *Medisch Contact* (in chronological order): Van der Mijjn, ‘Hoe Nu Verder?’; ‘Is de Gezondheidszorg het Waard? Oratie Prof. Dr. R.M. Lapré’, *Medisch Contact* 38: 16 (1983), pp. 481-2; Boelen, ‘Kwaliteit’; J. C. van Es, ‘Verantwoord Kiezen: Doelen in de Gezondheidszorg’, *Medisch Contact* 39: 9 (1984), pp. 273-5; Idem, ‘Waar Gehakt Wordt Vallen Spaanders’, *Medisch Contact* 39: 42 (1984), p. 1339; A. F. Tempelaar, ‘Iatrogene Schade: het Onvermijdelijke Neveneffect van de Geneeskunde’, *Medisch Contact* 39: 42 (1984), pp. 1345-8; Mansvelt, ‘Verantwoorde Gezondheidszorg’; A. W. Kessener, ‘Herwaardering en Heroriëntatie. 1: op het Verkeerde Been’, *Medisch Contact* 42: 6 (1987), pp. 172-4; H. Festen, ‘Wat is er aan de Hand in de Gezondheidszorg?’, *Medisch Contact* 42: 30 (1987), pp. 927-30; A. D. Molendijk, ‘Over Bevordering van de Geneeskunst: Ouverture tot het Jaar 2000’, *Medisch Contact* 44: 6 (1989), pp. 201-2; G van der Speld, ‘Regionale Verschillen in het Ziekenhuis’, *Medisch Contact* 45: 7 (1990), pp. 215-17; C. Spreeuwenberg, ‘De Discipline van een Discipline’, *Medisch Contact* 45: 16 (1990), p. 503. See also: Dwarswaard, *Dokter en Tijdgeest*, pp. 79-81, 109, 118, 122-3.
100. J. G. G. Borst, ‘Noodzakelijk, Overbodig en Schadelijk Geneeskundig Onderzoek’, *Nederlands Tijdschrift voor Geneeskunde* 105 (1961), pp. 2449-57. This paraphrase is derived from: Gill, ‘Protocollaire Geneeskunde’.
101. A. J. Dunning, *Broeder Ezel. Over het Onvermogen in de Geneeskunde*, Pocket ed. (Amsterdam/ Utrecht: Meulenhoff & Bunge, 1981), p. 65.

background, there were many calls within the medical world for more and better critical evaluation of (new) medical technologies with the help of Medical Technology Assessment (which will be discussed further in chapter 8).¹⁰²

Besides a more intrinsic motivation to work on a more efficient and thus better medical practice, there were also more specific reasons why some physicians were interested in instruments such as protocol medicine and clinical decision analysis. The most important of them was perhaps the growing need for a greater *grip* on medical practice. The problem of the increasing 'incompetence' of the individual physician, which was identified in 1978 by Winkler, also remained cause for concern in the 1980s. With great regularity and a sense of urgency, *Medisch Contact* devoted attention to the increased complexity and number of choices in medical practice, the unstoppable explosion of medical knowledge, and, in particular, the ever-increasing extent of *uncertainty* with which physicians were faced. This theme was also explicitly addressed in publications other than those in *Medisch Contact*, for example in *Broeder Ezel* by Dunning, which had as its subtitle: *Over het Onvermogen in de Geneeskunde (On the Incompetence in Medicine)*. Various authors called for more reflection on the many uncertainties within medicine. Rather than an air of self-confidence, physicians should adopt an attitude of doubt, scepticism and suspicion. It is conceivable that, as they thus increasingly became aware of the uncertainties of medicine and their own incompetence as individual professionals, medical professionals were more open to tools that could contribute to better, more substantiated and more efficient clinical decision-making. More so than peer review, consensus guidelines and clinical decision analysis promised to provide them with some grip on clinical practice.¹⁰³

102. See a.o.: A.J. Dunning, 'Medische Technologie: "Het Hoofd van Janus en de Kop van Jut"', *Medisch Contact* 37: 49 (1982), pp. 1574-7; Idem, "'Medische Besliskunde'"; Gill, 'Protocollaire Geneeskunde'; 'Is de Gezondheidszorg het Waard?'. In addition, there were many articles in which the same message was put forward, but without using the term 'médecine à la mitrailleuse'. See: Van Andel, 'Medische Technologie'; 'Artsen Dienen Beter na te Denken'; H. B. Bruins, 'Kostenbewaking in de Gezondheidszorg: een Plan voor Individuele Budgettering?', *Medisch Contact* 39: 5 (1984), pp. 148-9; Casparie, 'Maatstaven'; Dekkers, 'Naar een Herwaardering'; J. C. van Es, 'Laboratoriumonderzoek Onderzocht', *Medisch Contact* 41: 49 (1986), p. 1571; Idem, 'Medische Technologie en Indicatiestelling', *Medisch Contact* 41: 4 (1986), pp. 108-10; Idem, 'Carrot en Stick'; Idem, 'Medische Besliskunde'; Idem, 'Verantwoord Kiezen'; Idem, 'Waar Gehakt Wordt'; Greep, 'Nederlandse Gezondheidszorg'; Greep & Van der Heyde, 'Op Weg'; Van der Helm & Hische, 'Evaluatie'; Van der Heyde, 'Protocollaire Geneeskunde'; Kastelein, 'Kiezen of Delen'; Kastelein & Willems, 'Diagnostische Verrichtingen'; Knottnerus, 'Over Medicalisering'; J. Leenders, 'Technologische Veranderingen en Economische Evaluatie in de Gezondheidszorg', *Acta Hospitalia* 24: 1 (1984), pp. 37-46; R. A. de Melker, 'Controversen in de Geneeskunde', *Medisch Contact* 36: 6 (1981), pp. 163-4; 'Over Kostenbeheersing'; Roos, 'Protocol Toverkol?'; Vandeveld, 'Intercollegiale Toetsing'; T. C. G. M. Vissers, 'Strategieën om een Ongebreidelde Groei van Medische Technologieën te Voorkomen', *Medisch Contact* 41: 4 (1986), 105-7; Idem, 'Protocollaire Geneeskunde'.

103. See on all this (in chronological order): De Melker, 'Controversen'; 'Artsen Dienen Beter na te Denken'; Knottnerus, 'Over Medicalisering'; Casparie, 'Maatstaven'; Van der Heyde, 'Protocollaire Geneeskunde'; Kastelein, 'Kiezen of Delen'; Gerritsma and Smal, 'Besliskunde'; Van Es, 'Medische Besliskunde'; Dunning, "'Medische Besliskunde'"; Vissers & Casparie, 'Medische Besliskunde'; Lubsen & Hunink, 'Me-

In short, the shift towards ‘mechanical objectivity’, as it became apparent in the treatment of the issue of quality and efficiency of medical practice, was not only the result of ‘external’ pressure – in other words: of the need for cost containment, transparency and control on the part of politics and society. Support for this also existed among medical professionals themselves. How strong this ‘internal support’ was, however, is extraordinarily difficult to establish. Statements on these issues were usually made by the same ‘opinion leaders’ and board members of professional organisations. It remains a matter of conjecture what the views on this were among medical professionals in the country. It is very much conceivable that only a minority or ‘vanguard’ was committed to peer review, protocols and decision analysis. Without ‘external pressure’, perhaps little or nothing would have come of all the concrete efforts in these fields.

With regard to the introduction of budgeting in particular, it has been repeatedly said – already at that time – that it functioned as the crucial big stick. Several examples of this can be provided,¹⁰⁴ including some remarks from the KNMG report ‘Healthcare with Limited Resources’. In this report, it was explicitly stated that, after the still unsuccessful attempts of the CBO to monitor efficiency, it had now become necessary ‘partly under pressure from budgeting’ to set to work with protocol medicine.¹⁰⁵ This point was moreover addressed when one of the central arguments of the report was postulated and defended, namely: ‘Despite or *perhaps due to* the limited resources, the quality of healthcare could be improved.’ Typical for the way of thinking in the 1980s, as opposed to the 1970s, this argument was further explained with the help of a comparison between (inefficient)

dische Besliskunde’; R. Grol et al., ‘De Onzekere Huisarts: een Studie naar Onzekerheid bij Medische Beslissingen en de Gevolgen daarvan voor het Huisartsgeneeskundig Handelen’, *Medisch Contact* 40: 45 (1985), pp. 1400-2; Sips, ‘Protocolen’; Reerink, ‘Kwaliteitsbewaking’; C. Ridderikhoff, ‘Medische Besluitvorming bij Artsen’, *Medisch Contact* 42: 43 (1987), pp. 1383-6; J. M. Greep & L. M. L. Ch. Siezenis, ‘Principes van Medische Besluitvorming: Protocolen, Beslisbomen en Algoritmen’, *Medisch Contact* 43: 51/52 (1988), pp. 1589-92; Habbema, ‘Beslissingsondersteunende Technieken’; Molendijk, ‘Over Bevordering’; See also: Dwarswaard, *Dokter en Tijdgeest*, pp. 109, 116, 122.

104. ‘Arts Als Toetsbare Professional’; Y. Bally, G. Haan & R. Starmans, ‘Evaluatie Medische Technologie. Problemen en Mogelijkheden bij Diagnostiek’, *Medisch Contact* 40: 49 (1985), pp. 1521-3; Bierens, ‘Verantwoorde Gezondheidszorg’; Boelen, ‘Kwaliteit’; Bruins, ‘Kostenbewaking’; A. F. Casparie, ‘Interne Budgettering: Taak en Plaats van de Medische Staf in de Organisatie van het Ziekenhuis’, *Medisch Contact* 39: 20 (1984), pp. 623-6; Dwarswaard, *Dokter en Tijdgeest*, pp. 201-3; Van Es, ‘Budgettering een Strop’; Idem, ‘Verantwoord Kiezen’; O. Fokkens, ‘Waar Blijft de Stimulus? Fixatie op Normen Belemmert Afweging van Prioriteiten’, *Medisch Contact* 38: 50 (1983), pp. 1563-5; Idem, ‘Grenzen’; Groot, ‘Is Het Veld Rijp?’; Idem, *Budgettering*; Hoefnagels, ‘Gezondheidszorg bij Beperkte Middelen’; De Man, ‘Structurele Wijzigingen’; Reerink, ‘Kwaliteitsbevordering’; Roscam Abbing, ‘Kwaliteit’; J. H. Schaaf, ‘Budgettering in Ziekenhuizen: de Rolverdeling tussen Professie en Management’, *Medisch Contact* 39: 2 (1984), pp. 41-4; Van der Steeg & Jaspers, ‘Management en Professie’; Vissers, ‘Strategieën’.
105. ‘Gezondheidszorg bij Beperkte Middelen’, p. 368 See also: Sturmans, ‘Is De Gezondheidszorg Beheersbaar?’.

healthcare and (much more efficient) industry.¹⁰⁶ While it was a *conditio sine qua non* in industry that people kept looking for production processes that made it possible to place an increasingly better product on the market at the same or, preferably, a lower cost, in healthcare, 'the drive to constantly search for quality improvement with the same or declining resources' had been lacking 'until recently'. Therefore, the use of techniques such as 'operations research' had remained limited 'to a small circle of "hobbyists"' in healthcare. It was subsequently stated in the report: 'Due to the introduction of budgeting, this suddenly changed completely.'¹⁰⁷

Translated freely, this government measure rudely aroused the medical profession and other professions from their slumber, and forced them to become inventive. Already in 1983 – the year of the introduction of budgeting, one of the committee members, R.M. Lapré, had said in Rotterdam during his inaugural lecture as professor in healthcare policy and the economy of healthcare:

'If an economic crisis and cutbacks were necessary to examine the use of medical intervention in a more systematic and critical way than before, then perhaps something positive is born from this negative background.'¹⁰⁸

Thus, in the end, the political and economic circumstances of the 1980s, and, in particular, the austerity policy of the first Lubbers cabinet caused a significant change: the non-committal approach disappeared from the debates on quality and efficiency of healthcare. For the first time, a more or less focused 'quality policy' was created, both on the side of the ministry as on the side of institutions and professional organisations. At the end of the 1980s and at the beginning of the nineties, few issues in and surrounding healthcare attracted the level of attention of the issue of 'quality'. All manner of things were written about it, and all manner of initiatives were taken in this field. A good example of this

106. Just to mention a few interesting examples: KNMG-president Bierens stirred up a lot of controversy in 1985, by arguing, in the opening speech of the yearly member conference, that, by working more efficiently, 3 to 5 billion guilders could be saved in Dutch healthcare. The commotion thus created, forced him to elucidate his statement. He did so by maintaining that healthcare (as a whole) could and should be steered as if it were a business enterprise. See: 'Doelmatigheid en Doeltreffendheid in de Gezondheidszorg: KNMG-Voorzitter F.N.M. Bierens Verduidelijkt Visie', *Medisch Contact* 40: 42 (1985), pp. 1317-18. The Rotterdam professor of clinical chemistry, B. Leijnse, expressed this view even more concisely a year later: 'Healthcare will become business [...], because non-profit and efficiency are at odds with each other'. See: Leijnse, 'Economische Overwegingen'. See also: Cense, 'Uitdagend Perspectief'; Hoefnagels, 'Gezondheidszorg bij Beperkte Middelen'; A. Kroonen & J. M. Boot, 'Marktelementen in de Gezondheidszorg: over het Stellen van Rationele Voorwaarden', *Medisch Contact* 42: 30 (1987), pp. 931-3; G. de Wilde, 'Marketing in de Gezondheidszorg', *Medisch Contact* 36: 48 (1981), pp. 1481-4.

107. 'Gezondheidszorg bij Beperkte Middelen'. TB's italics. See also: Heckman, 'Kwaliteitsbewaking'; Sturmans, 'Is de Gezondheidszorg Beheersbaar?'

108. Cited in: 'Is de Gezondheidszorg het Waard?'

were the ‘Leidschendam Conferences’ on the ‘quality of healthcare’, which the KNMG organised as of 1989 at the request of the Ministry of Health. The theme of ‘quality of healthcare’ was, of course, a great deal broader than that of the quality of medical practice as such. The quality of organisations and of structures in healthcare was also discussed, as was, for example, the quality of the conduct by healthcare professionals towards patients. The quality (and efficiency) of medical-technical practice was nevertheless an important part of all the discussions and activities in this area. With regard to this, the development of (consensus) guidelines by the CBO and the NHG stood out. In addition, attempts were made to create more acceptance of clinical decision analysis, for example via a sub-programme of the Health Research Promotion Programme (Dutch abbreviation: SGO).¹⁰⁹

Conclusion: a Fluent Transition to the EBM Era

In summary, in the course of the 1980s, two related trends were visible. In the first place, efficiency was increasingly regarded as an inherent part of quality. Secondly, the specific activities with respect to quality improvement of medical practice displayed a shift towards what Porter would call ‘mechanical objectivity’. Thus viewed, the Porter thesis seems more applicable to the 1980s than to the 1970s. In both decades, the medical profession was under pressure, but the specific circumstances differed, so that there were important differences in emphasis in the chosen solution strategies.

These two trends may (in part) be attributed to a growing need, both with the government and with the profession, for more grip on medical practice. The government wanted to be able to finally contain the ever-rising cost of healthcare. Under the political and economic circumstances of the 1980s, the medical profession, too, benefited from a more

109. See for more on the CBO and the NHG: chapters 8 and 9, and: Dwarswaard, *Dokter en Tijdgeest*, pp. 115-17; Grol et al., ‘Consensus over Consensus’; Grol et al., ‘Standaard en Consensus’; Knottnerus, ‘Bouwenstenen’; Tielens, ‘Nederlands Huisartsen Genootschap. See with regard to the general trend described in this paragraph: Th. M. G. Berkesteijn & P. J. A. Colsen, ‘“Kwaliteit van Zorg”: een Conferentie van de KNMG voor WVC’, *Medisch Contact* 44: 13 (1989), pp. 423-5; A. P. M. Bersee, ‘De Hoofdlijnen van het Kwaliteitsbeleid’, *Medisch Contact* 45: 45 (1990), pp. 1337-8; Van den Burg & Ter Meulen, ‘Prioriteiten binnen de Gezondheidszorg’, pp. 40-2; A. F. Casparie, ‘De (Actieve) Rol van de Beroepsgroep bij de Kwaliteitsborging’, *Medisch Contact* 45: 51/52 (1990), pp. 1538-9; Idem, ‘Kwaliteit in de Gezondheidszorg: Huidige Inzichten en Toekomstige Ontwikkelingen’, *Medisch Contact* 44: 14 (1989), pp. 477-82; Centraal Bestuur LSV, ‘“De Specialist van Morgen”’; J. R. B. Polee, ‘Protocollaire Geneeskunde in de Oncologie’, *Medisch Contact* 38: 18 (1983), pp. 533-4; Schwarz, ‘Kwaliteitscontrole’; C. Spreeuwenberg, ‘Kwaliteit Centraal!’, *Medisch Contact* 44: 50 (1989), p. 1639; Idem, ‘Kwaliteit van Zorg’, *Medisch Contact* 44: 13 (1989), p. 419; Idem, ‘Discipline’; Idem, ‘Toetsing’; ‘Staatssecretaris H.J. Simons Streeft naar Consensusvorming in het Veld’, *Medisch Contact* 44: 49 (1989), pp. 1608-9. See for an overview of the activities on quality improvement and quality control of professional organisations of medical specialists: A. F. Casparie, J. J. E. van Everdingen & P. P. J. Touw, ‘Kwaliteitsbevordering en Kwaliteitsbewaking: een Taak van de Wetenschappelijke Verenigingen?’, *Medisch Contact* 44: 45 (1989), pp. 1478-81.

efficient use of the available resources. As a result of the rapid developments in health-care, physicians were moreover faced with all sorts of problems, such as the (relative) incompetence of the individual professional, the increasing complexity of and uncertainty in medical practice, doubts about the usefulness of all the new technological possibilities, and the increasingly generally accepted danger of (negative) medicalisation. Thus, the combination of an explosive development in costs and the side-effects of the fast medical progress of the latter half of the twentieth century, resulted in a situation where the various parties involved sought effective mechanisms of control for medicine.

The way the specific initiatives unfolded in the field of consensus guidelines and clinical decision analysis was nowhere near smooth or without difficulty and resistance in the 'field'.¹¹⁰ Yet it may be stated that, in a certain sense, they paved the way for the introduction of evidence-based medicine in the Netherlands. In the development of their guidelines and standards, the CBO and the NHG shifted the emphasis from the consensus method to 'EBM' in the course of the 1990s. There was also a close relationship between clinical decision analysis on the one hand, and clinical epidemiology and EBM on the other hand. In chapter 6, it was already discussed how various people who carried out pioneering work in the Centre for Clinical Decision Analysis in Rotterdam, subsequently took the lead in the further development of clinical epidemiology, the Dutch Cochrane Centre and evidence-based medicine – among others within the 'guidelines for clinical practice' programme of the Academic Medical Centre (AMC) in Amsterdam. Within the AMC, the decision analysis expert David Eddy was still considered an important inspirer, while, at the same time, there were attempts to give concrete form to clinical epidemiology and 'evidence-based medicine' according to McMaster's model.¹¹¹

Thus, it appears that the introduction of EBM in the Netherlands occurred as an extension of the above-mentioned developments in the 1980s. With the 'evidence-based' guidelines that emerged from the 1990s, essentially the same goals were pursued as with the consensus guidelines and decision analysis approaches that had already featured a decade earlier. In addition, there was the same underlying link between the efficiency and quality of medical practice. Moreover, many of the people who were involved in the developments in the fields of guidelines development, decision analysis, clinical epidemiology and patient-related research in the 1980s, subsequently became important repre-

110. See for example: Casparie, 'Maatstaven'; R. J. M. Dillmann, 'Het Protocol Nader Bekeken', *Nederlands Tijdschrift voor Geneeskunde* 132 (1988), pp. 340-3; Van Es, 'Carrot en Stick'; Van Es & Everwijn, 'Wijken en Wegen'; Fokkens, 'Waar Blijft de Stimulans?'; Van der Heyde, 'Protocollaire Geneeskunde'; Kasstelein, 'Kiezen of Delen'; Knottnerus, 'Bouwstenen'; Oosterhuis, 'Medische Besliskunde'; Polee, 'Protocollaire Geneeskunde'; Roos, 'Protocol Toverkol?'; Schwartz, 'Kwaliteitscontrole'; Vissers, 'Protocollaire Geneeskunde'.

111. See chapter 6 and the interviews with Borst-Eilers and Bossuyt; see also: Bossuyt & Kortenray, *Schaatsen op Dik IJs*; Westra, Portegies & Van Crevel, 'Gebruik van Protocollen'.

sentatives of the EBM movement in the Netherlands.¹¹² The transition from the ‘pre EBM’ to the ‘EBM’ era should, in short, be presented as being fairly fluent.

In a more negative sense, too, the various initiatives from the 1980s constituted an important ‘preparation’ for the subsequent rise of evidence-based medicine, as the consensus guidelines and the activities in the field of clinical decision analysis were not a resounding success.¹¹³ Besides all kinds of practical obstacles and resistance within the medical profession, perhaps, above all, the inherent weakness of both approaches was the underlying reason for this. From the very start, there appeared to be a host of drawbacks to the consensus method. In the words of some critics, the guideline development was largely dominated by a few experts, group processes played a very important role, the chairmen of consensus meetings could very easily manipulate affairs, there was insufficient support on the part of the ‘target group’ of the guidelines and a good implementation strategy was often lacking. That the CBO and the NHG eventually decided to switch to the ‘evidence-based method’ was not least due to dissatisfaction with the consensus approach.¹¹⁴

Clinical decision analysis also failed to live up to initially high expectations. In the Netherlands, in the early 1980s, considerably enthusiastic articles were already being published on this ‘new shoot’ on the tree of medicine.¹¹⁵ Towards the end of this decade, however, it was almost unanimously concluded that clinical decision analysis ‘stagnated’. Yet in terms of concept it was still considered valuable. It was helpful, for example, to reflect on a clinical problem in a structured way, and to make explicit all manner of considerations that could influence clinical decision-making. However, the immediate practical use of decision analysis as a supportive instrument for physicians in individual patient care was considered minimal. Such was the complexity of the phenomena upon which physicians were supposed to take decisions, that the decision analysis techniques did not ultimately reduce the uncertainties, as was concluded by, for example, Knottnerus in 1987. Also, in many cases, there was simply not enough information for decision analysis. It was not helpful here that clinical decision analysis did not have a strong research agenda, contrary to, for example, clinical epidemiology. According to Knottnerus, it also

112. This is illustrated, for example, by the symposium on clinical decision analysis, organized by the CBO in 1984 (see: ‘Symposium “Medische Besliskunde”’, *Nederlands Tijdschrift voor Geneeskunde* 127 (1983), p. 2307. The participants tot his symposium included: Van Es, Dunning, Van der Helm, Van Leeuwen, Van Crevel, Habbema, Mandema and Lubsen. They all featured in chapters 5 and 6 as advocates of applied clinical research and clinical epidemiology in the 1980s. In the 1990s, several of them were also part of the emerging Dutch EBM-movement, for example via the program ‘guidelines for clinical practice’ of the AMC in Amsterdam.

113. See n. 110 above.

114. See in particular: Dunning, “Medische Besliskunde”; Grol et al., ‘Standaard en Consensus’; Grol et al., ‘Consensus over Consensus’. See also n. 110 above.

115. Paraphrase derived from: Gerritsma & Smal, ‘Besliskunde’.

created resistance among physicians that clinical decision analysis presented itself as a difficult technique and a new specialism, rather than a new instrument that – such as subsequently was the case with EBM – could be integrated in the personal medical practice of every physician.¹¹⁶

In what way the stagnation of decision analysis was a factor in the rise of clinical epidemiology and EBM may be illustrated with Patrick Bossuyt's career. As a methodologist, he became involved with the Centre for Clinical Decision Analysis in Rotterdam towards the end of the 1980s. In retrospect, he looks back with some amazement on the time he spent there:

'The vision at the time was as praiseworthy as it was ridiculous: the idea was that the clinician would have a phone number of the decision analyst on duty. In the event of a clinical problem, he was then able to alert the decision theorist, sit down with them, and say for example: I have this lady here with an abdominal aortic aneurysm of 4 centimetres who also suffers from diabetes and a reduced pulmonary function. What am I to do? Operate on the aneurysm or leave it there? Upon which the decision analyst would say: I see, I will call you back tomorrow. And then the analyst would spend the night in the library – this was the end of the eighties, there was no PubMed yet – and reply the next day: dear colleague, in view of the current state of science, I would recommend you do not operate.'¹¹⁷

Bossuyt furthermore describes that, during his work as a decision analyst in Rotterdam, he constantly had to advise on decisions, but never had information on the basis of which he could build his decision models. He therefore eventually switched to clinical epidemiology, or: 'to setting up research that would yield the data so that clinical decisions could be taken.'¹¹⁸ In the AMC in Amsterdam, he experienced as a clinical epidemiologist how this type of research became an important component of the set-up of clinical guidelines. Bossuyt was one of the most important architects of the AMC guidelines programme, which soon became equated with evidence-based medicine. Bossuyt himself has always

116. Knottnerus, 'Bouwstenen'. See also : M. Berg & G. H. de Vries, 'Besliskunde en de Constructie van het Medisch Handelen', *Medisch Contact* 46: 22 (1991), pp. 702-4; Elstein, 'Decision Analysis', pp. 118-19; Van Es, 'Medische Besliskunde'; Habbema, 'Beslissingsondersteunende Technieken'; A. Hasman, 'Besluitvorming Ondersteunende Systemen', *Medisch Contact* 42: 42 (1987), pp. 1349-53; Knottnerus, *Dialectiek van het Onderzoek*, pp. 17-18; J. van der Meer, 'Moeilijke Keuzen aan het Ziekbed: Reken Niet op de Besliskunde', *Nederlands Tijdschrift voor Geneeskunde* 132 (1988), pp. 336-7; Ridderikhoff, 'Medische Besluitvorming'; Schwartz, 'Kwaliteitscontrole'; R. M. Timmermans & J. H. P. van der Meulen, 'Beslissingsanalyse: het Nut voor de Medische Praktijk; een Bespreking van de Eerste Bijeenkomst van het Landelijk Forum Medische Besliskunde', *Nederlands Tijdschrift voor Geneeskunde* 137 (1993), pp. 1816-19; Vissers & Casparie, 'Medische Besliskunde'; D. K. Warndorff, C. J. M. Pouls & J. A. Knottnerus, 'Medische Besliskunde in Nederland', *Medisch Contact* 43: 39 (1988), pp. 1174-8.

117. Interview with Bossuyt.

118. *Ibid.*

regarded EBM as ‘a simple man’s decision analysis’: more accessible, easier and more appealing to physicians, but also less complete and refined.¹¹⁹

In many respects, Bossuyt’s story underlines the finding that EBM fits in well with the trends of the 1980s, while, at the same time, the slow progress in the development of consensus guidelines and decision analysis methods ensured that there was also room for a new approach (– which emerged in the form of evidence-based medicine). The advance of EBM in the Netherlands in the 1990s and its (potential) impact on Dutch medicine and healthcare in the 21st century will be further discussed in the next two chapters.

119. Ibid.



Chapter 8.

Borst-Eilers, Healthcare Policy and the Rise of EBM in the Netherlands (1992-2000)

Evidence-based medicine took the Netherlands ‘by storm’ during the 1990s. Within several years of the international promotion of the concept in the famous *JAMA* article from 1992, it seemed impossible to imagine Dutch healthcare without it. In particular the Dutch College of General Practitioners (NHG) quickly appropriated the term EBM. As early as 1994, Siep Thomas, head of the Standard Development department of the college, wrote in *Nederlands Tijdschrift voor Geneeskunde* about the NHG standards – the guidelines for GPs that had been developed since 1987: ‘Their significance lies in the fact that they are based on the principles of evidence-based medicine to the greatest extent possible.’¹

Thomas’s article was one of only three that appeared in *Nederlands Tijdschrift voor Geneeskunde* in 1994 that mentioned EBM. At least, in the database of the journal the search term “evidence-based” yielded only three hits for 1994 (and zero hits in 1992 and 1993). The year 1995 yielded six hits, but subsequent years showed a sharp increase: 19 hits in 1996, 32 in 1997, gradually increasing to, for example, 72 in 2000. Naturally, these figures only provide a very rough indication of the rise of EBM in the Netherlands, yet they do support the conclusion by the chief editor of *Medisch Contact* at the end of the year 1996 that evidence-based medicine had made a ‘breakthrough’ in the Netherlands in that year.² In the same year, 1996, the attention to EBM was reason for *Nederlands Tijdschrift voor Geneeskunde* to organise a journal conference on this subject.³ In the latter half of the 1990s, the omnipresence of evidence-based medicine was considered to be so extensive and self-evident, that such terms as ‘the current era of evidence-based medi-

1. S. Thomas, ‘De Positie van Standaarden en Adviezen van het Nederlands Huisartsen Genootschap’, *Nederlands Tijdschrift voor Geneeskunde* 138 (1994), pp. 2638-40, on p. 2638. A year previously, Thomas did not yet make the connection with EBM in an overview article on the standards policy of the NHG, only speaking of ‘scientifically substantiated guidelines’, see: S. Thomas, ‘Standaarden van het Nederlands Huisartsen Genootschap’, *Nederlands Tijdschrift voor Geneeskunde* 137 (1993), pp. 2135-8.
2. C. Spreeuwenberg, ‘Bij de Afsluiting van 1996’, *Medisch Contact* 51: 51 (1996), p. 1641. See also the (kind of) ‘introductions’ to EBM and EBHC in two editorials in the same year: Spreeuwenberg, “Evidence-Based Medicine”; idem., “Evidence-Based PolicyMaking”.
3. Van Crevel, ‘Van Evidence naar Behandeling.’

ciné' were used.⁴ At the same time, reference was made to terms such as 'flagship', 'trend' and 'fashion'.⁵

Towards the end of the decade, EBM seemed to have acquired an established position within Dutch medicine. A milestone, for example, was the publication of the first Dutch-language text book on EBM, *Inleiding in Evidence-Based Medicine (Introduction to Evidence-Based Medicine)* in 2000.⁶ This book, which was explicitly intended for use as a textbook in educational settings, sold very well and was reprinted several times. The editors, Martin Offringa, Pim Assendelft and Rob Scholten, were all affiliated to the Dutch Cochrane Centre (DCC) which, after a few hesitant early years, increasingly proved its worth. This became clear, among others, from the sharp increase of the number of systematic reviews originating from the Netherlands, from 8 in 1991 to 69 in 2000, of which the vast majority consisted of 'Cochrane reviews'.⁷ In addition, the DCC regularly organised workshops and courses on EBM – on critical appraisal and creating systematic reviews and guidelines for medical practice – which invariably attracted many interested people.⁸

The success of the handbook edited by the three DCC-men illustrates that evidence-based medicine slowly began to establish itself in medical curricula and in training (courses) for GPs and specialists.⁹ Typical is the special 'educational edition' of *Medisch Contact* in 2000 of which, as was explicitly noted in the editorial, evidence-based medicine formed the main theme.¹⁰ It was made very clear, for example, that EBM was one of the pillars of the final attainment levels of the GP training program.¹¹ This special edition also featured a report on a course day for all educators in internal medicine, which was entirely dedicated to EBM. Nearly all attendees indicated that they would adapt the training methodology in the near future, with the most frequently mentioned change being: 'the increased integration of evidence-based medicine in the training program'.¹²

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4. There are numerous examples of this. Search, for example, Google.
 5. See a.o.: F. Meulenberg, 'Evidence-Based Medicine in de Interne Geneeskunde', *Medisch Contact* 52: 24 (1997), pp. 746-9.
 6. Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*.
 7. K. P. Grootens, W. J. J. Assendelft & A. J. P. M. Overbeke, 'Toename van het Aantal Nederlandse Systematic Reviews in de Periode 1991-2000', *Nederlands Tijdschrift voor Geneeskunde* 147 (2003), pp. 2226-30.
 8. Interviews with Assendelft, Bossuyt and Offringa; Bossuyt & Semin-Goossens, 'Verantwoording Afleggen', p. 66; Van Elzaker, 'Bloedverlies', p. 100; Scholten, *Hoe Sterk?.* See also the website of the DCC: dcc.cochrane.org.
 9. This was, for example, explicitly emphasized in the official report of the assessment of the curricula of all Dutch medical faculties of 2004: Stichting Quality Assurance Netherlands Universities, *Onderwijsvisie Geneeskunde* (Utrecht: QANU, 2004), see in particular p. 26.
 10. J. Visser, 'Onschuldig Computeren', *Medisch Contact* 55: 36 (2000), p. 1219.
 11. Ibid.; H. Maassen, 'Een Pak van Sjaalman: Jan Schuling over de Nieuwe Eindtermen van de Huisartsenopleiding', *Medisch Contact* 55: 36 (2000), pp. 1233-6.
 12. E. Pronk, 'De Kunst van het Opleiden: Meer Evidentie in de Geneeskunde', *Medisch Contact* 55: 36 (2000), pp. 1247-8.

Furthermore, there was a reflection on further training, in which EBM was explicitly put forward as the ideal, most comprehensive educational approach, which not only contributed to knowledge transfer and skills training but also to a change in attitude and the improvement of non-patient-related skills. It is true that EBM primarily focused on the decisions to be taken by the practitioner regarding the problems of individual patients, but, it was added: 'Nevertheless, the concept equally applies to *continuing professional development*, as an effective and globally applicable framework for a lifelong learning process'. Over a short period of time, according to the author, evidence-based medicine had developed into 'the almost moral-scientific basis of patient care' and the concept had already reached 'the centre of (post-academic) education'.¹³

There are more indications that, around the time of the millennium, EBM had become a significant factor within Dutch medicine. Following on from the NHG, the scientific associations of medical specialists and the CBO, for example, also started to increasingly develop their clinical guidelines according to 'the evidence-based method'.¹⁴ Furthermore, it was important that EBM be explicitly and emphatically embraced by non-medical parties, such as the insurers and the government, not least in the person of the then Minister of Health, Els Borst-Eilers.¹⁵

In the previous chapter, it was already stated that there was a fluent transition between the introduction of EBM in the Netherlands in the 1990s and developments in the preceding decades. Since the 1970s, all manner of approaches had already been embraced and initiatives taken, from peer review to the application of decision analysis techniques, with the aim of making medical practice more 'rational', effective and efficient. This seems to account for the rise of EBM in the 1990s to a large extent: the new concept of EBM was therefore off to a flying start, for it was an extension of what was already happening within Dutch medicine.

In one important respect, however, the rise of EBM could not simply be understood as a continuation of existing trends. This is because the rather painstaking progress in the

13. L. V. E. Benecke, 'Gedachten over Nascholing: Van Kennisoverdracht naar Professionele Ontwikkeling', *Medisch Contact* 55: 36 (2000), pp. 1253-5. Original italics.

14. See a.o.: R. C. Beljaards et al., 'Het Veranderende Profiel van de Huisarts', *Medisch Contact* 56: 11 (2001), pp. 422-5; A. F. Casparie et al., 'Ontwikkeling en Implementatie van Kosteneffectieve Richtlijnen', *Medisch Contact* 53: 3 (1998), pp. 88-90. Dwarswaard, *Dokter en Tijdgeest*, p. 212; J. J. E. van Everdingen, 'Van Consensus naar CBO-Richtlijn', *Nederlands Tijdschrift voor Geneeskunde* 143 (1999), pp. 2086-9; G. J. M. Herder et al., 'Evaluatie van de Diagnose Longcarcinoom: de Zin van Evidence-Based Richtlijnen', *Medisch Contact* 56: 11 (2001), pp. 406-9; J. G. P. M. Tjissen, M. L. Simoons & J. J. E. van Everdingen, 'Landelijke Richtlijnen voor het Klinisch Handelen, een Methodologische Beschouwing', *Nederlands Tijdschrift voor Geneeskunde* 142 (1998), pp. 2078-82.

15. That EBM was embraced by all these different parties (but not for the same reasons or objectives) was, for example, very clear in the various articles in the volume: Gerritsen & Van Linschoten, *Gezondheidszorgbeleid*.

area of peer review, protocol medicine (with the aid of the consensus method) and the clinical decision analysis of the 1980s, is in marked contrast with the high speed at which, and the extent to which, EBM became 'fashionable' in the 1990. The latter (apparently) left a much greater mark on Dutch medicine and healthcare than the aforementioned 'precursors'.

This may be partly explained by the academic foundation of clinical epidemiology in the Netherlands, which was discussed in part II. As a result, a significant institutional and academic basis existed for EBM, much more so than for clinical decision analysis, for example. The significance of this was most clearly visible within the AMC in Amsterdam. The department of clinical epidemiology and biostatistics played a pivotal role in the programme 'guidelines for clinical practice' with which EBM was shaped within the AMC. In addition, the Dutch Cochrane Centre was housed in this department (until 1 January 2014).¹⁶ Clinical epidemiology played a similar role in other medical faculties and university hospitals. Education in critical appraisal and EBM for example, was mostly developed and provided by staff members of these departments. Not without reason, it was argued in an opinion piece in *Medisch Contact* from 1994, that 'the major development of departments of Clinical Epidemiology' in the Netherlands during the preceding decade was 'closely related' to the rise of evidence-based medicine and clinical guidelines in this country.¹⁷

There is, however, an important additional explanation for the strong advance of EBM in the 1990s in the Netherlands. This concerns the interaction between, on the one hand, the efforts within the medical profession to increase the quality and efficiency of medical practice and, on the other hand, governmental healthcare policies. In this chapter, this relationship between developments at the micro-level and (in particular) those at the macro-level is further elaborated on. The focus will be on the debates and developments with regard to the health insurance system in the Netherlands, and in particular (the curtailment of) the standard package of insured healthcare. Central here are two advisory reports published in 1991, on the eve of the rise of EBM in the Netherlands, namely the report 'Choose and Share' (Dutch: 'Kiezen en Delen') by the Government Committee on Choices in Healthcare (Dutch: Commissie Keuzen in de Zorg) – better known as the Dunning Commission – and 'Medical Practice at a Crossroads' by the Health Council.¹⁸ By reference to the history of these reports and in particular to what was subsequently

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16. Bossuyt & Kortenaar, *Schaatsen Op Dik IJs*; A. Goossens, P. M. M. Bossuyt & R. J. de Haan, 'Richtlijnontwikkeling in het Academisch Medisch Centrum te Amsterdam, 1992-2001', *Nederlands Tijdschrift voor Geneeskunde* 147: 39 (2003), pp. 1919-22.
 17. H. J. van der Reijden, 'Zelfregulering in de Zorg: een Belangrijke Bijdrage aan de Kwaliteit', *Medisch Contact* 49: 42 (1994), pp. 1328-9.
 18. Commissie Keuzen in de Zorg, *Kiezen en Delen* ('s Gravenhage: DOP, [1991]); Gezondheidsraad, *Medisch Handelen*.

(not) done with them, specific insight will be given into how and why the rise of EBM in the Netherlands should be placed in the context of healthcare policy. There will be a particular focus on the role played by Els Borst-Eilers, who first made her mark on 'Medical Practice at a Crossroads' as vice chairwoman of the Health Council, and who was subsequently strongly committed to more 'evidence-based healthcare' in her capacity as Minister of Health as of 1994.

From 'Boundaries Debate' to 'Package Debate'

The two above-mentioned reports originated in the intensive debates that were held in the 1980s on the theme of 'the boundaries of healthcare'. All manner of reports appeared on this subject, often as result of requests for advice from the then State Secretary for Health, Van der Reijden. This applied to the reports by the Harmonisation Council for Welfare Policy from 1983, by the Health Council from 1986¹⁹, and by the National Council for Public Health, also from 1986.²⁰ In addition, several 'spontaneous' publications appeared on the 'boundaries of healthcare', including reports from two conferences that were devoted to this subject.²¹ The theme was also given an important place in the KNMG report 'Healthcare with Limited Resources' (Dutch: *Gezondheidszorg bij Beperkte Middelen*), with the subtitle: 'Grounds and *Boundaries* of Healthcare' (Dutch: 'Gronden en *Grenzen* van de Gezondheidszorg').²² The Health Insurance Council published an interim advice in 1983 and a final advice in 1986 on more specific boundaries, to wit the 'Limits to the Growth of the Statutorily Insured Package'.²³

Five types of boundaries of healthcare were distinguished in these reports as well as in the requests for advice by the state secretary:

1. The boundary between what can still be called healthcare and what can no longer be called healthcare.
2. The boundary between what should still be considered ethically permissible and what should no longer be considered ethically permissible.

19. Gezondheidsraad, *Grenzen*.

20. Nationale Raad voor de Volksgezondheid, *Advies Grenzen van de Zorg* (Zoetermeer: Nationale Raad voor de Volksgezondheid, [1986]).

21. Namely: The Dutch Conference for Public Health Regulations of 1982 and, the conference of Stichting Gezondheidszorg '82 ('Healthcare Foundation '82), which was held in 1984. See respectively: H. J. J. Leenen, 'Grenzen van de Gezondheidszorg', *Tijdschrift voor Sociale Gezondheidszorg* 61 (1983), 370-3 (and several other articles in the same issue of this journal); C. Hovenkamp (ed.), *De Grenzen van de Gezondheidszorg* (Apeldoorn: Stichting Gezondheidszorg '82, 1984).

22. 'Gezondheidszorg bij Beperkte Middelen'; Thung, 'KNMG-Rapport'. TB's italics.

23. Ziekenfondsraad, *Interim-Advies*; Idem, *Eindadvies*. See also: Idem, *Grenzen aan de Groei van het Verstrekkingspakket: Derde Advies* (Amstelveen: Ziekenfondsraad, 1993).

3. The boundary between effective healthcare and healthcare that is no longer effective and, related to this, the boundary between efficient healthcare and inefficient healthcare.
4. The boundary between fundable healthcare and healthcare that is no longer fundable.
5. The boundary of the constitutional duty of the government to promote public health under Article 22 of the Constitution.²⁴

In several ways, this sheds more light on the need for a mechanism of control in healthcare, which was described in the previous chapter. To start with, the ‘boundaries debate’ of the 1980s shows that, however much the cost issue was the dominant theme, the need was felt not only to steer, regulate and limit (developments in) healthcare in an economic respect, but also in an ethical, legal, political and social respect. The introduction of evidence-based medicine may, in other words, be considered to be part of a much broader trend. The rapid manner in which medicine and healthcare had developed in the latter half of the twentieth century had resulted in a debate on no less than five types of boundaries, and a whole range of initiatives and measures to get a grip on this domain.

This broad perspective is all the more relevant because, as was explicitly argued in the various reports, the five types of boundaries mentioned could not be strictly separated from each other. It was obvious, for example, that issues that were not considered to be ethically permissible would not be considered to be part of (publicly) fundable healthcare. In addition, the boundary between what was or was not to be considered part of healthcare also determined the question as to how far government responsibility for healthcare extended.

The overlap and mutual influence of the various types of boundaries underlined the complexity of the issue of controlling the cost of healthcare. Even in an apparently clear matter, such as what forms of healthcare should and should not be included in the statutorily insured package, not only medically substantive and economic considerations but also political, ethical and legal aspects played an important role. For this reason, the issue of the distribution of scarce financial resources in healthcare was referred to as ‘ethics at the macro-level’ in the Government Position ‘Boundaries of Healthcare’ from 1988 – in which the official cabinet response to several of the reports mentioned was recorded. It was also noted here that the objectives of the government were by no means always compatible with each other. The government faced the task of curbing expenditure on the one

24. *Grenzen van de Zorg. Regeringsstandpunt inzake het Advies van de Ziekenfondsraad, de Nationale Raad voor de Volksgezondheid en de Gezondheidsraad* (’s Gravenhage: Tweede Kamer der Staten-Generaal, Vergaderjaar 1987-1988, 20 620, nrs. 1-2, [1988]). See also: Gezondheidsraad, *Grenzen*; Hovenkamp, *Grenzen*, pp. 8-11; Nationale Raad voor de Volksgezondheid, *Advies Grenzen*.

hand, but on the other hand it had to maintain and, where possible, improve the (high) quality, availability and accessibility of healthcare and protect the rights of patients.²⁵

In order to be able to fulfil its difficult task, the government, in particular, had high expectations of the 'Dekker Plan'. As discussed in chapter 7, the Structure and Financing of Healthcare Committee, chaired by former Philips executive Wisse Dekker, had proposed to introduce an entirely different insurance system for healthcare in 1987, which offered the opportunity to introduce market mechanisms in this sector. The government considered that this 'had already largely made for the realisation' of several *boundaries*, namely: those between what could and could no longer be called healthcare, those between fundable and non-fundable healthcare, as well as the boundary of the constitutional duty of the government to promote healthcare.²⁶

As the 'Dekker plan' had already provided for many issues, the Government Position 'Boundaries of Healthcare' focused on two subjects: *priority setting* and *technology assessment*. The focus on priority setting was a result of the consensus in the various advisory reports on how to achieve a responsible and fair distribution of the scarce resources in healthcare. In broad terms, two strategies were available. The first was *rationing*, or 'the introduction of a certain provision on a limited scale'. However, this was almost unanimously considered to be an undesirable strategy. Because a provision was only available 'on a limited scale', not just any patient qualified for this but patient selection had to occur. This was punctuated by numerous objections, including the feelings caused to 'rejected' patients, the reliance on the 'wisdom' of the physician, the danger of juridification and the red tape, and the costs involved in such a selection procedure. Moreover, patients who complied with selection criteria would often end up on a waiting list, with all resulting consequences, such as emotions running high in patients and their family and friends, an excessive burden for healthcare providers and institutions, and the deployment of the media with the aim of influencing selection procedures. Due to the many fundamental and practical objections to rationing, there was a wide agreement that the second strategy – that of setting priorities – was to be preferred in terms of achieving distributive justice in healthcare.²⁷

The big question, of course, was how to achieve this prioritisation. To this end, various reports mainly put forward Medical (or: Health) Technology Assessment (MTA/HTA) as an instrument. MTA was sometimes described as the macro-counterpart of clinical decision analysis. MTA did not involve decisions on healthcare for individual patients, but rather a more general evaluation of medical technologies. The concept of 'medical technology' was interpreted in a very broad sense here. Not only 'high technology', but all possible preventative, diagnostic and therapeutic interventions as well as organisational

25. *Grenzen van de Zorg*; See for more on these thematics: Huisman & Oosterhuis, *Health and Citizenship*.

26. *Grenzen van de Zorg*, p. 2.

27. *Ibid.*

forms and even insurance schemes qualified for assessment. Ideally, MTA involved a broad, comprehensive evaluation of ‘technologies’, where medical, ethical, social, legal and economic effects were studied. In practice, however, the emphasis – at least in the Netherlands – has always (virtually exclusively) been placed on cost-effectiveness.²⁸

Chapter 5 already discussed how in 1983 the Health Insurance Council pleaded for MTA/HTA as a means to impose limits to the health insurance package. The automatic nature of the inclusion of new diagnostic methods and therapies in the continually expanding statutorily insured package needed to be broken. First of all, it had to be established with the help of *technology assessment* whether a certain provision was useful at all, before it could be included in the package. Old technologies would have to be evaluated as well and, in the event of proven lack of effectiveness and efficiency, be removed from the package.

In circles other than those of the Health Insurance Council as well, attention and enthusiasm for MTA increased in the course of the 1980s. Within the medical profession, there was increasing talk of the dangers of premature and excessive application of new medical technologies and by extension the importance of more and better critical evaluation of these technologies was also pointed to.²⁹ The policymakers at the Ministry of Health soon also embraced MTA as an ideal instrument for cost containment, without compromising the quality of healthcare.³⁰ Furthermore, the Health Council developed into perhaps the most important player in the field of technology assessment in the Netherlands. In 1985, the Council became a member of the International Society of Technology Assessment in Health Care (ISTAHC), which had been founded in the same year. In 1987, the international conference of the ISTAHC was organised by the Health Council, in the persons of the then vice-chairwoman and general secretary of the Council, Els Borst-Eilers and Henk Rigter. After this conference, Borst-Eilers became secretary to the society.³¹

28. Van Anel, ‘Medische Technologie’; Bally, Haan & Starmans, ‘Evaluatie Medische Technologie’; Banta, ‘What is Technology Assessment?’; D. Banta & W. J. Oortwijn, ‘The Netherlands’, *International Journal of Technology Assessment in Health* 25: Supplement S1 (2009), pp. 143-7; Bierens, ‘Verantwoorde Gezondheidszorg’; H. van Crevel & H. J. van der Helm, ‘Geneeskunde en Technologie’, *Nederlands Tijdschrift voor Geneeskunde* 131 (1987), pp. 248-50; Van Es, ‘Laboratoriumonderzoek Onderzocht’; Gezondheidsraad, *Grenzen*, pp. 77-84; ‘Gezondheidszorg bij Beperkte Middelen’; Leenders, ‘Technologische Veranderingen’; Leijnse, ‘Economische Overwegingen’; J. H. Mulder, ‘“Technology Assessment”. Wat Moet een Arts ermee?’; *Medisch Contact* 42: 15 (1987), pp. 457-8; Raat & Goudriaan, ‘Kwaliteitssystemen’; H. D. C. Roscam Abbing, ‘Gezondheidszorgbeleid en Medische “Technology Assessment”: Enige Gezondheidsrechtelijke Aspecten’; *Medisch Contact* 44: 41 (1989), pp. 1343-5; Sturmans, ‘Is de Gezondheidszorg Beheersbaar?’; Vissers, ‘Strategieën’; Ziekenfondsraad, *Interim-Advies*; Idem, *Eindadvies*.

29. See n. 28 above and see also chapter 7.

30. See a.o.: Banta & Oortwijn, ‘The Netherlands’; Mulder, ‘“Technology Assessment”’.

31. Interviews with Borst-Eilers and Rigter; Bal, Bijker & Hendriks, *Paradox*, pp. 262-3. In 1993, the Health Council also was co-founder of the International Network of Agencies for Health Technology Assessment (INAHTA).

Thus, it was not surprising that the Government Position 'Boundaries of Healthcare' paid ample attention to MTA.³² In particular with respect to the implementation of the boundaries between effective and non-effective, and between efficient and inefficient healthcare, great importance was attached to technology assessment. This resulted in policy intentions focused on: (1) strengthening the existing (organisational) structures for MTA; (2) the programming, coordination and stimulation of research in this area – among others via the SGO and the Investigative Medicine Fund; and (3) increasing attention for and participation in *technology assessment* within the medical profession.³³

Both the plans of the Dekker Commission and the intention of the government to achieve the greatest possible prioritisation in healthcare with the help of MTA, caused the debates on healthcare policy to focus strongly on the composition of the 'package' (or actually: the various packages) for insured healthcare. Three separate insurance systems were involved here. First of all, there was the General Act on Exceptional Medical Expenses (Dutch abbreviation: AWBZ), a national insurance for serious or special medical risks that were often considered to be uninsurable. The AWBZ included, for example, a long-term stay in institutions for (mentally) disabled people or in nursing homes. In addition, there was the Social Health Insurance Act (in Dutch: Ziekenfondswet), which decreed that all people below a certain income threshold, approximately two-thirds of the Dutch people, had to have *compulsory* insurance with one of the regionally organised health insurance funds. A national, government-imposed statutorily insured package applied to the health insurance funds, consisting of GP care, specialist care, obstetric care, the supply of artificial devices, aids and medicines, dental care, physiotherapy, sanatorium nursing, rehabilitation care and hospital care. The remaining proportion, approximately a third of the Dutch people, consisted of privately insured people, who had *voluntarily* taken out a health insurance policy with a private insurance company. The Dekker Commission proposed to merge the AWBZ, the health insurance funds and the private health insurances into one 'basic insurance'. An important point of discussion concerned the question as to which elements should and should not be included in the 'basic package' of insured healthcare to be established to this end. There was an excellent opportunity here to arrive at prioritisation and to make rational choices based on MTA.³⁴

32. *Grenzen van de Zorg*, pp. 26-39.

33. *Ibid*, pp. 36-39.

34. See on all this, a.o.: Van den Burg & Ter Meulen, 'Prioriteiten binnen de Gezondheidszorg', pp. 29-34; Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 34-39, 587-590, 772-778, 782; E. Elsinga, 'Voor Wie is MTA van Nut? De Toepassing van Medische Technology Assessment', *Medisch Contact* 51: 12 (1996), pp. 411-16; *Health Insurance in the Netherlands* (The Hague: Ministry of Health, Welfare and Sports, 2011), pp. 14-20; J. Mos & M. P. Galema, *Achtergrondstudies 10 Jaar Pakketdiscussie* (Zoetermeer: Stichting Toekomstscenario's Gezondheidszorg, [2000]).

As long as the new basic insurance did not yet exist – and perhaps in anticipation of this – it was possible to take a critical look at the provisions that were reimbursed via the AWBZ or the health insurance fund. The statutorily insured package was one of the most tangible starting points that could be used to actually make choices and arrive at prioritisation. It was high time for this as well according to the responsible members of government. Between the lines of the Government Position ‘Boundaries of Healthcare’ it could be clearly read that there had been enough talk and philosophising about this subject and that results ultimately had to be delivered. It was noted, for example, that:

‘Speaking about boundaries is one thing, creating boundaries in practice quite another. Where the one thing may still occur with a certain intellectual distance, one may be faced with harsh decisions in practice.’³⁵

This outlines the background of the two aforementioned reports from 1991 – ‘Choose and Share’ by the Dunning Commission and ‘Medical Practice at a Crossroads’ by the Health Council – which, in many respects, marked the beginning of the EBM era in the Netherlands. The debates on the boundaries of healthcare from the 1980s resulted in an intensive discussion about the ‘package’ of insured healthcare – both in the existing and in the future system – and how to set priorities within it by means of technology assessment. Towards the end of the decade, the government was eager to finally move from thinking and speaking to actual action with regard to these issues.

At the same time, the responsible members of government realised how difficult this would be. In the Government Position, they even spoke of ‘a feeling of powerlessness’, which they linked to the question: ‘how may priorities in healthcare be formulated in such a way that justice, equality of rights as well as manageability may be expressed in the best possible way?’³⁶ This is why the Dunning Commission and the Health Council were requested to give advice on how choices could be actually made, in particular with respect to the statutorily insured package for insured healthcare.

Two Complementary Reports – Dunning and Borst-Eilers

Upon the appointment of the third Lubbers cabinet in November 1989, it was stated in the government declaration that a committee would be established ‘which will consider what limits are to be imposed on the application of new medical technologies with patients and how public support may be found for the solution to the problems caused by

35. *Grenzen van de Zorg*, p. 41.

36. *Ibid.*, p. 20.

scarcity, rationing of healthcare and necessary selection of patients.³⁷ This became the Government Committee on Choices in Healthcare chaired by the Amsterdam professor of cardiology A.J. Dunning and additionally consisting of ten members, who were experts in a wide variety of fields, including general medicine, psychiatry, medical ethics, philosophy, health law, social health insurance and policy and organisation in healthcare. On 30 August 1990, this ‘Dunning Committee’ was put to work with a dual mission by the then State Secretary of Health, Hans Simons. Firstly, the committee had the task of developing a strategy with which dilemmas in healthcare could be made *manageable*. Secondly, it served to kick-start a public debate on this matter, with the aim of ‘gaining public acceptance of the necessity of making choices’.³⁸

The strategy the committee developed for making choices in healthcare is known as ‘Dunning’s funnel’. This ‘funnel’ was a tool to be able to make choices with regard to the composition of the (future) basic package for insured healthcare. A diagnostic technique, treatment method or other medical provision had to comply with four criteria. In the first place, it had to concern *necessary healthcare*. Secondly, its *efficacy* needed to be established. Thirdly, sufficient *efficiency* of the care provision was required. In the fourth place, it had to be considered, according to the committee, whether, in certain cases, necessary, effective and efficient healthcare qualified as being at the *patient’s own expense and responsibility*. Within ‘Dunning’s funnel’, these four criteria functioned as filters or sieves: only provisions that went through all four filters were eligible for inclusion in the basic package.

The four criteria or sieves had a highly political content, as was emphasised by the Dunning Committee. Scientific and professional insights gained through *technology assessment*, for example, did generate information on efficacy and efficiency in particular. However, where the boundaries were eventually established was something that needed to be determined in the political and public debate. This applied even more to the identification of the necessity of healthcare provisions and to the question of whether or not they needed to be left at the patient’s own expense and responsibility. The public debate the committee wished to initiate, for which a ‘communication plan’ was also made, fitted well within this approach.

In summary, the Dunning Commission placed the responsibility for making choices with politics and society. The emphasis here was on choices at the macro-level of the package of insured healthcare, where the four filters served as a tool to systematically arrive at these choices. The introduction of this ‘funnel’ essentially constituted a plea for the application of MTA in the broadest possible sense – so not only an evaluation of economic, but also of medical, ethical, social and legal aspects.

37. Commissie Keuzen in de zorg, *Kiezen en Delen*, pp. 5, 223.

38. Ibid. TB’s italics.

In December 1991, a month after the publication of the report by the Dunning Commission, the Health Council presented the report 'Medical Practice at a Crossroads.' This advice had its origins two years prior to this. In a letter dated 11 September 1989, Dees, the then State Secretary of Health, had asked the Health Council to 'issue advice with respect to the boundaries of healthcare.' The first two sentences of this letter read:

'As established in the Government Position with respect to the Boundaries of Healthcare, the existing insurance package will be tidied up where possible and necessary. The tidying up is necessary in order to remove superfluous, marginally effective and/or inefficient components from the package.'³⁹

A number of issues may be derived from this letter. In the first place, it appears that the request for advice to the Health Council which would eventually lead to 'Medical Practice at a Crossroads' was a *direct* result of the 'boundaries debate' of the preceding years. Secondly, it is confirmed once more that this initially broad 'boundaries debate' over time evolved into a debate that was strongly geared towards the composition of the package for insured healthcare. Thirdly, it becomes clear that Dees hoped and expected that the Health Council would supply a list featuring 'superfluous, marginally effective and/or inefficient components' that could be removed from the package.

However, the report 'Medical Practice at a Crossroads' contained something of a totally different order, namely a reflection on the way in which physicians took their clinical decisions and the resulting high degree of variation in medical practice. The Standing Committee on Medicine of the Health Council – which wrote the report – had decided to include in its advice not the (insured) diagnostic procedures and medical treatments themselves, but their *application* by physician. The Standing Committee had decided on this for strategic and substantive reasons.

From a strategic perspective, the Health Council was not happy with the nature of the request for advice by the state secretary as the removal of provisions from the statutorily insured package was regarded as a political rather than a scientific issue. René Rigter – the brother of Henk Rigter, the then general secretary of the Council – therefore calls this request for advice 'relatively inappropriate'⁴⁰ in his book on the history of the Health Council. It was established in the 1956 Health Act, after all, that the Health Council should exclusively concern itself with the provision of *scientific* advice, which was explicitly distinguished from the much more political provision of *societal* advice, which formed part of the tasks of other bodies, such as the National Council for Public

39. Gezondheidsraad, *Medisch Handelen*, appendix A, p. 75.

40. R. B. M. Rigter, *Met Raad en Daad. De Geschiedenis van de Gezondheidsraad 1902-1985* (Rotterdam: Erasmus Publishing, 1992), p. 336.

Health. Although, as René Rigter emphasises, a clear line between both forms of advice could not be drawn in practice and ‘purely scientific’ advice is a fiction, this has always been an important and influential ideal.⁴¹ In his book, as in the study by Bal, Bijker and Hendriks which was published in 2002 on the occasion of the hundredth anniversary of the Council,⁴² it was made very clear that, over the course of time, the Health Council acquired a great deal of authority, partly because the Council was able to profile itself as a *fully independent, scientific* advisory body.⁴³

Against this background, it is understandable that the Health Council was not happy with the above-mentioned ‘political’ request for advice. Yvonne van Duivenboden, the secretary to the committee that wrote ‘Medical Practice at a Crossroads’, remarked about this:

‘We particularly did not want to be forced into the position where the Health Council would have to say: those provisions would have to be scrapped. That really gets you into political waters.’⁴⁴

According to Van Duivenboden, the scrapping of provisions from the statutorily insured package could ‘not or barely be defended from a scientific perspective’, but the Health Council was able to ‘indicate how existing provisions could be better applied in a qualitative sense’.⁴⁵ The redefining of the problem about which advice was requested fitted, in short, within the strategy of the directors of the Health Council, aimed at ‘preventing the Council from having to do the politically heavy lifting on the authority of science’.⁴⁶

In addition, the Health Council faced another strategic issue, namely the relationship with regard to other ‘fora’. Besides the Health Council, the government had also asked the Health Insurance Council, the KNMG, and within the KNMG the LSV (National Association of Specialists) and the LHV (National Association of GPs), as well as the Dunning Commission to issue advice on largely the same issues. It was therefore important for the Health Council to distinguish itself in its advice from the other ‘fora’ and in particular from the Dunning Commission, ‘the most significant fellow player at that time’.⁴⁷ By not

41. Ibid.

42. Bal, Bijker & Hendriks, *Paradox*.

43. Rigter, *Met Raad en Daad*, pp. 341-3. The special position of the Health Council was confirmed once more at the end of the 1980s and the early 1990s because, precisely at that time, the advisory structure of the Ministry of Health was transformed. Various advisory bodies lost influence or were even abolished, yet the position of the Health Council was never (really) subject to debate and, on balance, was only becoming stronger. See on this: Bal, Bijker, & Hendriks, *Paradox*, pp. 33-8.

44. Cited in: Bal, Bijker & Hendriks, *Paradox*, p. 96.

45. Ibid., pp. 96-7.

46. Cited in: Ibid., p. 96.

47. Ibid., p. 98.

discussing medical procedures and technologies as such, but their application in practice, the Health Council was able to sharply position its advice alongside that of the ‘competitor’:

‘In the Netherlands, as in other countries, we have to conclude that quality improvement and in particular increasing the efficiency of medical practice is at issue. The recently published report ‘Choose and Share’ by the ‘Government Committee on Choices in Healthcare’ makes recommendations to this end, *thus showing the rational way*. In the present advice, the committee of the Health Council attempts to show which – *often irrational* – *hurdles* block the road towards efficiency.’⁴⁸

This is not to say, however, that the Health Council *opposed* the Dunning Commission.

Rather, the two reports represented two different approaches that complemented each other and were highly compatible. There had, moreover, been a degree of mutual coordination to this end. It was concluded that both actors ‘were not at cross-purposes with each other’ and ‘were rather on the same wavelength’.⁴⁹

Apart from the strategic considerations, those involved in the Health Council were also driven by important substantive motives to reformulate the problem about which they were to issue advice. They were clearly convinced that the key to more effective and efficient healthcare was not to be found at the level of the package and the provisions but at that of the setting of indications by physicians in medical practice. Borst-Eilers, the chairwoman of the committee that wrote ‘Medical Practice at a Crossroads’, said about this over twenty years after the event:

‘So Hans Simons, the state secretary, thought: you just make a list of things that are no longer allowed: a certain operation, a certain diagnostic intervention and so on. Yet there was almost nothing that had been introduced in practice which was rubbish from A to Z. Most of it was applied too *broadly*. And this is why we said: it is not just about a list of provisions, it is about the *application*. And with this application you touch upon medical practice. So that is how we made this jump.’⁵⁰

This ‘jump’ was far from obvious, as the boundaries of the legal duty of the Council – advising with regard to the state of *science* – were stretched by so emphatically making medical *practice* the subject of ‘Medical Practice at a Crossroads’. Moreover, the authors of the report did not hesitate to engage in ‘future rhetoric’ – as Bal, Bijker and Hendriks

48. Gezondheidsraad, *Medisch Handelen*, p. 10. See also: Bal, Bijker & Hendrik, *Paradox*, pp. 98-9. TB’s italics.

49. Bal, Bijker & Hendriks, *Paradox*, p. 99.

50. Interview with Borst-Eilers.

call it. The report sketched a future filled with threats to the medical profession, which could only be averted if immediate action was taken – if not, then the government, insurers and managers would take over the initiative. This call on the profession was, partly due to the use of the metaphor of the *crossroads*, highly mandatory in nature.⁵¹ In short, ‘Medical Practice at a Crossroads’ was not a neutral, scientific report, but a pamphlet intended to urge the medical profession to effect a change in medical *practice* that was deemed necessary.

According to Bal, Bijker and Hendriks, Borst-Eilers and her fellow committee members took a certain risk with this.⁵² After all, the authority enjoyed by the Health Council was based on its status as an independent and ‘purely’ scientific advisory body. Borst-Eilers’s assessment, however, was that precisely the Health Council, by virtue of its good reputation, could occasionally afford to issue a groundbreaking advice such as ‘Medical Practice at a Crossroads’. During one of the meetings of the committee that wrote this report she said about this: ‘Precisely the Health Council, with its reputation of being independent, is the designated authority to provide this analysis and make these recommendations.’⁵³

The reports of the committee meetings are testimony to the substantive enthusiasm that drove Borst-Eilers and other involved parties. When, for example, during a meeting, a discussion arose about the question of whether the Health Council had to provide a detailed report of the 63 interviews that had been conducted with medical professionals throughout the country and in which inevitably (also) ‘bad practices’ came to the fore, Borst-Eilers called on those present to ‘muster the courage to publicise this specific description of everyday medical practice’. She was supported in this by fellow committee member Van Crevel – the professor of neurology who was one of the pioneers of clinical epidemiology and EBM at the AMC in Amsterdam – who said he was inclined to speak not so much of the *courage* as of the *duty* to publish these findings.⁵⁴

Precisely how important Borst-Eilers and associates thought this report, also became evident from the ‘missionary work’ they carried out after the publication of the report and which, according to Bal, Bijker and Hendriks, ‘occurred a great deal more vociferously’ than usual. To start with, all scientific associations within the medical profession were contacted to draw attention to the report. Moreover, all physicians in the Netherlands received a letter from the ministry which said that they could request the advice free of charge. 4,000 physicians actually did this.⁵⁵ The most important ‘missionary work’, how-

51. Bal, Bijker & Hendriks, *Paradox*, pp. 99-100, 174-5.

52. *Ibid.*, pp. 99-101.

53. Quoted in: *Ibid.*, p. 100.

54. Both quotes are derived from: *Ibid.*, p. 100, n. 58. See also for similar discussions during the committee meetings: *Ibid.*, p. 98.

55. *Ibid.*, p. 223.

ever, occurred at a later stage, namely after it appeared that the advice – and in particular the ‘yellow appendix’ featuring the reports of the interviews – caused a considerable stir within the medical profession. Although a great deal of what it revealed on everyday medical practice was experienced as very recognisable by physicians and medical associations, some of them ‘struggled with the negative image of the profession that would be invoked by the advice’. Due to these mixed feelings, the members of the Standing Committee on Medicine feared that the advice would become ‘bogged down’. They decided to make an effort – and use their access to the various scientific associations, among others – to prevent this. In particular Borst-Eilers and Van Duivenboden put a great deal of time and effort into this. They replied extensively to the many letters about ‘Medical Practice at a Crossroads’, which the Health Council had received from both individual physicians and from professional organisations. In addition, they visited all manner of hospitals and institutions to provide a further explanation on the advice, and they discussed the various responses to the report in an article in *Medisch Contact*. The aim of all these missionary activities was to uphold and convey the message of ‘Medical Practice at a Crossroads’ as well as possible.⁵⁶

With this report, which was special in many respects, a second strategy – in addition to ‘Dunning’s funnel’ – had been offered for cost control of insured healthcare in the Netherlands. The Dunning Committee placed the emphasis on choices at the macro-level of the package of insured care, which primarily needed to be made by politicians and society. MTA in the broadest sense of the word could serve as a tool here. The Health Council shifted the focus towards the micro- and meso-level of medical practice. The medical profession in particular was addressed here: it had to put its affairs in order *itself*, before the government, hospital management or the insurers would do this. Recommendations were made to this end – for example with respect to the ‘clinical-epidemiological mindset’ in the medical curricula and the drafting and implementation of guidelines – which may be interpreted as a plea for evidence-based medicine (*avant la lettre*).

Upon closer reading, it is striking that there is hardly any difference between both reports. The Dunning Commission too, paid considerable attention to ‘appropriate care’ at the micro- and meso-level, in a chapter that started with the comment: ‘Most choices in healthcare are not made at the Binnenhof (the site of Dutch parliament in The Hague) or behind the desk of a health insurance company, but in the consultation room, on the

56. *Ibid.*, p. 208, 223-4; See for examples of this ‘missionary work’: ‘Mw. Dr. E. Borst-Eilers, Vice-Voorzitter Gezondheidsraad: “Doelmatig Handelen: Alleen Artsen Kunnen Orde op Zaken Stellen...”’, *Medisch Contact* 47: 5 (1992), pp. 135-8; E. Borst-Eilers & Y. A. van Duivenboden, ‘Reacties op “Medisch Handelen op een Tweesprong”’. *Wetenschappelijke Verenigingen en het Advies van de Gezondheidsraad*, *Medisch Contact* 48: 12 (1993), pp. 359-60.

operating table or around the sickbed.⁵⁷ In ‘Medical Practice at a Crossroads’, the Health Council, in turn, besides ‘EBM’, also championed MTA as an instrument for making choices at the macro-level.

In practice, however, both reports were interpreted by policymakers and other involved parties as two fundamentally different strategies for controlling healthcare costs. The one strategy stood for MTA and political choices at the macro-level, the other one for EBM and a more rational – and therefore more effective – medical practice at the meso- and micro-level. One was additionally characterised by a more *systemic* approach, the other one by a more *intrinsic* approach, focused on behavioural change of the physician.⁵⁸

From Macro-Choices to Efficiency at the Micro Level

Both above-mentioned strategies were to greatly impact healthcare policy in the Netherlands during the 1990s. This was partly the result of the failure of the so-called ‘Simons plan’. Immediately upon his appointment, the Social Democrat Hans Simons, who was State Secretary of Health from 1989 until 1994, got off to a vigorous start with an unprecedentedly radical reform of insured healthcare in the Netherlands. His ‘plan’ was broadly, albeit with a few adjustments, in line with the proposals from the report by the Dekker Committee from 1987 – including the merging of the three existing forms of insurance (health insurance fund, private insurances and AWBZ) into one basic insurance and the introduction of a limited form of regulated marketisation.

The realisation of this ‘major system change’ initially seemed to progress well. For example, several provisions, including aids, psychiatry and medicines, were transferred from the health insurance funds and private insurances to the AWBZ so that the latter could eventually be transformed into the intended basic insurance. Other measures required for the preparation of the system change were also taken with decisiveness. In the autumn of 1991, however, problems were encountered quite suddenly. In the Dutch senate, the Upper House of Parliament, the CDA faction – the Christian Democratic party that, together with the PvdA, Simons’s party, formed the government coalition at the time – threatened to withdraw its support for the Simons plan. As a result, the state secretary needed to make significant concessions. He had to agree, moreover, that all future deci-

57. Commissie Keuzen in de Zorg, *Kiezen en Delen*, p. 187.

58. See for example: A. Ankoné, ‘Gepast Gebruik van “Kiezen en Delen” en “Tweesprong”’: Indien de Artsen Niet Goed Kiezen, Kiest de Overheid’, *Medisch Contact* 47: 42 (1992), 1217-19; D. W. Erkelens, ‘De “Trechter” in de Spreekkamer: Kiezen of Delen voor de Medicus Practicus’, *Medisch Contact* 50: 10 (1995), pp. 323-4; *Gepast Gebruik. Samenvatting van het Kabinetsstandpunt op de Rapporten ‘Kiezen en Delen’ van De Commissie Keuzen in de Zorg en ‘Medisch Handelen op een Tweesprong’ van de Gezondheidsraad* (Rijswijk: Ministerie van WVC, [1992]); “Medisch Handelen op een Tweesprong” Vakmanschap Volstaat Niet Langer’, *Medisch Contact* 47: 1 (1992), pp. 13-14.

sions on the further implementation of the system change would first be submitted to both Houses of Parliament for approval. In effect, the state secretary was thus put under guardianship.⁵⁹

The obstruction by the CDA did not come out of nowhere. In the ‘field’ too, resistance to the Simons plan had increased considerably. In part, this seems to have been due to the modus operandi of the state secretary himself. By operating ‘far too audaciously’⁶⁰ and ‘clumsily’⁶¹, he is purported to have antagonised the umbrella organisations of GPs, the health insurance funds and the health insurance companies.⁶² However, according to Peter Dols and Toon Kerkhoff, respectively researcher and emeritus professor in the field of the structure and functioning of healthcare, the large scope and great complexity of the Simons plan were the main sore point. Nobody could foresee what exactly would be the consequences of its implementation in terms of money, power, influence, status, employment and income for the people and organisations that were to form the new healthcare system. In the midst of all this uncertainty, the discussion flared up, where all involved and interested parties made their own visions, interests, fears and arguments perfectly clear. ‘The divergence in views and beliefs flourished’, Dols and Kerkhoff conclude, which was actually not surprising ‘in the Dutch situation with its fragmented, decentralised power and influence configurations’. In this respect, it was hardly surprising that the CDA faction in the Upper House of Parliament ‘found it all too risky’.⁶³

In the summer of 1992, it became clear that Simons had abandoned ‘the strategy of the great leap forward’⁶⁴. In a memorandum with the revealing title ‘Modernising the Healthcare Sector: *Moving on in a Measured Way*’ (Dutch: ‘Modernisering Zorgsector: *Weloverwogen Verder*’), he opted for a phased, gradual reform of the healthcare system.⁶⁵ Major interventions in the system did not materialise during the remainder of his time in office, which lasted until 1994.⁶⁶ He was succeeded by Borst-Eilers – a member of the pragmatic, social liberal party, D66 (Democrats 66) – who, in her own words, ‘had learned a great deal’ from the failure of the Simons plan. As Minister of Health in the

59. See on the ‘Simons-plan’ and its failure, a.o.: Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 589-90, 796-803; Vonk, *Recht of Schade*, pp. 301-16.

60. Interview with Borst-Eilers.

61. Companje, *Tussen Volksverzekering en Vrije Markt*, p. 590. See for similar qualifications: Bottenburg, De Vries & Mooij, *Zorg tussen Staat en Markt*, p. 180; K. P. Companje, *Convergerende Belangen: Belangenbehartiging van de Zorgverzekeraars in Historisch Perspectief* (Zeist: Zorgverzekeraars Nederland, 2001), pp. 298-300, 304; Vonk, *Recht of Schade*, pp. 302-4, 307, 310-11.

62. Companje, *Tussen Volksverzekering en Vrije Markt*, p. 590.

63. Dols & Kerkhoff were among the authors of the volume edited by Companje, See: *Ibid.*, p. 803 (and see also n. 61 above).

64. *Ibid.*, p. 801

65. Ministerie van Welzijn, Volksgezondheid en Cultuur, *Modernisering Zorgsector: Weloverwogen Verder* (‘s Gravenhage: SDU, [1992]). TB’s italics.

66. Companje, *Tussen Volksverzekering en Vrije Markt*, p. 802; Vonk, *Recht of Schade*, p. 314.

period 1994-2002, she maintained a very prudent policy with regard to the reform of the insurance system. She focused on taking ‘small steps’ by means of compromises with the various parties in the field. This policy was also referred to as an ‘incremental policy’ and as a ‘non-regret policy’ by herself and others.⁶⁷

Because the ‘major system change’ was postponed for the time being, the reports by the Dunning Committee and the Health Council – which had been published at the end of 1991, exactly at the time of the failure of the Simons plan – became the focus of attention. The mass media paid extensive attention, in particular, to ‘Dunning’s funnel’, partly because it involved a ‘communication plan’ including the related funding, in accordance with the mission of the Dunning Committee.⁶⁸ In policy-making circles and in health professional organisations, however, ‘Medical Practice at a Crossroads’ was taken at least as ‘seriously’ and debated as intensively. The two reports were often mentioned in the same breath, jointly discussed or compared to each other.⁶⁹

After several years, it became clear that the approach by the Health Council had prevailed. This was very explicitly mentioned by J.H. Mulder, a high-level official at the Ministry of Health, who had been closely involved in the realisation of both reports and in the attempts to translate them into policy. In 1997, Mulder wrote in *Medisch Contact*:

‘Politicians seem barely capable of establishing priorities within the existing package. This places the issue of choices in healthcare at the meso- and micro-level [...]. *Funnelling according to the Dunning method is old hat. ‘Evidence-based medicine’, appropriate use and guidelines are all the rage.* I call this ‘the tilting of Dunning’, which occurred in political circles in The Hague.’⁷⁰

The ‘tilting of Dunning’ will have been no surprise to insiders. Immediately upon the publication of the report ‘Choose and Share’ by the Dunning Committee, it already appeared that Simons was not very pleased with it. According to the reconstruction that Bal, Bijker and Hendriks made of this episode, the state secretary disliked the fact that

67. A. Ankoné, ‘Minister Borst: “In de Praktijk Komt Meer Zorgvernieuwing van de Grond dan op Koepelniveau”’, *Medisch Contact* 50: 27/28 (1995), pp. 885-7; E. Borst-Eilers, ‘De Agenda 2000+: Kernvragen in het Beleid voor de Volksgezondheid’, in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 49-56; Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 590, 803-8; Vonk, *Recht of Schade*, pp. 314-15.

68. Commissie Keuzen in de Zorg, *Kiezen en Delen*, pp. 233-55. See also: *Gepast Gebruik. Samenvatting van het Kabinetsstandpunt*.

69. See n. 58 above, and also: ‘Professionele Standaard Uitgangspunt voor Keuzen in de Gezondheidszorg’, *Medisch Contact* 47: 9 (1992), pp. 263-6; C. Spreeuwenberg, ‘Medisch Handelen op een Tweesprong’, *Medisch Contact* 47: 1 (1992), p. 3.

70. J. H. Mulder, ‘Dunning Gekanteld: Terug naar de Zorg’, *Medisch Contact* 52: 39 (1997), pp. 1219-20. TB’s italics.

the Dunning Commission put the hot potato – making choices in the statutorily insured package – in the hands of politicians. In addition, ‘Choose and Share’ made a distinction between the AWBZ and other insured healthcare, while Simons wanted to realise a single undivided basic package.⁷¹

‘Medical Practice at a Crossroads’ found much more favour with Simons and the policymakers at the department of Health. They were even downright enthusiastic about the report and in particular about the so-called ‘yellow appendix’ that included the report of the 63 interviews that had been conducted with medical professionals around the country. According to Mulder, they confirmed what he and his peers at the ministry had thought all along: medical practice had irrational traits and, as a result, was frequently insufficiently efficient. It was ‘politically fortunate’ moreover, that the Health Council mainly placed the responsibility for more efficient healthcare with the medical profession itself.⁷²

This difference in reception was clearly expressed in the official cabinet position on the reports ‘Choose and Share’ and ‘Medical Practice at a Crossroads’, which was published in 1992 – significantly enough as an appendix to the Memorandum ‘Moving on in a Measured Way’, in which Simons was forced to shelve his ‘grand design’. On the Dunning Committee it stated that it ‘launched a workable initiative to make the debate on the scope of the statutorily insured package more objectifiable’. ‘Several reservations’ were then immediately expressed concerning all four criteria from the ‘Dunning funnel’.⁷³

The cabinet was able, however, to muster some enthusiasm for the chapter in which the Dunning Commission addressed the issue of ‘appropriate and inappropriate healthcare’. In a substantive sense, the recommendations made in it largely coincided with the report of the Health Council, it was concluded. The Cabinet Position was therefore entitled ‘Appropriate Use’; this subject formed ‘the hinge point [...] between both reports.’⁷⁴

The Cabinet Position then elaborated on ‘Medical Practice at a Crossroads’. Here, the reserved and critical comments on the Dunning Commission made way for warm approval of the recommendations by the Health Council, including the comment: ‘The Cabinet quite agrees with this approach.’⁷⁵ In addition, there were recurrent phrases such as ‘Along with the Health Council, it is the opinion of the Cabinet....’⁷⁶ In the conclusion of the Cabinet Position, it was explicitly stated once more:

71. Bal, Bijker, & Hendriks, *Paradox*, p. 203.

72. Interview met Borst-Eilers; Bal, Bijker, & Hendriks, *Paradox*, p. 204.

73. Ministerie van Welzijn, Volksgezondheid en Cultuur, *Modernisering Zorgsector*, pp. 34-5.

74. *Ibid.*, p. 40.

75. *Ibid.*, p. 41.

76. *Ibid.*, see for two examples p. 46. See for similar remarks: pp. 43-4, 47-9. See also on all this: Ankoné, ‘Gepast Gebruik’; Van den Burg & Ter Meulen, ‘Prioriteiten binnen de Gezondheidszorg’, pp. 38-40; *Gepast Gebruik. Samenvatting van het Kabinetsstandpunt*.

‘that we *consciously opt for the “crossroads idea” sketched by the Health Council*’. According to this idea, the profession itself should, at the first instance, do all that is necessary to promote appropriate use, and more explicit government intervention in this respect shall only be appropriate if it appears that the profession does not sufficiently succeed in this.⁷⁷

According to the high-ranking official, Mulder, the report by the Health Council was thus ‘officially overrated’ and ‘politicised’, because it was used as an ‘attractive alternative so as to be able to ignore Dunning’s message’.⁷⁸ In an interview from 2002, he was very critical at this point of Borst-Eilers’s performance as Minister of Health in the period 1994-2002. She had admittedly converted the recommendations from ‘Medical Practice at a Crossroads’ with regard to ‘evidence based medicine, appropriate use and guidelines’ into policy but, in Mulder’s view, she had ‘actually neglected Dunning’. She had ‘often avoided’ choices at the macro-level, ‘consistently’ putting the ‘hot potato’ in the hands of ‘professionals in the consultation room or at the sick bed’, who, with resources being limited, were forced to ration anyway.⁷⁹

With these statements, however, Mulder does not do full justice to the minister. In fact, upon her appointment as minister, Borst-Eilers made it clear that she would retrieve ‘Dunning’s funnel from the drawer’ in which it had ended up under Simons. She also announced that, with a view to the assessment of new medicines, aids and treatment procedures, an Act on Medical Technology Assessment would come into effect. Both policy intentions were included in the coalition agreement and were also (slightly more implicitly) mentioned in the government declaration of the first Kok cabinet (1994-1998).⁸⁰ All this suggests that the minister and her officials were seriously interested in pursuing this.⁸¹

In the summer of 1995, however, not even a year after the appointment of the first Kok cabinet, the chief editor of *Medisch Contact*, C. Spreeuwenberg, concluded that the attempts to apply ‘Dunning’s funnel’ had failed.⁸² Dental care for people aged over 18 had admittedly been removed from the package in 1995 – according to official Mulder the first (and virtually only) ‘real *funnel* intervention’⁸³ – but then things started going awry

77. Ministerie van Welzijn, Volksgezondheid en Cultuur, *Modernisering Zorgsector*, p. 51. TB’s italics.

78. Quoted in: Bal, Bijker, & Hendriks, *Paradox*, p. 204.

79. *Ibid.*, pp. 204-5.

80. A. Ankoné, “Doelmatigheidsplannen Zullen Veld Wellicht Verrassen.” Vage Vragen bij Regeerakkoord Binnenkort Beantwoord’, *Medisch Contact* 50: 7 (1995), pp. 203-5; C. Spreeuwenberg, ‘Een Dokter voor de Volksgezondheid’, *Medisch Contact* 49: 36 (1994), p. 1107; S. E. Wildevuur, ‘Prof. Drs. J. Van Londen: “Regeerakkoord als Stimulans en Uitdaging”’, *Medisch Contact* 49: 46 (1994), pp. 1451-3. See for pdf’s of both coalition agreement and government statement the website of Parlement & Politiek (Parliament & Politics): http://www.parlement.com/id/vh8lnhronvvu/kabinet_kok_i_1994_1998#p5.

81. See n. 70 above and also: Interview with Borst-Eilers; S. E. Wildevuur, ‘Het FOZ 1996: Kostenoverschrijding Meer dan een Miljard’, *Medisch Contact* 50: 39 (1995), 1215-16.

82. C. Spreeuwenberg, ‘Na de Pil: Systematiek of Pragmatiek?’, *Medisch Contact* 50: 27/28 (1995), p. 883.

83. Mulder, ‘Dunning Gekanteld’.

when the minister decided to abandon her earlier intention to remove the birth control pill for women aged over 18 from the package. Spreeuwenberg thought it highly regrettable that the minister had caved in on this, under pressure from an intense political and societal debate. According to him, every future decision regarding the package would be assessed against the one on the birth control pill, with all the attendant consequences for Dunning's systematics:

'With every measure, the question arises if its object with regard to participation in society is more important or less important than the pill. This will happen if pragmatism prevails over systematics.'⁸⁴

Spreeuwenberg's prediction largely came true. While long-term physiotherapy did disappear from the package in 1996,⁸⁵ apart from that, 'the yields of the funnel operation [...] were ultimately not impressive', as concluded in 1997 by the official Mulder, who was closely involved in this operation. According to him, the attempts made to 'funnel' the pill, IVF, long-term physiotherapy, speech therapy and domestic assistance after physiological childbirth had been 'downright disappointing'. He also mentioned 'the political furor' that had arisen when there was talk of the removal of the reimbursement for dentures – a plan that was subsequently withdrawn. In his view, these examples pointed to 'an important reason for the fact that Dunning's funnel barely works', namely 'that the political and societal unrest is disproportionate to the financial proceeds.'⁸⁶

Mulder's analysis was shared by many others. At the end of the 1990s, various authorities, including the KNMG, the Council for Public Health and Healthcare and the Steering Committee on Future Health Scenarios (Dutch abbreviation: STG), qualified the attempts to establish priorities at the macro-level of the healthcare package as less than successful or even as failed.⁸⁷ The most commonly cited cause was the difficulty in-

84. Spreeuwenberg, 'Na De Pil'.

85. And even this measure was considered to be 'rather arbitrary' and not a truly good example of the application of the criteria from Dunning's funnel. See, among others: Mos & Galema, *Achtergrondstudies 10 Jaar Pakketdiscussie*, p. 35

86. Mulder, 'Dunning Gekanteld'.

87. Caparie et al., 'Ontwikkeling en Implementatie'; J. M. Minderhoud, 'Passende Medische Zorg', *Medisch Contact* 52: 15 (1997), p. 464; J. Mos & M. P. Galema, *Deelstudies 10 Jaar Pakketdiscussie* (Zoetermeer: Stichting Toekomstscenario's Gezondheidszorg, [2000]); Idem, *Achtergrondstudies 10 Jaar Pakketdiscussie*; J. N. D. de Neeling, *Passende Medische Zorg: over Keuzen en Richtlijnen* (Utrecht: KNMG, [2000]), pp. 5, 10-14; Raad voor de Volksgezondheid en Zorg, *Ethiek Met Beleid: Advies over Beleid bij Ethische Vraagstukken in de Gezondheidszorg* (Zoetermeer: RVZ, [1999]), see in particular 'bijlage 6' which contains an evaluative case-study of 'Dunning'. See also: A. Boer, *Het Basispakket: Inhoud en Grenzen. Rapport naar Aanleiding van de Evaluatie van "10 Jaar Pakketdiscussie"* (Amstelveen: College voor Zorgverzekeringen, [2001]); R. van Herk, *Artsen onder Druk: over Kwaliteitsbeleid van Medische Beroepen* (Utrecht: Elsevier/De Tijdstroom, 1997), p. 44; Raad voor Gezondheidsonderzoek, *Advies HTA-Onder-*

volved in garnering sufficient public and political support for interventions in the package, whether or not with the aid of the ‘funnel’. The study on ‘10 Years of Package Debate’ conducted by the STG and commissioned by the Healthcare Insurance Board – the successor of the Health Insurance Council – summarised it very well:

‘Package debates are unmanageable for the interests are sizeable, conflicting and inter-linked. Health is a great good [...]. Anyone who is ill or in need of (medical) care and treatment, claims their entitlement to healthcare. Politicians are very sensitive to the often unspoken feeling of social justice and reluctant to enforce categorical exclusion. Acquired rights can barely be reversed.’⁸⁸

Dunning himself, who expressed deep disappointment about the state of affairs, placed the blame above all with politics. In 2001, he spoke of the ‘disagreement that paralyses all policy’. The major political parties fundamentally disagreed on virtually all themes in healthcare policy, with the result that choices in healthcare failed to materialise.⁸⁹

Yet this problem partly lay with ‘Dunning’s funnel’ itself. It appeared that, from the word go, policymakers and politicians considered the criteria prescribed therein to be unclear and difficult to use.⁹⁰ This especially applied to the criterion of ‘necessity’. This was, as the STG observed, ‘so difficult to operationalise that it does not play a role in the debates whatsoever.’⁹¹ The criterion was moreover highly politically charged. The Dunning Committee had described ‘necessary care’ as care ‘enabling individuals to share, preserve and, if possible, improve life with other members of society.’ Thus, the committee had explicitly opted for a ‘community-oriented approach’ to health, which was closest to the vision of society of the Christian Democrats. Based on the ‘liberal perspective’ of the liberal parties VVD and D66 and the ‘egalitarian perspective’ of the Social Democrats of the PvdA, quite different definitions of ‘necessary care’ could be drawn up – and it was precisely these parties that happened to form the government coalition in the period 1994-2002. Similarly, for the criterion of ‘care provisions being left at the ‘patient’s own

zoek, pp. 21-2, 28-9; F. F. H. Rutten & E. W. M. Grijseels, ‘De Voorwaarden voor Invoering en Financiering van Nieuwe Technieken’, *Nederlands Tijdschrift voor Geneeskunde* 143 (1999), pp. 2329-32.

88. Mos & Galema, *Achtergrondstudies 10 Jaar Pakketdiscussie*, p. 35. This report is also included as Annex 2 in: Boer, *Basispakket*.

89. A. J. Dunning, ‘Kiezen en Delen: Omzien in Verwondering’, in P. Bossuyt & J. Kortenaar (eds.), *Schaatsen Op Dik Ijs: Evidence-Based Medicine in de Praktijk* (Amsterdam: Boom, 2001), pp. 101-110, on pp. 106-107.

90. See n. 87 above. See in addition: Gerritsen & Linschoten, *Gezondheidszorgbeleid*, pp. 141, 143-5; H. Roelink, ‘Keuzen in de Zorg: een Gebed Zonder Einde?’, *Medisch Contact* 48: 49 (1993), pp. 1563-5.

91. Mos & Galema, *Achtergrondstudies 10 Jaar Pakketdiscussie*, p. 35. This report is also included as Annex 2 in: Boer, *Basispakket*.

expense and responsibility' it applied that the way in which it was used strongly depended on the vision of society and political ideology.⁹²

From within the healthcare 'field' too, a number of objections to 'Dunning's funnel' could be heard. Spreeuwenberg, for example, wrote in an editorial in *Medisch Contact* that 'at a time in which self-determination and autonomy were highly valued', it was not incomprehensible that the community-oriented approach of the Dunning Commission was subject to criticism.⁹³ In a special issue of *Medisch Contact* on 'funneling' from 1995, the following conclusion was drawn: 'All in all, the workers from the key fields of our sector *only seem to see the merits of the use of the criterion of efficiency*.'⁹⁴ The criterion of *efficacy* was still deemed acceptable, but was considered to be superfluous as efficacy was thought to be encapsulated in *efficiency*.⁹⁵

Efficiency under the motto 'economical and sensible care' was also the central notion in the policy of Minister Borst-Eilers right from the start.⁹⁶ In this respect, in her attempts to 'funnel', she appears to have selected a narrower approach than that advocated by the Dunning Commission right from the outset. This was possibly motivated by the composition of the cabinet of which she formed part: in the coalition of liberals and social democrats it was almost impossible to reach consensus on the more politically charged criteria of necessity and personal expense and responsibility. Making choices based on the criterion of efficiency – with the criterion of efficacy encapsulated within it – was more attractive for it seemed to allow for the pursuit of a neutral, technocratic, objective and scientific procedure.⁹⁷

In practice, however, it also proved 'difficult [...] to use more care-related considerations, such as efficacy and efficiency, within the package debate'.⁹⁸ As a result, the efforts of the minister to establish priorities at the macro-level of the statutorily insured package

92. See n. 87 and n.90 above. See also: Van den Burg and Ter Meulen, 'Prioriteiten binnen de Gezondheidszorg', pp. 34-6; C. Spreeuwenberg, 'Verkiezingen', *Medisch Contact* 49: 17 (1994), p. 555; D. Willems & M. Veldhuis, *Wegen in de Zorg: Dilemma's, Keuzen en Afwegingen in de Spreekkamer* (Assen: Van Gorcum, 2002), pp. 74-81.

93. C. Spreeuwenberg, 'Geneesmiddelenvoorziening: Verdelen door Verdunnen', *Medisch Contact* 49: 33/34 (1994), p. 1027.

94. C. Spreeuwenberg, 'Een Trio over Trechters', *Medisch Contact* 50: 10 (1995), p. 317. TB's italics.

95. See on all this, a.o.: Erkelens, "'Trechter' in de Spreekkamer"; Gerritsen & Linschoten, *Gezondheidszorgbeleid*, pp. 141, 143-5; Roelink, 'Keuzen in de Zorg'; Spreeuwenberg, 'Trio over Trechters'.

96. See in particular the report: J. L. M. Wesemael et al., *Zuinig Met Zorg: Rapport Ambtelijke Taskforce Volumebeheersing en Kostenbeperving* (Rijswijk: Ministerie van Volksgezondheid, Welzijn en Sport, [1995]). See also: Ankoné, "'Doelmatigheidsplannen'"; H. D. Banta, W. T. van Beekum & W. J. Oortwijn, 'Een Wet op de Medische Technology Assessment', *Medisch Contact* 50: 1 (1995), pp. 19-21; Gerritsen & Linschoten, *Gezondheidszorgbeleid*, p. 55, 132; C. Spreeuwenberg, 'Technology Assessment', *Medisch Contact* 50: 1 (1995), p. 3.

97. Van den Burg & Ter Meulen, 'Prioriteiten binnen de Gezondheidszorg', pp. 53-5; Gerritsen & Linschoten, *Gezondheidszorgbeleid*, pp. 68-9; De Neeling, *Passende Medische Zorg*, pp. 30-4.

98. Mos & Galema, *Achtergrondstudies 10 Jaar Pakketdiscussie*, p. 35. See also: n. 97 above.

evaporated fairly quickly. At the beginning of 1996, eighteen months after her appointment, she indicated that ‘the statutorily insured package has already been reduced to such an extent that it cannot suffer any further depletion.’⁹⁹ This viewpoint is somewhat surprising in view of the very limited yields of the ‘funnel operation’. There was no dramatic ‘reduction’ of the package. The substantive consideration from ‘Medical Practice at a Crossroads’ will undoubtedly have played a role – namely that the package included few provisions that were entirely ineffective, and that first and foremost the wrong and excessive applications of diagnostic techniques and treatment methods needed to be dealt with. In addition, Borst-Eilers will have been disillusioned with the extremely laborious process of attempting to remove a provision from the package. From then onwards, all her efforts were aimed at increasing the efficiency of healthcare at the micro- and meso-level.

From MTA to ‘Appropriate Medical Care’

The above-mentioned key orientation in Borst-Eilers’s policy was strongly emphasised in the way in which she tried to strengthen medical technology assessment in the Netherlands. Already since her spell with the Health Council, she had been closely involved in the MTA movement. Even many years later, she mentioned the book *High Technology Medicine: Benefits and Burdens* by the American MTA-‘guru’ Bryan Jennett as one of her major sources of inspiration.¹⁰⁰ That she strongly supported MTA also came to the fore in the ‘Policy Letter Medical Technology Assessment (MTA) and Efficiency of Care’ that she sent to the Lower House in 1995. In it, she concluded that MTA could ‘lead to a colourful palette of activities and measures at various levels to promote efficient practice as well as to more “evidence based” healthcare’.¹⁰¹ It is telling that the minister linked technology assessment, efficient practice and evidence-based healthcare in one sentence. It appears that her embracing EBM cannot be viewed independently from her efforts to keep the costs of healthcare (somewhat) under control by means of increased efficiency, with MTA being used as an instrument.¹⁰²

99. Cited in: A. Ankoné, “Minister Borst Houdt Volumegroei Onvoldoende in de Hand”, *Medisch Contact* 51: 13 (1996), pp. 434-5.

100. Interview with Borst-Eilers.

101. E. Borst-Eilers, *Beleidsbrief Medische Technology Assessment (MTA) en Doelmatigheid van Zorg* (’s Gravenhage: Sdu, [1995]). p. 17.

102. (The pursuit of) this merging of EBM and MTA also strongly comes to the fore in the article in *Medisch Contact*, in which Mulder, a high-ranking official at the Ministry of Health spoke of the ‘tilting of Dunning’ – and also of ‘evidence-based rationing’. See: Mulder, ‘Dunning Gekanteld’.

In her policy letter, the minister concluded that, while ‘so much’¹⁰³ was already happening around MTA in the Netherlands, its return on investment was very limited because it was lacking in cohesion, structure and impact in policy and practice. The minister did not intend to solve this by introducing new laws and regulations – she saw no cause for an Act on MTA which had been previously announced in the coalition agreement. Rather, she saw the benefits of stimulating and facilitating the existing activities in the field of MTA, where it was mainly important to ensure the ‘streamlining and promotion of cooperation and coordination of the various involved authorities.’¹⁰⁴ In the letter, she announced a wide range of policy measures to this end, explicitly ‘placing the emphasis on the promotion of efficiency of professional practice at the meso- and micro-level.’¹⁰⁵

This was a remarkable shift in the approach to technology assessment, which had been put on the agenda in the Netherlands in the 1980s, precisely as an instrument for priority setting at the *macro-level* of the statutorily insured package.¹⁰⁶ In the mid-1990s, however, it became clear that little had come of the translation of MTA into policy. This became evident, for example, in a study published in 1995 on the state of affairs of MTA in the Netherlands, which had been commissioned by the Rathenau Institute. On the one hand, it praised the progress made in the Netherlands in this field, especially with regard to the production of ‘an impressive volume of high-quality research,’¹⁰⁷ to which in particular the Investigative Medicine Fund had contributed. At the same time, many obstacles were identified, above all with regard to the lack of cohesion, synthesis, distribution and implementation of MTA knowledge. The people who were supposed to use MTA knowledge were often not even aware of its existence.¹⁰⁸

This is not to say that there was a complete lack of policy-relevant MTA research – whether or not funded by the Investigative Medicine Fund – of which the results also impacted the decision-making process with regard to the statutorily insured package. This concerned new ‘technologies’ that, based on the research results, were or were not admitted to the statutorily insured package. Yet the contribution of MTA towards the *removal*

103. Borst-Eilers, *Beleidsbrief Medische Technology Assessment*, p. 21.

104. *Ibid.*, p. 21, see also pp. 13-17.

105. *Ibid.*, p. 17. TB’s italics. This was called a ‘striking’ approach to the use of MTA in: Boer, *Onderzoek op Maat*, p. 9, see also pp. 139, 215.

106. See for more on this: Banta & Oortwijn, ‘The Netherlands’; Banta, Oortwijn & Van Beekum, *Organization of Health Care Technology Assessment*, pp. 79-92 (see also the Dutch version of this report: Rathenau Instituut, *De Organisatie van Technology Assessment in de Gezondheidszorg in Nederland* (Den Haag: Rathenau Instituut, [1996]), pp. 89-104); Elsinga, ‘Voor Wie is MTA van Nut?’; E. Elsinga & F. F. H. Rutten, ‘Medische Technology Assessment. Toepassing in de Nederlandse Gezondheidszorg’, *Medisch Contact* 50: 1 (1995), pp. 13-18; Raad voor Gezondheidsonderzoek, *Advies HTA-Onderzoek*, pp. 11-12; Van der Sande, Lamberts & Rooijmans, ‘Kennis op de Plank?’.

107. Banta, Oortwijn & Beekum, *Organization of Health Care Technology Assessment*, p. 23.

108. *Ibid.* pp. 117-130 (see also the Dutch version: Rathenau Instituut, *Organisatie*, pp. 333-148). See also: Boer, *Onderzoek op Maat*; Raad voor Gezondheidsonderzoek, *Advies HTA Onderzoek*.

from the package of inefficient 'items' that had already (long) been part of the statutorily insured package was not or barely successful. An important cause was that hardly any research into 'old' technologies was conducted. In addition, there was a growing belief within the 'MTA field' too that there was little glory to be gained with package reduction, as in policy decisions with regard to the statutorily insured package 'not only [...] scientific arguments were involved'.¹⁰⁹ In this respect, it seemed simpler to concentrate on the (limitation of) needs assessments, which was politically less sensitive and scientifically perfectly defensible, moreover.¹¹⁰

In short, a clear consensus originated among the people and parties involved in MTA in the Netherlands to shift the focus of the activities towards the micro-level.¹¹¹ Minister Borst-Eilers's policy letter on MTA from 1995 dovetailed well with this.¹¹²

The big question, however, was how to induce medical professionals and other healthcare professionals to actually take data on efficiency into consideration in their daily practice. From her policy letter it appears that the minister foresaw an important role here for the CBO, the NHG, the (other) scientific associations of the professional associations of healthcare and the Dutch Cochrane Centre – which was pledged additional money.¹¹³ Especially the NHG and the standards of this society were highly commended by the minister. In her view, this example needed to be followed. She therefore announced: 'I will meet with the CBO to discuss the possibilities of developing guidelines [...] more in accordance with the methodology of the NHG.'¹¹⁴ In addition, she announced she endeavoured to ensure that in guideline development – but also in peer review and inspections – 'quality' was structurally linked to 'efficiency'. In other words: the CBO and the

109. Raad voor Gezondheidsonderzoek, *Advies HTA-Onderzoek*, p. 28.

110. See on all this: Banta, Oortwijn & Beekum, *Organization of Health Care Technology Assessment*, in particular pp. 81-92, 100-1; E. Elsinga, 'Het Gebruik van MTA. 2: Remmende en Stimulerende Factoren', *Medisch Contact* 51: 13 (1996), pp. 447-50; Idem, 'Voor Wie is MTA van Nut?'; Raad voor Gezondheidsonderzoek, *Advies HTA-Onderzoek*, pp. 18-22, 27-8; Van der Sande, Lamberts & Rooijmans, 'Kennis op de Plank?'

111. See n. 110 and, in addition: Banta & Oortwijn, 'The Netherlands'; Banta, Beekum & Oortwijn, 'Wet op de Medische Technology Assessment'; Banta, Oortwijn & Beekum, *Organization of Health Care Technology Assessment*, pp. 109-16; Boer, *Onderzoek op Maat*, pp. 126-8, 131; Van den Burg & Ter Meulen, 'Prioriteiten binnen de Gezondheidszorg', pp. 43-55; Casparie et al., 'Ontwikkeling en Implementatie'; Elsinga & Rutten, 'Medische Technology Assessment'; Rutten & Grijseels, 'Voorwaarden'; Spreeuwenberg, 'Technology Assessment'; Wetenschappelijke Raad voor het Regeringsbeleid, *Volksgezondheidszorg. Rapport 52* (Den Haag: Sdu, 1997), pp. 160-1.

112. See, for example, Wetenschappelijke Raad voor het Regeringsbeleid, *Volksgezondheidszorg*, pp. 160-1. This was, by the way, not surprising because the aforementioned study commissioned by the Rathenau Institute left a strong mark on the policy letter. Although the policy letter was published prior to this study, the minister was up to date with the hearings that had been held as part of this study and with other research data that had already been collected.

113. Borst-Eilers, *Beleidsbrief Medische Technology Assessment*, pp. 15, 17, 19-20.

114. *Ibid.* p. 19.

professional associations in healthcare, which admittedly vigorously pursued their quality policy, should, in future, 'take more account of the necessity of efficiency promotion and appropriate use'.¹¹⁵ The minister emphatically left the initiative with 'the field' here: according to her, it was here where 'the substantive and financial responsibility' for the development of guidelines lay. She did undertake to make available resources to promote the implementation and evaluation of the use of guidelines.¹¹⁶

Two years later, in 1997, the minister shifted up a gear. In the 'Progress Report on Medical Technology Assessment and Efficiency in Healthcare' (Dutch: 'Voortgangsrapportage Medische Techology Assessment en Doelmatigheid van Zorg'), she announced additional measures. They were required, in her view, because there was still a lack of sufficient coordination and synergy in efficiency research – the minister spoke of 'a patchwork' – above all because not enough headway was being made into the implementation in practice. To do something about the latter, she commissioned the institute for Medical Technology Assessment (iMTA) of Erasmus University in Rotterdam¹¹⁷ and the Dutch Cochrane Centre (DCC) to re-evaluate a number of existing protocols and guidelines on the basis of cost-effectiveness analyses. In addition, the Quality Research Working Group (Dutch abbreviation: WOK) of Nijmegen University was commissioned to develop a multi-year implementation programme. With the help of these projects, the minister attempted to ensure an increased integration of MTA data on cost-effectiveness into clinical guidelines.¹¹⁸

With these measures, the minister followed up on what she had announced in the autumn of 1996, during the discussion of her budget in the Lower House of Parliament: namely that she intended to appoint an institute for the drafting of protocol programmes. The KNMG was not pleased with this. The medical association made it clear that the development and implementation of protocols, standards and guidelines was 'primarily the responsibility of the medical profession'.¹¹⁹ Explicitly with the intention of 'keeping

115. Ibid.

116. Ibid. See also: Boer, *Onderzoek op Maat*, p. 9.

117. The iMTA was a product of the Incentive Programme for Health Research (SGO), see on the SGO: chapter 5.

118. Boer, *Onderzoek op Maat*, p. 57-8; Casparie et al., 'Ontwikkeling en Implementatie'; Gezondheidsraad, *Van Implementeren naar Leren: het Belang van Tweerichtingsverkeer tussen Praktijk en Wetenschap in de Gezondheidszorg* (Den Haag: Gezondheidsraad, [2000]), pp. 16-17; Raad voor Gezondheidsonderzoek, *Advies HTA-Onderzoek*, pp. 13-14; F. F. H. Rutten & E. W. M. Grijseels, *Richtlijnenprogramma (1997-2002). Deelprogramma iMTA: Ontwikkeling Richtlijnen op Basis van Informatie over Kosten-Effectiviteit. Eindrapportage Maart 2002* (Rotterdam: iMTA, [2002]); Idem, 'Voorwaarden'. It is perhaps not a coincidence that in 1997 too, the official, Mulder, argued in an opinion piece in *Medisch Contact* – in other words: an article targeted at the medical profession – that the issue of the choices was not at the macro-level (anymore), but at the meso- and micro-level (which he called 'the tilting of Dunning') and subsequently explicitly called for 'appropriate use' of EBM as well as MTA in order to arrive at 'evidence-based rationing'. See: Mulder, 'Dunning Gekanteld'.

119. 'KNMG-Reactie op het Jaaroverzicht Zorg 1997', *Medisch Contact* 51: 40 (1996), pp. 1293-5. See also on this: J. Kingma, 'Een Instituut voor Kwaliteit van Medische Zorg: Rationele Keuzen in een Niet-

control in its own hands as much as possible¹²⁰, the KNMG launched the project 'Appropriate Medical Care' (Dutch: *Passende Medische Zorg*) in 1997. In two pilot projects, in psychiatry and in cardiology, the extent to which it was possible to indicate what treatment methods were 'appropriate' was examined. The innovative aspect was that not only the 'customary parameters for guideline development, such as evidence-based medicine, practical experience and consensus outcomes' were involved here, but also 'cost-effectiveness and normative aspects'.¹²¹ In terms of content, this made the project of the KNMG highly comparable to the above-mentioned guideline projects the minister had commissioned and which launched virtually simultaneously.

Although it remains to be seen how these projects impacted medical clinical practice, they greatly contributed to the intensifying and streamlining of 'bottom-up' activities in the field of development and implementation of clinical guidelines, which had been ongoing for a longer period of time. Not only the KNMG itself, but also the Netherlands Society of Cardiology, the Dutch Psychiatric Association, the Trimbos Institute, the Dutch Organisation for Health Research and Development (ZON) and the Rotterdam-based institute for Medical Technology Assessment (iMTA) were involved in the project, 'Appropriate Medical Care'. The iMTA, in turn, co-conducted a research programme with the Dutch Cochrane Centre, which had been commissioned by the minister, and for which there were collaborations with the CBO, the NHG, the WOK and various scientific associations. The contacts and cooperation between all these parties led, among others, to the formulation of common criteria for the assessment and weighing of evidence in the literature research for guideline development. This occurred under the heading 'Evidence-Based Guideline Development' (Dutch abbreviation: EBRO). The so-called 'EBRO platform' was initiated by the Association of Medical Specialists (the successor of the LSV – the National Association of Specialists), but the CBO, the Dutch Cochrane Centre and the iMTA were involved in it as well. The vision on guideline development shared by these parties – including the integration of data from economic evaluation studies – was also 'taken on board' in the text book *Inleiding in Evidence-Based Medicine (Introduction to Evidence-Based Medicine)* which was published in 2000 by people from the Dutch Cochrane Centre, and which has been frequently used in education, workshops and training courses ever since.¹²²

Rationele Wereld, *Medisch Contact* 52: 41 (1997), pp. 1278-81.

120. Minderhoud, 'Passende Medische Zorg'. See also: De Neeling, *Passende Medische Zorg*.

121. Minderhoud, 'Passende Medische Zorg'.

122. Boer, *Onderzoek op Maat*, p. 56; Casparie et al., 'Ontwikkeling en Implementatie'; Van Everdingen, *Evidence-Based Richtlijnontwikkeling*, see in particular pp. 21, 33-4, 158-59, 169; Herder et al., 'Evaluatie'; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*; Rutten & Grijseels, *Richtlijnenprogramma*, pp. 4-5, 71-2; Idem, 'Voorwaarden'.

Thus, during the 1990s, a merging occurred between the government policy with regard to efficiency and appropriate use and the activities of professional associations in the field of rationalisation and improvement of medical practice, which had been developing over a longer period of time. EBM was given a powerful boost as a result of this, but in the specific sense of the proliferation of guidelines for the benefit of increasing the effectiveness and efficiency of medical practice. Evidence-based medicine became more or less synonymous with terms such as appropriate use, appropriate care and sensible and economic care, and even – if it was up to the minister – with MTA.¹²³

Admission of Weakness or Sensible Policy?

At first sight, the policy of Borst-Eilers seems to be something of an ‘admission of weakness’ or an ‘emergency solution’ – to use terms that were also used by critics at the time.¹²⁴ There were repeated complaints that the government all too easily passed on the responsibility for controlling the cost of healthcare to practicing professionals. A case in point was an article by Spreeuwenberg in *Medisch Contact*, in which the by then former chief editor of the journal discussed the election programmes of the various political parties for the 1998 elections to the Lower House of Parliament. He concluded that the various parties were ‘strikingly silent’ on the subject of making choices in healthcare, while in the previous elections, four years earlier, this had been an important theme. Over the past period, however, nothing had come of the proposals by the Dunning Committee and the focus had shifted towards the protocolisation and standardisation of medical practice. Spreeuwenberg qualified this as follows: ‘Politics [...] is not able to withstand the social pressures and political consequences of consistent choices [...]. With some *desperation*, politics therefore urges healthcare professionals to be serious about efficiency and to participate in “evidence-based rationing”’.¹²⁵

However understandable and perhaps partly justified this criticism may be, there is another side of the coin: the minister followed a very consistent course with conviction, which was entirely in line with ‘Medical Practice at a Crossroads’ and, moreover, well-

123. This was evident and/or explicitly mentioned in: Gezondheidsraad, *Van Implementeren naar Leren*, pp. 16-17; Mulder, ‘Dunning Gekanteld’; Kingma, ‘Instituut voor Kwaliteit’. See for examples of the (more or less) equating of EBM and MTA: Banta, Beekun & Oortwijn, ‘Wet op de Medische Technology Assessment’; Borst-Eilers, *Beleidsbrief Medische Technology Assessment*, p. 15.

124. See a.o.: A. C. A. van den Hout, “Vallen en Opstaan”: Analyse vanuit het “Disasterperspectief”, in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 57-65, on p. 59; A. W. Mulder, ‘Medisch Handelen op een Tweesprong?’, *Medisch Contact* 47: 8 (1992), p. 228; ‘Professionele Standaard’; C. Spreeuwenberg, ‘Verkiezingsprogramma’s vanuit Zorgperspectief’, *Medisch Contact* 53: 1 (1998), pp. 25-8. See also: Dunning, ‘Kiezen en Delen’.

125. Spreeuwenberg, ‘Verkiezingsprogramma’s vanuit Zorgperspectief’, p. 27.

geared to the political circumstances of the 1990s. For a number of reasons, there barely seemed to be a workable alternative to the (promotion of) *self-regulation* by the medical profession, towards which Borst-Eilers steered.¹²⁶

Firstly, the possible alternative of more government control was not an obvious one in the political climate of the 1990s, in which the 'retreating government' was the adage. Already, during the preceding decade, there had been a parting with the model of the 'strong state' in healthcare policy, and a trend of 'deregulation' and 'self-organisation' had been launched.¹²⁷ Nevertheless, the government did intervene strongly in the 1980s, with strict austerity measures, including the introduction of budgeting in 1983. This instrument proved effective, but came at a high price: the relationship between the government and the medical profession was severely disrupted as a result.¹²⁸

This 'high price' touched upon a second reason why it seemed 'logical' in the 1990s to focus the policy on the stimulation of self-regulation by the medical profession. The distorted relationship between the government and the medical profession was increasingly regarded as a major problem in political and policy-making circles, for there was a growing conviction that it is virtually impossible to successfully bring about structural changes in healthcare without the cooperation of the medical profession (and of other parties in the 'field' for that matter). To many, the failure of the Simons plan and the limited yields of 'Dunning's funnel' confirmed the correctness of this point of view.¹²⁹

In this context, the health scientist Van Herk mentioned in his 1997 dissertation the 'obstructive power' the medical profession could exercise. As soon as the government threatened to impinge too much on the income and the clinical autonomy of medical professionals, the latter proved capable of significantly frustrating changes. One of the reasons for this mentioned by Van Herk is that for the implementation of quality or funding instruments, the government, to a certain extent, depended on information submitted by the physicians themselves. He concluded that both the government and 'institution

126. Paraphrased from: N. S. Klazinga, 'Het Keurslijf van de Professionaliteit', *Medisch Contact* 51: 40 (1996), p. 1292.

127. Paraphrased from: Van Herk, *Artsen onder Druk*, p. 41. See also: Van den Burg & Ter Meulen, 'Prioriteiten binnen de Gezondheidszorg', p. 46. See for more on this: chapter 7 and notes 128-131 below.

128. L. Gunning-Schepers, 'Solidair Zolang het Werkt: de Ongemakkelijke Symbiose van Arts en Overheid', in P. Bossuyt & J. Kortenaar (eds.), *Schaatsen Op Dik Ijs: Evidence-Based Medicine in de Praktijk* (Amsterdam: Boom, 2001), pp. 121-131, on p. 125. The 'disrupted' relationship between the government and the medical profession in the 1980s was addressed and discussed frequently, a.o. in *Medisch Contact*. See for example (several editorials and an interview with the chairman of the KNMG): 'Arts als Toetsbare Professional'; J. C. van Es, 'De Dokter en de Overheid', *Medisch Contact* 41: 15 (1986), p. 463; Idem., 'Behoeften en Toewijzing', *Medisch Contact* 41: 17 (1986), p. 527; Idem., 'Structuur Gezondheidszorg', *Medisch Contact* 41: 25 (1986), p. 779; C. Spreeuwenberg, 'Overheid en Medische Beroepsgroep: Fiend or Foe', *Medisch Contact* 42: 47 (1987), p. 1481; Idem., 'Afschaffing Contracteerplicht: Niet Zo!', *Medisch Contact* 44: 45 (1989), p. 1467.

129. See for example: J. M. Greep & K. E. Pijnenburg, 'Plan-Simons: Wat Kunnen we ervan Leren?', *Medisch Contact* 47: 44 (1992), pp. 1277-9. See also notes 128 above and 130, 131 and 141 below.

management' were very aware of this 'obstructive power' of physicians. As a result, 'the dominant role of the medical profession in healthcare remained a force to be reckoned with'.¹³⁰

The conclusions by Van Herk were in accordance with the opinions presented during a major conference held in 1997, which was centred around an analysis of '25 years of healthcare policy' and to which virtually all possible stakeholders contributed – (ex-) ministers and state secretaries, officials, politicians, directors of care institutions, representatives of insurance companies, various professional associations and unions and several (policy) scientists.¹³¹ The following statement that was made during the conference on 'the power of the factual' and the decisive role of individual practitioners in the healthcare sector is typical:

'The *power of the factual* is great in the healthcare sector. There is no other sector where it is so great [...]. When you have a toothache, you want to be relieved of this toothache immediately and so there are good dentists who take care of this. If the ambulance does not arrive on the emergency scene within 10 minutes, the municipal council is too small to deal with the ensuing tumult of the protests. And so ambulances are operated in spite of a ramshackle ambulance act. And when we are ill, we visit the doctor and no-one accepts that what is agreed upon in the consultation room between the patient and the medical professional would not be able to be carried out or that third parties would interfere with it. The quality and efficiency in everyday practice is therefore *strongly determined* by what *individual practitioners*, nurses and carers deem necessary in their care relationships with patients and individuals in need of care, where they allow themselves to be led by professional standards and feelings of compassion, much more so than by whatever government regulation.'¹³²

If anyone was aware of the 'power of the factual', the decisive role of individual practitioners and of the 'obstructive force' of the medical profession, it was Borst-Eilers. This was already the case during her spell at the Health Council. In her own words, she and the other committee members responsible for 'Medical Practice at a Crossroads' had made a very important 'tactical' choice. Where all previous reports on the issue of the boundar-

130. Van Herk, *Artsen onder Druk*, the quote is from p. 182, but see also pp. 16-17, 181, 245, 248-9. See also on this: Companje, *Tussen Volksverzekering en Vrije Markt*. pp. 832-3, 856-7, 874-5; B. V. M. Crul, 'Meer Verstand van Verzekeren', *Medisch Contact* 53: 5 (1998), p. 147; R. van Herk, 'Artsen onder Druk', *Medisch Contact* 52: 43 (1997), p. 1344.

131. Gerritsen & Linschoten, *Gezondheidszorgbeleid*. See in particular: Van Hout, "'Vallen en Opstaan'"; F. J. M. Werner, 'Een Voortreffelijke Gezondheidszorg: Dankzij of Ondanks Beleid?', in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie En Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 67-73.

132. Werner, 'Voortreffelijke Gezondheidszorg', p. 71-2.

ies of healthcare – including that of the Dunning Committee – remained too much on the ‘outside’ and were therefore not supported ‘from within’, Borst-Eilers and her peers, as she would formulate it in retrospect, years later, ‘had taken the wise step of “entering the bowels” of the medical profession and having the issues raised from there.’¹³³ She explained this as follows:

‘Yes, we thought we had done this very cleverly. Namely completely presenting our ‘message’ as something physicians are already working on themselves. The sensibilities of specialists are *easily* touched, so if you start by saying that it should be done differently and the way they are doing things is wrong – then you might as well *not* write it down because then the shutter on the other side will close completely. So you sing their praises first about the fact that they have been working on improving their discipline for such a long time, and about the fact that they have been trying to develop increased rational medical practice. And then you say that you have spoken with a great many of them and that they conclude *themselves* that it all can and should be done better. This is how we built this up in a slightly tactical way. And it worked.’¹³⁴

Irrespective of the ‘tactical’ role of addressing medical professionals ‘from within’, the Health Council also advocated a ‘bottom-up’ approach in terms of content. The committee members who wrote the report were intent on tying in with existing initiatives within the medical profession, which they wanted to encourage and support with their advice. During one of the committee meetings it was remarked about this that these initiatives ‘could do with a shot in the arm’, which had to come from within.¹³⁵ After all, the key message of the report was that the medical profession had to put its affairs in order *itself*. In order to convey this message and to prompt the medical profession in to action, ‘future rhetoric’ was practised and ‘missionary work’ performed. Apparently, in the eyes of Borst-Eilers and the other committee members, the key to the required changes in healthcare lay with the medical profession – rather than with politics, the insurers and hospital management.¹³⁶

As a minister, Borst-Eilers followed exactly the same course – both in terms of content and from a ‘tactical’ perspective.¹³⁷ In this regard, it certainly helps that her medical background enabled her to effectively remind the medical profession of its responsibil-

133. Interview with Borst-Eilers.

134. Interview with Borst-Eilers.

135. Interview with Borst-Eilers; Bal, Bijker & Hendriks, *Paradox*, p. 100.

136. Borst-Eilers made this, for example, very clear in interviews in *Medisch Contact* in 1992, 1995 and 1998, see, respectively: ‘Mw. Dr. E. Borst-Eilers’; Ankoné, ‘Minister Borst’; B. V. M. Crul, ‘Minister Borst Adviseert Haar Opvolger’, *Medisch Contact* 53: 1 (1998), pp. 7-10, on p. 8.

137. See n. 141 below.

ity. In her view, Health was one of the departments that required a *specialist minister*, somebody who knows the policy area from the inside, as it was a policy area ‘in which so many psychological mechanisms are at work and in which so many tricks are played’.¹³⁸ She provided the following example of the latter:

‘Then someone says with a pious face: “Yes, minister, we are doing our best, there is no other way.” While, having worked in the discipline yourself, you know very well that there is certainly another way. And you can say this as well.’¹³⁹

Within the medical profession it was noted from the word go that minister Borst-Eilers, in part because she used to be a physician, was capable of improving the relationship and cooperation between government and profession.¹⁴⁰ There was a need for this as well, for in particular the relationship between the government and the specialists had been seriously ruined. According to friend and foe alike, it was one of the great achievements of the minister that she, precisely in this area, had brought peace and quiet. When, for example, her first term in office was evaluated in 1999 by the chief editor of *Medisch Contact*, it was noted that:

‘She did [...] ensure that fewer people from the field were unnecessarily needed and that we were better listened to. Thus, the work carried out to optimise healthcare was more constructive and collective in nature than it had been under many of her predecessors.’¹⁴¹

This merit of Borst-Eilers was partly attributable to her nature – the chief editor of *Medisch Contact* characterised her as ‘an example of a compromising species that always sees something positive in somebody else’s opinion’.¹⁴² As noted, the cautious policy of the minister with a focus on compromises and cooperation with the field fitted in with the political circumstances of the 1990s. Regardless of the dominant climate of the ‘retreating government’, after the failure of the Simons plan, nobody was waiting for a minister who wanted to realise grand, sweeping plans.¹⁴³ In addition, Borst-Eilers’s tenure as a minister – especially her second term of office – was marked by the issue of the sometimes very long waiting lists in healthcare. This was found to be unacceptable in politics

138. Interview with Borst-Eilers.

139. Ibid.

140. Spreeuwenberg, ‘Dokter voor de Volksgezondheid’.

141. B. V. M. Crul, ‘De Minister Gaat’, *Medisch Contact* 54: 21 (1999), p. 751. See also: Ankoné, ‘Minister Borst’; Borst-Eilers, ‘Agenda 2000+’; Companje, *Tussen Volksverzekering en Vrije Markt*, p. 851; Spreeuwenberg, ‘Verkiezingen’; Vonk, *Recht of Schade*, p. 317; Wetenschappelijke Raad voor het Regeringsbeleid, *Volksgezondheidszorg*, p. 16.

142. Crul, ‘De Minister Gaat’.

143. See n. 141 above and n. 144 below.

and society, all the more because the Netherlands was experiencing a spell of economic prosperity. The minister was therefore not so much under pressure to change the system, make macro-choices and control costs, but first and foremost to do something about the waiting lists. She realised full well that she needed the cooperation of the ‘field’ for this. The solution to the waiting list problem was not so much a money issue, but depended mainly on the willingness of institutions and professionals to start working more effectively and efficiently.¹⁴⁴

There were other similar factors that caused Borst-Eilers to try and create ‘calm’ as a minister, so that efforts could be made *from within* towards an increased efficiency of healthcare. Her policy that was focused on encouraging evidence-based medicine – and in particular the development and applications of clinical guidelines – fitted in this context. She did not try so much to impose something on the professional associations as to encourage and (financially) support initiatives from within, such as those of the NHG and the CBO. She did continually keep the pressure on here, such as for example in her policy with regard to MTA, which she was not thanked for in all respects. However, she limited herself to ‘pushing’ the profession to step up its own activities. Under her rule, there was no substantive government intervention in the development of guidelines.¹⁴⁵

All in all, the conclusion may be justified that the *self-regulation* by physicians and medical associations was not in jeopardy with this minister. She was convinced that the improvement of quality and efficiency had best be realised from within, ‘bottom-up’. Staff members at the institute for MTA in Rotterdam spoke in this context of a ‘covenant between the medical profession and the government to work together to promote efficiency in healthcare’, referring to the various efforts in the field of the evidence-based guideline development.¹⁴⁶ Comparable to this is the analysis of the relationship between EBM and government policy, which was provided in 2001 by Louise Gunning-Schepers, the then dean and chairwoman of the Board of Directors of the AMC. In it, she stated that the relationship between physician and government had been disrupted in the 1980s, but also that evidence-based medicine ‘was able to breathe new life into the sometimes awkward, but in the past successful *symbiosis* of professional and government.’¹⁴⁷

144. Borst-Eilers, ‘Agenda 200+’; Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 590-2, 803-8, 821-2, 825-6, 834, 849-51, 856-7; Van Hout, “Vallen en Opstaan”, p. 62.

145. See notes 141 and 144 above. See also: Van Herk, *Artsen onder Druk*, p. 150; J. L. M. Wesemael, ‘Reactie op het Basisdocument “Samen Beter”’, in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorg-beleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 131-4, on p. 132.

146. Rutten & Grijseels, ‘Voorwaarden’.

147. Gunning-Schepers, ‘Solidair Zolang het Werkt’, p. 130. See for more on (the notion of) the *symbiotic relationship* between the state and the medical profession, a.o.: Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 27-8.

Conclusion

This (temporary) outcome of the healthcare policy of the 1990s was entirely in line with the report, 'Medical Practice at a Crossroads', which had been published at the beginning of this decade. With the core message that the medical profession itself needed to put its 'affairs in order', the Health Council – under the inspiring leadership of Borst-Eilers – managed to pull off something special. On the one hand, the Council presented an advice that, in many respects, was much more *political* than had been usual for publications by this independent, scientific advisory body. In addition, the report was used politically by politicians – including State Secretary Simons and the officials and policymakers at the Ministry of Health – so as to be able to somewhat distance themselves from the recommendations by the Dunning Committee. On the other hand, 'Medical Practice at a Crossroads' caused the *depoliticisation* of the issue of cost and choice in healthcare, as the advice – partly due to the way in which it was handled by the various interested parties – led to the emphasis being placed on a solution strategy that looked 'objective' and 'technical', to wit: enhancing efficiency of medical practice using evidence-based guidelines. This seemed to make it possible to avoid sensitive and morally charged choices at the macro-level.

Of great importance, in addition to this, was that Borst-Eilers became Minister of Health, not even three years after the publication of the advice by the Health Council on which she left such a strong mark. She initially intended to carry out the recommendations from 'Medical Practice at a Crossroads' as well as those from the report by the Dunning Committee. She soon experienced how difficult it was to set priorities and make choices with regard to the package of insured healthcare using 'Dunning's funnel'. Already since the 'boundaries debate' of the 1980s, the pursuit of a 'more rational' composition of the statutorily insured package had dominated healthcare policy, but it ultimately seemed to produce little. The minister therefore decided to explicitly shift the emphasis towards increased efficiency at the meso- and (especially) the micro-level, for example in her policy with regard to medical technology assessment. She decided on a 'bottom-up' approach, where initiatives from and within the profession itself were encouraged.

This could perhaps be considered an 'admission of weakness' on the side of the government. On the other hand, this was a conscious, 'tactical' *and* substantive choice by, in particular, minister Borst-Eilers. Already during her time with the Health Council, she expressed that the required changes in healthcare cannot or can barely be enforced from above, but primarily have to come from the medical profession itself. This is because she was very aware – and all the more so after the failure of the Simons plan and the difficult progress of the 'funnel operation' – of the 'obstructive force' the profession could exert. In the political circumstances of the 1990s, it was, for several reasons, not an illogical choice to first and foremost steer towards improvement of the relationship between the government and medical profession in healthcare policy.

Of course, the big question – which will be addressed in the following chapter – is how effective this policy ultimately was. While in the previous section the shift in emphasis in healthcare policy from the macro- to the micro-level was discussed, in chapter 9 the more or less reverse movement will be made. What happened (or did not happen) in terms of the improvement of the efficiency of medical practice with the help of evidence-based guidelines will first be described. The chapter will then address how the government decided to intervene in the health insurance system after all, which led to the establishment, in 2006, of both the Health Care Market Regulation Act (Dutch: Wet Marktordening Gezondheidszorg (Wmg) and the Health Insurance Act (Dutch: Zorgverzekeringswet (Zvw)). This will result in an epilogue-like reflection on the question as to what role and function EBM could (continue) to fulfil in the healthcare system of the 21st century.



Chapter 9.

The Role and Impact of EBM in the 21st Century

‘The proof of the pudding is in the eating.’ Borst-Eilers referred to this proverb in 1993, during her inaugural speech as extraordinary professor in evaluation research of clinical practice at the University of Amsterdam, underlining ‘the golden rule that new treatments, even when they seem effective on theoretical grounds, should invariably first be tested in practice via a well-designed evaluation study’.¹ Thus, she showed her affinity with the philosophy of EBM, which opposed medical practice based on purely pathophysiological reasoning and clinical expertise, and emphasised the use of empirical evidence for the efficacy of medical treatments.²

However, as EBM proponents have admitted themselves, the irony is that it is impossible to prove the favourable effect of evidence-based medicine *itself* in an ‘evidence-based’ way.³ All manner of studies have been conducted into, for example, the effects of the implementation of individual evidence-based guidelines. The highly heterogeneous results of these studies emphasise the accuracy of the comment by Timmermans and Berg: ‘Standards are not one uniform thing, with one uniform effect’.⁴ EBM proponents furthermore often point to specific practices that, under the influence of knowledge from (systematic reviews of) clinical research, have fallen into disuse or have substantially changed. An example that appeals to the imagination, which Iain Chalmers, the founder of the Cochrane Collaboration, frequently uses, concerns the relationship between the prone position and sudden infant death syndrome. On the basis of a very logical-sounding pathophysiological argument, shortly after the Second World War, the famous paediatrician Benjamin Spock had recommended allowing infants sleep on their stomach regularly. For tens of years, this advice was followed in many Western countries, until (finally) someone decided to do empirical, epidemiological (case-control) research into

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1. Borst-Eilers, *Geneeskunde Op Recept?*, pp. 10-11.
 2. Evidence-Based Medicine Working Group, ‘Evidence-Based Medicine’.
 3. See for example: Gezondheidsraad, *Van Implementeren naar Leren*, pp. 7-8; Kristiansen & Mooney, ‘Evidence-Based Medicine’; K. Rasmussen, ‘Evidence-Based Medicine and Clinical Practice: Does it Work?’, in I. S. Kristiansen & G. Mooney (eds.), *Evidence-Based Medicine: in its Place* (London/New York: Routledge, 2004), pp. 151-9; M. G. Samarkos, ‘The Philosophy of Evidence-Based Medicine’, *Hospital Chronicles* 1 (2006), pp. 27-35; J. P. Vandenbroucke, ‘De Cochrane Collaboratie en “Evidence-Based Medicine”’, *Nederlands Tijdschrift voor Geneeskunde* 139 (1995), pp. 1476-7.
 4. Timmermans & Berg, *Gold Standard*, p. 23.

sudden infant death syndrome. As a result, it became clear that, through the practice of the prone position, thousands of babies had unnecessarily died of sudden infant death syndrome. When this realisation eventually dawned (which also took some time – too much time, according to Chalmers), governments and healthcare professionals invested a great deal in the provision of information to parents, recommending them not to lay their infants on their stomach, which (in any event in the Netherlands) led to a significant decrease of mortality from sudden infant death syndrome.⁵

Yet all this does not prove that evidence-based medicine has generally done more good than harm for patients. It is virtually impossible to appreciate the full scale of all the possible benefits as well as all the unintended negative consequences.⁶ It already becomes complicated when, instead of the effects of individual guidelines or medical interventions, the positive and negative effects of the complex of all the (sometimes contradictory) guidelines and trial results have to be assessed across the entire spectrum of medicine. EBM moreover, represents much more than just the implementation of guidelines or trial results. According to many proponents, EBM is primarily concerned with the cultivation of a certain attitude or mentality, which is one of the reasons it has also been allocated an important position in education. What the exact consequences of this are for medical practice is virtually impossible to assess. It will be even more challenging to additionally determine the effect of the ‘macro-dimension’ of EBM. The body of ideas of EBM has clearly played a role in healthcare policy, yet what it has ultimately produced for healthcare in terms of good and bad seems an unanswerable question.

In the previous chapters, an attempt was made to provide a historical explanation for the rise of EBM in the Netherlands. It was discussed how, in the 1970s and (in particular) the 1980s, there was a growing need among several parties for a mechanism of control in medicine. It was additionally detailed with which motives and in what political context minister Borst sought to stimulate the production and implementation of evidence-based guidelines. The remaining question is: what is ultimately the historical *significance*

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5. R. Bal, ‘Van Beleid naar Richtlijnen en Weer Terug: over het Belang van “Vage Figuren”’, J. K. Helderman, P. Meurs & K. Putters (eds.), *Orkestratie Van Gezondheidszorgbeleid: Besturen met Rationaliteit en Redelijkheid* (Assen: Van Gorcum, 2006), pp. 81-93, on p. 81; E. Pronk, “‘Het is Tijd voor Radicale Veranderingen’”, *Medisch Contact* 61: 43 (2006), pp. 1706-8; Scholten, *Hoe Sterk?*, p. 5; T. van der Weijden, *Richtlijnen in de Spreekkamer. Van Dogma naar Dans* (Maastricht, Maastricht University, 2010), p. 5. I (TB) myself experienced this, when I was present at the short course History and Philosophy of EBHC in Oxford in July 2012, where Chalmers used this very same example. See for a different, but similar example of ‘anecdotal evidence’ for the benefits of EBM: Kristiansen & Mooney, ‘Evidence-Based Medicine’, p. 4. See also: ‘Buikligging en Wiegedood: Enige Vragen en Antwoorden’, *Medisch Contact* 48: 44 (1989), p. 1595; C. Spreeuwenberg, ‘Eenvoudig: Niet Goed Genoeg?’, *Medisch Contact* 44: 48 (1989), p. 1575.
 6. See on the possible unintended negative consequences: H. Bastian, ‘Learning from Evidence Based Mistakes’, *British Medical Journal* 329 (2004), p. 1053. Greenhalgh, Howick & Maskrey, ‘Evidence-Based Medicine’.

of the rise of EBM in the Netherlands, or: what impact and effects does it have (or has it had)? Has it indeed *functioned* as a mechanism of control? Did the policy of Borst-Eilers, in accordance with her intentions, actually contribute to an increased efficiency of medical practice? In view of the considerations above, it seems impossible to answer these questions. Add to this that there is a lack of sufficient historical distance. It is obvious that the ‘reverberations’ of EBM – certainly when it also involves a change in behaviour and mentality – will take a long time. This would mean that it is still too early to make any statements about this from a historical perspective.

It will nevertheless be attempted in this chapter to tentatively shed some light on the impact of EBM on Dutch medicine and healthcare. The abovementioned methodological problems will be circumvented here by approaching this issue via three *detours*. The first detour concerns a discussion of the debate on the consequences of the application of evidence-based guidelines for the professional autonomy of the physician. The second detour pertains to an analysis of the changes that occurred in thinking about (the problems surrounding) the implementation of evidence-based guidelines. The third detour relates to a sketch of the ‘opportunities’ and ‘threats’ perceived by (Dutch) exponents of the EBM movement, among others as a result of the introduction of a new health insurance system and a stronger ‘market organisation’ of healthcare in 2006.

Apart from pragmatic reasons, these three ‘detours’ were selected because they fit in well with the notions derived from Porter on a shift from disciplinary to mechanical objectivity, on EBM as a mechanism of control and on EBM as a professional response to external pressure. They therefore provide a good ‘route’ for several reflections, in the conclusion of this chapter, on the historical significance and role of EBM in the 21st century.

Detour 1: Professional Autonomy at Stake

During the 1990s, few subjects were discussed so intensively within the medical profession as precisely that of the pressure on the professional autonomy of physicians. It was all over the pages of *Medisch Contact* and the annual conferences of the KNMG in 1996 and 1997 also largely focused on this issue.⁷ Admittedly, the (threatened) autonomy of physicians had been a recurrent theme ever since the seventies, when government inter-

7. See for just a selection of examples of relevant articles: G. den Hartogh, ‘KNMG-congres 1997: Autonomie is het Woord Niet’, *Medisch Contact* 52: 44 (1997), pp. 1386-9; J. T. M. van der Heyden & J. C. L. van der Hoeven, ‘Professionele Verantwoordelijkheid en Professionele Autonomie’, *Medisch Contact* 53: 16 (1998), pp. 540-1; E. H. Hulst & I. Tiems, ‘Geïntegreerde Zorg en Professionele Autonomie’, *Medisch Contact* 52: 40 (1997), pp. 1251-4; N. S. Klazinga, ‘Het Keurslijf van de Professionaliteit’, *Medisch Contact* 51: 40 (1996), p. 1292; ‘Professioneel Kiezen 1992’, *Medisch Contact* 48: 21 (1993), pp. 665-8; ‘Professionele Standaard Uitgangspunt voor Keuzen in de Gezondheidszorg’, *Medisch Contact* 47: 9 (1992), pp. 263-6; C. Spreeuwenberg, ‘Professionele Verantwoordelijkheid: KNMG-Congres 1997’, *Medisch Contact*

ference in healthcare clearly increased, but in the 1990s, this subject was higher on the agenda than ever for several reasons. New legislation came into force in this decade, for example with, among others, the Dutch Individual Healthcare Professions Act (Dutch abbreviation: Wet BIG⁸) of 1993 and the Medical Treatment Agreement Act (Dutch abbreviation: WGBO⁹) of 1994, in which respectively (access to) the medical profession was regulated and the rights of patients were laid down. This led to a great deal of debate on the possible negative consequences of this ‘juridification’ of medicine. In addition, in this period, (proposed) measures by the government for increased integration of medical specialists in the organisational structure of hospitals led to great unrest – and division – among medical specialists. Some of them were of the opinion that these measures heralded the end of the free medical profession in the Netherlands.¹⁰

The rise of EBM featured strongly in all the debates on professional autonomy.¹¹ There are several explanations for this. In the first place, EBM touched upon ‘the core of the clinical autonomy’ of physicians: the freedom of diagnostic and therapeutic practice.¹² Implicitly and sometimes explicitly – as in the report ‘Medical Practice at a Crossroads’ by the Health Council – the message of proponents of EBM was that the decisions taken by physicians about the care for their patients were often *not rational*. Thus, with the rise of EBM, medical decision making – the ‘special expertise’ of the physician – came under scrutiny.¹³

Secondly, EBM was increasingly equated with the production and implementation of clinical guidelines, in which ‘proper’ medical practice was prescribed, standardised and embedded in rules. In his dissertation from 1997, the health scientist Van Herk grouped guidelines under the category of ‘normative quality instruments’, which he distinguished from the more traditional ‘educational’ quality instruments, such as medical training courses and medical disciplinary law. While the latter category of quality instruments formed part of the long-standing tradition in the Netherlands of self-regulation by the medical profession, ‘normative’ quality instruments such as clinical guidelines could threaten this self-regulation. If medical practice were to be explicated in guidelines, it

52: 44 (1997), pp. 1382-5; Idem, ‘Op het Snijvlak van Samenleving en Professie’, *Medisch Contact* 51: 47 (1996), p. 1519; Idem, ‘Professionele Autonomie’, *Medisch Contact* 46: 43 (1991), p. 1287.

8. Wet op de Beroepen in de Individuele Gezondheidszorg.

9. Wet op de Geneeskundige Behandelingsovereenkomst.

10. See n. 7 above and see also: Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 651-654, 688-689, 822-823; B. V. M. Crul, ‘Beklaagde Dokters’, *Medisch Contact* 53: 11 (1998), p. 347; Van Herk, *Artsen onder Druk*, pp. 13, 62, 129-35, 139-45; C. Spreeuwenberg, ‘Professionele Autonomie van de Medisch Specialist’, *Medisch Contact* 50: 37 (1995), p. 1145; Idem, ‘Professioneel Kiezen’, *Medisch Contact* 47: 3 (1992), p. 67.

11. See n. 7 above and n. 15 below. See in addition: Spreeuwenberg, “Evidence-Based Policymaking”; Idem, “Evidence-Based Medicine”.

12. This is derived from: Van Herk, *Artsen onder Druk*, pp. 13, 33, 45, 49 But see also n. 13 and n. 14 below.

13. Timmermans & Berg, *Gold Standard*, pp. 13-14.

would also become more transparent to ‘third parties’, so that supervision of medical practice by non-medical parties could increasingly become a reality.¹⁴

The medical profession did not need to fear this external supervision (initially), as demonstrated by the findings from the previous chapter. Borst-Eilers’s policy was geared towards an increase in efficiency from the inside and ‘bottom-up’. Partly for this reason, the development and implementation of guidelines primarily remained an issue for physicians and medical associations themselves. This raises the question of how great or real the threat to professional autonomy actually was. At the same time, however, physicians and medical associations were extremely preoccupied with this possible threat – and not least in relation to the emergence of evidence-based guidelines. Exemplary is a statement from 1997 by the then chairman of the KNMG in *Medisch Contact*:

‘With a certain mischievous glee, policymakers seem to *whittle away at the professional autonomy* of physicians for the benefit of a cost-benefit analysis where the emphasis is solely on the financial aspects. The positive effects of ‘*evidence-based medicine*’, a system designed by the profession itself, are shown up in a peculiar light as a result of this.’¹⁵

This quotation is exemplary for the difficulties many medical professionals experienced in the link between evidence-based guidelines and the financial objective of increasing efficiency and cost control, which played a key role in Borst-Eilers’s policy. Many physicians considered it to be their primary responsibility to provide each individual patient with the best possible care. It was therefore not up to them to solve the problem of scarcity in healthcare.¹⁶ This viewpoint was expressed in 1998, for example, by Spreeuwenberg, the now former chief editor of *Medisch Contact*:

‘Patients are allowed [...] to ask their physician to provide them with the best available advice, without being influenced by social considerations or by considerations relating to other patients.’¹⁷

14. Van Herk, *Artsen onder Druk*, pp. 14, 38 See for more on the distinction between ‘normative’ and ‘educational’ quality instruments pp. 55-8. See also: Berg, *Rationalizing Medical Work*; Dwarswaard, *Dokter en Tijdgeest*, p. 117; Timmermans & Berg, *Gold Standard*, pp. 16-18, 82-116; Weisz, et al; ‘Emergence’.

15. J. M. Minderhoud, ‘Alleen een Veranderd Decor?’, *Medisch Contact* 52: 39 (1997), p. 1206.

16. See a.o.: Gezondheidsraad, *Van Implementeren naar Leren*, p. 32; E. M. de Bruijn, W. H. Cense & N. S. Klazinga, ‘Passende Medische Zorg’, *Medisch Contact* 55: 26 (2000), pp. 979-81; Kingma, ‘Instituut voor Kwaliteit’; De Neeling, *Passende Medische Zorg*, pp. 5, 21; H. Rigter, ‘Passend Gebruik van het Begrip “Gepast” in Discussies over de Gezondheidszorg’, *Nederlands Tijdschrift voor Geneeskunde* 138 (1994), pp. 4-7.

17. C. Spreeuwenberg, ‘Verkiezingsprogramma’s’, pp. 27-8.

Incidentally, Spreeuwenberg – as well as the KNMG¹⁸, the CBO¹⁹, the Association of Medical Specialists²⁰ and the NHG²¹ – did hold the view that physicians, due to the importance of the accessibility of healthcare, were supposed to take effectiveness *as well as* efficiency of medical practice seriously. He therefore argued: “The pursuit of “evidence-based medicine” and the combating of redundant medicine should therefore be fully supported.”²² This seems to be entirely in line with Borst-Eilers’s policy which he criticised, however, in the same article. Where then did the problem lie?

It seems the answer can be found in the distinction between evidence-based medicine and medical technology assessment. The minister tried to integrate MTA within EBM to the greatest extent possible, and even used both notions more or less as synonyms. Yet from the profession it was repeatedly argued that it concerned two entirely different matters here.²³ Spreeuwenberg, for example, wrote in an editorial in *Medisch Contact*:

‘MTA should be distinguished from research within the framework of “evidence-based medicine”. After all, the latter aims to support clinical decisions by checking the literature for the best answer to relevant *clinical questions*. Research in which questions *other than clinical questions* are answered, such as efficiency research, quickly belongs to the domain of MTA research [...]’²⁴

The sharp distinction Spreeuwenberg made between the *clinical* questions and objectives of EBM and clinical research, and the questions and objectives of MTA *other than clinical ones*, reveals a highly essential point. Evidence-based medicine was considered to be something from ‘within’ the medical profession, while MTA, on the other hand, was something from the ‘outside’. Technology assessment and clinical decision analysis, too, of which MTA was thought to be the macro-variant, were not attractive to physicians because they were perceived as separate, non-medical disciplines. According to Knottnerus,

18. See for example: De Bruijn, Cense & Klazinga, ‘Passende Medische Zorg’; J. M. G. Lanphen, ‘Meer Preventie en Geen Commercie’, in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 137-9; ‘Professioneel Kiezen 1992’.

19. See for example: Boer, *Onderzoek op Maat*, p. 154.

20. See for example: J. H. Kingma & F. W. M. Hol, ‘Inhoud, Structuur en Financiering van de Gezondheidszorg: Gisteren, Vandaag en Morgen’, in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 143-6.

21. See for example: S. Broersen, ‘NHG Presenteert Honderdste Standaard’, *Medisch Contact* 67: 37 (2012), pp. 1998-2000.

22. Spreeuwenberg, ‘Verkiezingsprogramma’s’, p. 27.

23. See a.o.: Kingma, ‘Instituut voor Kwaliteit’; R. Otten, ‘MTA-Mes in Praktijk Nog Niet Scherp Genoeg’, *Medisch Contact* 51: 49 (1996), pp. 1579-80; C. Spreeuwenberg, ‘Leidt MTA van Longtransplantaties tot Beleidsbeslissingen?’, *Medisch Contact* 52: 14 (1997), p. 433. Also people who were not physicians made this observation, see for example an article from Henk Rigter, the former secretary to the Health Council: Rigter, ‘Passend Gebruik’.

24. Spreeuwenberg, ‘Leidt MTA van Longtransplantaties tot Beleidsbeslissingen?’.

this was caused by the terms alone: they were ‘specialist’ and, as a result, made one think of ‘techs’. The idea that there were allegedly external experts – ‘techs’ – who had something to say about medical practice, was hard for many a physician to believe.²⁵ It was quite different in the case of EBM: this was widely perceived to be something from, for and by physicians.²⁶ This already came to the fore in the previously cited quotation by the chairman of the KNMG, who spoke of ‘a system designed by the profession itself’.²⁷

The minister seemed to infringe precisely on EBM as an ‘own’ activity of the medical profession itself by seeking to inject it with MTA and efficiency. As a result, non-medical considerations and interests threatened to invade medical practice. Such notions as ‘proper’ and ‘appropriate care’, which the minister and other politicians liked to use, seemed to lose their purely medical-substantive significance and become contaminated with the financial-economic interests of insurers and the government.²⁸

The various medical associations attempted to put up a barrier against this. The chairman of the Association of Medical Specialists, for example, argued in 1996: ‘Specialists are capable of contributing to cost-effectiveness, but their first priority is the quality of medical practice according to professional criteria, based on evidence-based medicine’.²⁹ Within the framework of the project ‘Appropriate Medical Care’, it was furthermore argued by the KNMG: ‘Because financial considerations are becoming more and more dominant, physicians shall have to make a stand to ensure that choices are made primarily on the basis of the substance and quality of healthcare’.³⁰ As mentioned earlier, this project (partially) had a defensive aim, namely for the medical profession ‘to maintain control in its own hands as much as possible’.³¹

In short: medical professionals and health professional organisations were apprehensive about ‘improper’ interference by non-medical parties with guidelines for medical practice. There are strong arguments in favour of the fear of limitation of professional autonomy – whether or not justified – forming an incentive for physicians and medical associations to demonstrate that they have made serious efforts to safeguard and improve the quality and efficiency of medical practice. The development of (evidence-based) guidelines was therefore also regarded by the medical professionals and organisations in-

25. Interview with Knottnerus. Similar remarks were made by Borst-Eilers and Bossuyt (during the interview conducted by TB). See also on the attitude of (many) Dutch physicians towards MTA: Banta & Oortwijn, ‘The Netherlands’; Boer, *Onderzoek op Maat*, pp. 4, 212.

26. See notes 23-25 above en n. 27 below.

27. Minderhoud, ‘Alleen een Veranderend Decor?’.

28. See n. 23 above, and see in particular: Rigter, ‘Passend Gebruik’. See also: Berg, Bezemer & Van den Burg, ‘Normatieve Aspecten’, pp. 19-22; R. van Herk, ‘Artsen onder Druk’, *Medisch Contact* 52: 43 (1997), p. 1344.

29. Cited in: Otten, ‘MTA-Mes’, p. 1580.

30. De Bruijn, Cense & Klazinga, ‘Passende Medische Zorg’, p. 981.

31. Minderhoud, ‘Passende Medische Zorg’. See also: De Neeling, *Passende Medische Zorg*.

volved as the *salvation* of the self-regulation and professional autonomy of physicians.³² By systematically developing and implementing evidence-based guidelines, it was argued that the medical profession could ‘divest others (insurers, government, politicians) of the weapons aimed at influencing medical practice from the outside.’³³

Thus, the quality improvement and rationalisation of medical practice was repeatedly typified as a form of further professionalisation of the medical profession, allowing for the trust of said parties *and* of patients in self-regulation to be preserved, as well as satisfying the requirements of an era that demanded transparency and accountability.³⁴

This preservation of self-regulation *due to* evidence-based medicine did come at a price, according to several parties involved, namely that *the professional autonomy* of the individual physician *shifted towards the collective of the profession*. This ‘collective’ referred, for example, to the scientific association, the professional association, the medical staff or the GP partnership.³⁵ Many proponents of EBM had no objections here. Typical is the remark:

‘Does EBM affect the autonomy of the physician? In essence it does. But it makes a difference whether the autonomy shifts towards the collective of the medical profession or is – partly – handed over to other agencies.’³⁶

This ties in with the argument by Van Herk that normative quality instruments had a second ‘possible side effect’. Apart from (theoretically) bringing closer supervision by non-medical parties, according to him, such instruments could be accompanied by increasing ‘stratification’ within the medical profession. He referred to the distinction ‘between an

32. This is a paraphrase from: Kingma, ‘Instituut voor Kwaliteit’, p. 1280. See also n. 34 below.

33. Ibid. This was actually a quotation by Kingma of Borst-Eilers! See for a similar remark: C. Spreeuwenberg, ‘De Kloof tussen Theorie en Praktijk’, *Medisch Contact* 51: 40 (1996), p. 1270.

34. R. C. Beljaards et al., ‘Het Veranderende Profiel van de Huisarts’, *Medisch Contact* 56: 11 (2001), pp. 422-5; Berg, Bezemer & Van den Burg, ‘Normatieve Aspecten’, pp. 16-22; Boer, *Onderzoek op Maat*, p. 5; Bossuyt & Kortenaar, *Schaatsen op Dik IJs*, pp. 44-5; J. C. C. Braspenning et al., *Werken aan de Kwaliteit in de Huisartsenpraktijk: Indicatoren Gebaseerd op de NHG-Standaarden* (Houten: Bohn Stafleu van Loghum, 2005), pp. 1-3; Dwarswaard, *Dokter en Tijdgeest*, pp. 115-16, 212-14; J. van Everdingen, ‘Honderd NHG-Standaarden: Mijlpaal, Einddoel of Tussenstation?’, *Huisarts en Wetenschap* 55 (2012), pp. 402-3; Gezondheidsraad, *Van Implementeren naar Leren*, p. 27; Van Herk, *Artsen onder Druk*, pp. 13, 61-2, 248-9; J. Swinkels & S. Bollen, ‘Kwaliteit in de Psychiatrie’, *Medisch Contact* 54: 21 (1999), pp. 763-6. See also: D. Armstrong, ‘Clinical Autonomy, Individual and Collective: the Problem of Changing Doctor’s Behaviour’, *Social Science & Medicine* 55 (2002), pp. 1771-7.

35. Klazinga, ‘Keurslijf van de Professionaliteit’.

36. N. Klazinga, ‘Van Algemeen naar Bijzonder: Vijf Variaties op een Misverstand’, in P. Bossuyt & J. Kortenaar (eds.), *Schaatsen op Dik IJs: Evidence Based Medicine in Praktijk* (Amsterdam: Boom, 2001), pp. 79-90, on p. 82.

elite among physicians drawing up the medical standards and the physicians who are expected to be in compliance with the standards.³⁷

At first sight, this picture of ‘stratification’ within the medical profession and of a shift from individual to collective autonomy seems plausible. Regular reference was made, in any event, in the many debates on the subject of professional autonomy, to this alleged development.³⁸ During the 1996 KNMG conference, for example, a symposium was devoted to this, entitled ‘the straitjacket of professionalism’.³⁹ This symposium was introduced by Niek Klazinga, a staff member of the CBO, as follows:

‘Over the past decades, the professionalisation of the medical profession has led to increased formalisation of medical practice. Protocols, guidelines, informed consent, occupational practices, visitation, quality systems: they are all developments aimed at making medical practice more manageable and controllable. *This ‘control’ is not so much imposed from outside as organised within the profession itself*’.⁴⁰

Klazinga linked this analysis to the argument by the sociologist Freidson that ‘professionalism is being reborn in a hierarchical form in which everyday practitioners become subject to control of professional elites’.⁴¹ This is why, during the partial symposium, the question: ‘Does professional autonomy increasingly shift from the individual physician to the collective of the profession?’⁴², was explicitly addressed.

This question may best be answered by looking at the use and handling of the NHG standards as, in many respects, they seem to be a perfect example of a (successful) ‘professional straitjacket’. They were not imposed externally, but originated from ‘within’, enjoying support in the circles of the Dutch College of General Practitioners (Dutch abbreviation: NHG), the scientific association of GPs. The active core within this association, which was also responsible for the standards policy, was considered to be a type of ‘elite’ or ‘progressive vanguard’ within the total population of GPs.⁴³

37. Van Herk, *Artsen onder Druk*, p. 14.

38. See for example: Ankoné, ‘Gepast Gebruik’; Berg, Bezemer & Van den Burg, ‘Normatieve Aspecten’, p. 21; J. H. A. M. van den Bergh, ‘Onmacht op een Tweesprong. LSV: Back to Basics’, *Medisch Contact* 48: 19 (1993), pp. 583-4; Boer, *Onderzoek op Maat*, p. 5; A. F. Casparie & P. P. M. Harteloh, ‘Kwaliteit van Zorg en Kwaliteitsbevordering’, *Medisch Contact* 48: 6 (1993), pp. 173-5; B. V. M. Crul, ‘Redactionele Vrijheid onder Druk’, *Medisch Contact* 54: 45 (1999), p. 1540-2; J. K. M. Gevers, ‘Professionele Autonomie, Vrijheid van Medisch Handelen en Beperkte Middelen’, *Medisch Contact* 46: 43 (1991), pp. 1291-2; Spreeuwenberg, ‘Op het Snijvlak’; Idem, ‘Professionele Autonomie van de Medisch Specialist’.

39. Klazinga, ‘Keurslijf van de Professionaliteit’.

40. Ibid.

41. Cited in: Ibid. See also on Freidson in this context: Van Herk, *Artsen onder Druk*, pp. 34-6.

42. Klazinga, ‘Keurslijf van de Professionaliteit’.

43. See a.o.: Dwarswaard, *Dokter en Tijdeest*, pp. 43-6, 111-16; Van Herk, *Artsen onder Druk*, pp. 167-8.

The NHG standards were the result of the crisis that the association experienced in the mid-1980s. Peer review, which had been supported by the NHG, was not widely adopted among GPs. The University Institutes for General Practice (Dutch abbreviation: UHI's), which had originated in the 1970s, partly under pressure from the NHG lobby, conducted research in the field of general practice. The National Association of GPs (Dutch abbreviation: LHV) was successfully involved in the representation of professional interests. In short, it seemed as if the role of the NHG had come to an end, which was also expressed in declining membership.⁴⁴

In the midst of this 'misery', the standards policy originated, with the aim of 'breaking the deadlock', as it was phrased by one of the people directly involved.⁴⁵ Using their own limited available resources, the NHG funded the development of the first three standards. The NHG even got into debt to send these standards to all GPs in the Netherlands. Only when it appeared a 'gap in the market' was thus found – it became evident that there was a great need among GPs for some grip on their 'medical-technical' practice – the NHG also received government subsidy so as to be able to continue with the development of standards.⁴⁶

According to Siep Thomas, the second head of the standards programme, it nevertheless took a long time before the main areas of resistance among GPs in the country were removed and the standards were widely accepted. A small group of 'leading figures' started applying the standards, with gradually more physicians taking note of this, of whom some also decided to work with the standards. Thus, the oil slick effect occurred due to what Thomas terms 'customary law'.⁴⁷

The NHG explicitly propagated the standards as *the* vehicle to strengthen the professional position of general medicine. This was to do with the relatively weak position of general medicine as a 'young discipline' at the end of the 1980s, as perceived by the NHG and its followers. In the eyes of both the developers and many users, the guidelines were to function as an instrument of *empowerment* of their own discipline (in relation to the medical specialists).⁴⁸ Much more so than was the case with the CBO guidelines for

44. Interview with Thomas; Van Herk, *Artsen onder Druk*, pp. 165-73.

45. Interview with Thomas. See also: Van Herk, *Artsen onder Druk*, pp. 173, 177.

46. Interview with Thomas; Broersen, 'NHG Presenteert Honderdste', J. Burgers, 'De Honderdste NHG-Standaard: een Mijlpaal', *Huisarts en Wetenschap* 55 (2012), pp. 398-401; Van Everdingen, 'Honderd NHG-Standaarden'; Van Herk, *Artsen onder Druk*, pp. 173-7.

47. Interview with Thomas. See also: Broersen: 'NHG Presenteert Honderdste'; C. J. in 't Veld & R. P. T. M. Grol, 'Standaarden en Praktijkaccreditering: Hoogtepunten van 50 Jaar Kwaliteitsbeleid van het Nederlands Huisartsen Genootschap', *Nederlands Tijdschrift voor Geneeskunde* 151 (2007), pp. 2916-19.

48. See n. 47 above, and see (moreover): R. M. M. Geijer et al. (eds.), *NHG-Standaarden voor de Huisarts I*, 2nd revised ed. (Utrecht: Nederlands Huisartsen Genootschap, 1999), p. VII.; G. E. H. M. Rutten & S. Thomas (eds.), *NHG-Standaarden voor de Huisarts I* (Utrecht: Bunge, 1993), pp. 1-2; Evenblij, '25 Jaar CBO-Richtlijnen'; 'De 50ste Standaard: Richtlijnen, Geen Wetten', *Huisarts en Wetenschap* 38 (1995), 94-5.

medical specialists (see chapter 7), the ‘evidence-based’ character of the NHG standards was emphasised as well.⁴⁹ It was thus conveyed that general medicine, with the help of the standards, was provided with a solid, collectively shared scientific foundation.

It seems that this had a positive impact on general medicine – and on the NHG, too, which experienced a renewed influx of members from the launch of the standards programme. The standards programme was held in high regard at the national level, not least by minister Borst-Eilers, and also enjoyed a great deal of international attention and recognition.⁵⁰ Viewed in this light, the NHG standards (and the embracing of ‘EBM’ in general) may be considered to be a form of *professionalisation* of general medicine, enhancing the status and position of the discipline.⁵¹

The question, however, is whether this professionalisation was also accompanied by a considerable shift in the professional autonomy of the individual GP towards the profession as a whole, and in particular towards an elite of guideline developers. In this context, Van Herk points to a crucial factor in the ‘success’ of the NHG standards: ‘*Key for the acceptance of standards was respecting the autonomy of every GP*’.⁵² This ‘respect for clinical autonomy’ was reflected, among others, in repeated explicit claims from the NHG that GPs could always deviate from the standards, provided this occurred in a rational fashion.⁵³ Typical in this context was an interview with two leading figures from the NHG, which appeared in the journal *Huisarts en Wetenschap* (‘GP and Science’) under the heading: ‘Guidelines, Not Laws’.⁵⁴

It became evident from several studies that GPs indeed in no way considered the standards to be ‘laws’ and regularly exercised their ‘right to deviate’.⁵⁵ On average, GPs followed approximately *two thirds* of the recommended procedures in a standard. This,

49. See for example, the chapter devoted to the link between EBM and the NHG-standards in the official ‘standard book’ published by the NHG: J. S. Burgers, ‘NHG-Standaarden en de Invloed van En. (Utrecht: Nederlands Huisartsen Genootschap, 1999), pp. 11-21. See also: Thomas, ‘Positie van Standaarden’.

50. In 2000, the NHG received the prestigious German Carl Bertelsmann Prize. See a.o.: Van Everdingen, ‘Honderd NHG-Standaarden’.

51. This was also the claim of the NHG. See, for example, the first introductory chapter of the first NHG ‘Book of Standards’ from 1993: Rutten & Thomas, *NHG-Standaarden voor de Huisarts I*, pp. 1-2. See also: A. P. Stoop, M. Berg & G. J. Dinant, ‘Tussen Afwijken en Afwijzen van Richtlijnen: de NHG-Standaard Diabetes Mellitus Type II’, *Huisarts en Wetenschap* 41 (1998), pp. 5-9, on p. 5.

52. Herk, *Artsen onder Druk*, p. 176.

53. Interviews with Assendelft and Thomas. See for example the official book of standards, published by the NHG: Geijer et al., *NHG-Standaarden voor de Huisarts I*, p. 2.

54. ‘50ste Standaard: Richtlijnen, Geen Wetten’.

55. ‘Handelen volgens de Standaarden?’, *Huisarts en Wetenschap* 38 (1995), p. 154; Van Herk, *Artsen onder Druk*, pp. 176-7, 180-1; G. P. J. M. Konings, G. E. H. M. Rutten & D. Wijker, ‘Waarom Werken Huisartsen Niet volgens de NHG-Standaard Diabetes Mellitus Type II?’, *Huisarts en Wetenschap* 38 (1995), pp. 602-7; G. P. J. M. Konings, D. Wijker & G. E. H. M. Rutten, ‘Lukt het Werken volgens de NHG-Standaard Diabetes Mellitus Type II?’, *Huisarts en Wetenschap* 38 (1995), pp. 10-14; M. Wensing, R. Grol & V. Dubois, ‘Kwaliteitsbevordering in de Huisartsgeneeskunde: Knelpunten en Behoeften’, *Medisch Contact* 49: 41 (1994), pp. 1281-3.

in itself, was a high score, both from an international perspective and in comparison with the Dutch specialists. It was calculated in a frequently quoted international overview article on various implementation studies that, on average, 55% of the researched recommendations were actually followed up in medical practice. Even more striking is the great heterogeneity that emerged from this article: the variation around this average of 55% went from almost 0% to 100%.⁵⁶ Although the figures of the NHG standards compared favourably to this, at the same time, they showed that Dutch GPs, too, regularly deviated from the standards. Significant differences occurred here between GPs: some physicians performed fewer than half of the procedures recommended in the standards, while others scored above 80%.⁵⁷ The GPs that complied with the standards to a lesser extent, could comfortably afford to do so, for following the standards was not compulsory in any way, there was no monitoring of compliance with the standards and sanctions were (therefore) not imposed upon them in the event of non-compliance.⁵⁸

Without these 'conditions', according to Van Herk, the introduction of NHG standards would not have been as successful. This is confirmed by several sources. It became evident from a study by the Quality Research Working Group (WOK), for example, that GPs 'feel a need to use NHG standards critically, to not have them mandatorily imposed upon them and to use them in a peer atmosphere'.⁵⁹ This also regularly explicitly came to the fore in comments and letters to the editor in the journal *Huisarts en Wetenschap*. A good example is the article 'Between Golden Standard and Golden Calf' from 1995, which stated:

'NHG standards are *flexible guidelines*, from which it is possible to *deviate* so long as this occurs in a rational manner. The best indication for NHG standards is therefore the use in review groups for it is there that a trade-off occurs between guideline and practice. An NHG standard is *not a golden standard* for proper practice in terms of quality. It is therefore *not appropriate to hold GPs to account for not implementing the guidelines in a literal sense*.'⁶⁰

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56. See for an overview of the international implementation research: Gezondheidsraad, *Van Implementeren naar Leren*, p. 24.
57. See n. 55 above. See also: R. Grol et al., 'Implementatie van NHG-Standaarden: Succes of Probleem?', *Huisarts en Wetenschap* 53 (2010), pp. 42-6.
58. See notes 55-57 above. See also: Stoop, Berg & Dinant, 'Tussen Afwijken en Afwijzen'; P. Visch, 'Prof. Dr. W. P. M. M. van de Ven: 'Artsen en Verzekeraars Samen Verantwoordelijk voor Doelmatigheid', *Medisch Contact* 49: 41 (1994), pp. 1275-7.
59. Wensing, Grol & Dubois, 'Kwaliteitsbevordering in de Huisartsgeneeskunde', p. 1282.
60. N. P. van Duijn & B. Meyboom-de Jong B., 'Tussen Gouden Standaard en Gouden Kalf. Functie en Toepassing van NHG-Standaarden', *Huisarts en Wetenschap* 38 (1995), pp. 3-6, on p. 5. See also the discussions that were provoked by this article: F. G. Schellevis, 'NHG-Standaarden 1', *Huisarts en Wetenschap* 38 (1995), p. 272; D. Wijker, G. E. H. M. Rutten & G. P. J. M. Konings, 'NHG-Standaarden 2', *Huisarts en Wetenschap* 38 (1995), pp. 272-3; R. A. de Melker & M. M. Kuyvenhoven, 'NHG-Standaarden 3', *Huis-*

That GPs were apprehensive about being held to account, in particular in disciplinary law, for (whether or not) they applied the NHG standards,⁶¹ was also experienced by Thomas, the head of the standards programme. He claimed that only by continually explaining and demonstrating that this threat was not realistic, was it possible to slowly eliminate the resistance from GPs.⁶² Within the NHG, moreover, the least desirable scenario was non-medical parties – besides legal experts, the government and insurers too – hijacking the standards (read: affecting the autonomy of GPs).⁶³ This is why the association explicitly emphasised that ‘the standards are no more than “state-of-the-art”, the best advice at this moment, and that they may quickly prove incorrect, unachievable or ineffective in practical circumstances’.⁶⁴

However, not only did this avert the threat of supervision by non-medical parties and the legal use of standards, but it also hampered ‘internal control’ within the profession. As a result, according to Van Herk, the NHG standards functioned not so much as ‘normative’, but rather as ‘educational’ quality instruments, of which the use was thought to mainly lie in further training and peer review.⁶⁵ He concluded:

‘Thus, the NHG standards seem to convince non-medical parties that the quality of medical practice of individual physicians is guaranteed, while the clinical autonomy of these very GPs is respected and does not shift towards the NHG, the LHV or the medical disciplinary boards.’⁶⁶

Van Herk’s analysis at least applies as much to other guideline programmes, such as those of the AMC and the CBO. The general picture is that guidelines were not mandatorily imposed, compliance was not monitored and no sanctions were imposed on physicians who did not comply with them. As noted by Van Herk, the guidelines were not so much

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- arts en Wetenschap* 38 (1995), pp. 273-4; N. P. van Duijn & B. Meyboom-de Jong, ‘Naschrift’, *Huisarts en Wetenschap* 38 (1995), p. 274.
61. See for example: R. A. de Melker, ‘De Invloed van Juridisering op de Huisarts-Patiëntrelatie’, *Huisarts en Wetenschap* 42 (1999), pp. 570-6. See also, on the more concerns about disciplinary board in the age of EBM, (the references in): M. E. van Zanten, ‘Medische Deskundigheid in Tuchtcolleges’, *Medisch Contact* 56: 25 (2001), pp. 987-9.
62. Interview with Thomas.
63. Interview with Thomas. See also notes 64 and 65 below.
64. R. Grol Kwaliteitssystemen in de Huisartsgeneeskunde: Wat Betekent dit voor de Huisarts?, *Huisarts en Wetenschap* 36 (1993), pp. 106-12, on p. 108. Also cited in: Van Herk, *Artsen onder Druk*, p. 177. See for similar remarks, for example, the official book of standards, published by the NHG: Geijer et al., *NHG-Standaarden voor de Huisarts I*, p. 2.
65. Van Herk, *Artsen onder Druk*, pp. 177, 248 See also: Grol et al., ‘Implementatie van NHG-Standaarden’, p. 43; In ‘t Veld and Grol, ‘Standaarden en Praktijkaccreditering’; D. Willems et al., *Passend Bewijs: Ethische Vragen bij het gebruik van Evidence in het Zorgbeleid* (Den Haag: Centrum voor Ethiek en Gezondheid, 2007), pp. 19-20.
66. Van Herk, *Artsen onder Druk*, p. 177.

used normatively as educationally, where it was up to the individual professional to assess whether and in what way a guideline applied to the treatment of an individual patient.⁶⁷ In addition to this, the implementation of guidelines was fraught with difficulties. Many physicians were simply not aware of the existence of guidelines, did not use them or deviated from them at the drop of a hat.⁶⁸ The 'implementation problem' alone warrants the sole conclusion that the rise of evidence-based guidelines during the 1990s and early 2000s did not (yet?) lead to a 'professional straitjacket' that was accompanied by a significant shift from the professional autonomy of the individual towards the collective.

Detour 2: From Implementation (Problem) to Learning

As of the mid-1990s, 'the implementation problem' featured high on the agenda of the EBM and guideline movement, both internationally and in the Netherlands. In all manner of commentaries and publications, it was pointed out that physicians often did not adhere to guidelines. There was speculation on the reasons for this and all sorts of strategies were discussed that could contribute to a better distribution and implementation of guidelines. Against this background, in addition, there was a growing interest in research into the 'impeding and promoting factors' for the actual following of guidelines by physicians. Many of the factors emerging from such research related to the knowledge, skills, mentality, attitude and (financial) interests of the individual physician. Furthermore, factors were identified at the level of the organisation, including: the attitude of peers, the culture within a care organisation and the time and opportunities for further training as well as financial resources made available so as to be able to integrate guidelines into medical practice. Another category of factors pertained to the shortcomings of the guidelines themselves and to the limitations of the evidence on which they were based.⁶⁹

67. Ibid., pp. 163-6, 179-81, 247-8. See also, for example: Bossuyt & Kortenray, *Schaatsen op Dik IJs*, pp. 51-3, 87-8.

68. This 'implementation-problem' was repeatedly addressed, for example in: Bossuyt & Kortenray, *Schaatsen op Dik IJs*, pp. 23, 88, 94, 100, 114; Van Herk, *Artsen onder Druk*, pp. 165-6. And see, moreover, n. 69 below.

69. See notes 55-57 and 68 above. See, in addition: Bal, 'Van Beleid naar Richtlijnen', pp. 82, 84; N. van Dijk, L. Hooft & M. Wieringa-de Waard, 'What are the Barriers to Residents' Practicing Evidence-Based Medicine? A Systematic Review', *Academic Medicine* 85 (2010), pp. 1163-70; R. Grol, 'Successes and Failures in the Implementation of Evidence-Based Guidelines for Clinical Practice', *Medical Care* 39 (2001), pp. II46-II54; Idem, 'Beliefs and Evidence in Changing Clinical Practice', *British Medical Journal* 315 (1997), pp. 418-21; R. Grol et al., 'Attributes of Clinical Guidelines that Influence Use of Guidelines in General Practice: Observational Study', *British Medical Journal* 317 (1998), pp. 858-61; R. Grol et al., 'Welke Kenmerken van Richtlijnen zijn van Invloed op Toepassing in de Praktijk?', *Huisarts en Wetenschap* 42 (1999), pp. 303-6; G. J. M. Herder et al., 'Evaluatie van de Diagnose Longcarcinoom: de Zin van Evidence-Based Richtlijnen', *Medisch Contact* 56: 11 (2001), pp. 406-9; L. Lemaire et al., 'Richtlijnen met Elkaar in Strijd', *Medisch Contact* 68: 44 (2013), pp. 2290-3; M. Lugtenberg et al., 'Welke Barrières Er-

It would go beyond the scope of this dissertation to elaborate on the countless, mainly *impeding* factors that were identified, but several of them are worthy of further attention. This applies, first of all, to the so-called ‘Not Invented Here (NIH)-Syndrome’. This ‘syndrome’ referred to the fact that physicians were often rather reluctant to adopt guidelines – and innovations in general – which were not ‘theirs’ or had not been produced by their ‘own people’. Conversely, there was a great willingness to apply guidelines that were experienced as ‘close-by’, ‘theirs’ or ‘their own’.⁷⁰ The lesson learnt from the NIH syndrome was that, for effective implementation, it was essential that, during the development stage of a guideline, there be as little distance and as much contact and feedback as possible between the developers and the intended users. In addition, many considered it to be a prerequisite that clinical guidelines be drawn up to the greatest possible extent by physicians and their scientific associations themselves.⁷¹

This was also acknowledged by minister Borst-Eilers, yet it did present a dilemma to her and her successors. The fact that, in the Netherlands, the development of guidelines mainly lay and remained in the hands of medical associations was, on the one hand, favourable in respect of the implementation, but involved a major drawback on the other hand. This way, the medical associations also largely determined the ‘agenda’ for guide-

varen Huisartsen bij de Toepassing van Aanbevelingen uit NHG-Standaarden?’, *Huisarts en Wetenschap* 53 (2010), pp. 13-19; Meulepas, M., ‘Invoering NHG-Standaard op Lokaal Niveau’, *Medisch Contact* 47: 43 (1992), pp. 1257-9; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*. 4th ed., pp. 159, 176; C. Schoemaker et al., ‘Grade Zet Bewijs om in Concreet Advies’, *Medisch Contact* 66: 45 (2011), pp. 2756-9; M. H. Swennen et al., ‘Doctor’s Perceptions and Use of Evidence-Based Medicine: A Systematic Review and Thematic Synthesis of Qualitative Studies’, *Academic Medicine* 88 (2013), pp. 1384-96; M. H. Swennen et al., ‘Career Stage and Work Setting Create Different Barriers for Evidence-Based Medicine’, *Journal of Evaluation in Clinical Practice* 17 (2011), pp. 775-85; S. Zwolsman et al., ‘Barriers to GP’s Use of Evidence-Based Medicine: a Systematic Review’, *British Journal of General Practice* 62 (2012), pp. e511-21.

70. The relative success of the guidelines programme of the AMC in Amsterdam – although the implementation problem was also present there (see several contributions to the volume: Bossuyt & Kortenray (eds.), *Schaatsen op Dik IJs*) – was in large part based on this ‘principle’. Borst-Eilers said about this (in the interview by TB): ‘The guideline programme was set up in this manner, because Urbanus had rightly said: “Why are guidelines often not followed? Because they are *‘not invented here’*. But if a clinical department *itself* raises the clinical issue, subsequently conducts the study on this issue *itself* and therefore *itself* sees the results, then the people of this department will implement the guideline for the rest of their lives, because they will have internalized it completely.” That is, of course, also a *psychological* aspect – I am not sure whether it occurs in all professions, but the so-called N.I.H. syndrome is to a certain extent linked to the arrogance that is still a little attached to the medical profession.’ See for more on the N.I.H. syndrome: n. 71 below.
71. Interview with Thomas; J. C. M. Ankoné, ‘Protocol voor een Protocol’, *Medisch Contact* 48: 27/28 (1993), p. 837; Gezondheidsraad, *Van Implementeren naar Leren*, p. 24; Grol, ‘Successes and Failures’, p. II53; Herder et al., ‘Evaluatie’; J. P. Kahan, E. J. Frinking & M. van het Loo, ‘Hoe kan het Gebruik van Nieuwe Medische Kennis in de Praktijk worden Bevorderd?’, *Medisch Contact* 51: 40 (1996), pp. 1271-3; P. L. Meurs, P. T. van Splunteren & W. T. P. F. van der Werf, ‘De Uitdagingen van Implementatie’, *Medisch Contact* 54: 6 (1999), pp. 54-5; De Neeling, *Passende Medische Zorg*, pp. 5, 21; In ‘t Veld & Grol, ‘Standaarden en Praktijkaccreditering’; Warndorff, Pouls and Knottnerus, ‘Medische Besliskunde’.

line development. This touches on a second impeding factor, namely that, as a rule, medical associations do not act contrary to their professional interests. If, for example, the assessment was that guideline development regarding a specific subject could have negative consequences for the revenue of their followers, they would not be likely to make this subject a priority. This is why the idea often surfaced of creating a quality institute at a more central and political level, which could play a role similar to that of the British NICE.⁷²

A third impeding factor concerns the integration of cost aspects in clinical guidelines. The Health Council wrote about this in 2000: ‘The application of cost components in guidelines remains problematic [...]. It turns out that, across the world, physicians experience trouble dealing with a definition of ‘appropriate care’ in which financial arguments play a distinct role.’⁷³ In the final report of the KNMG project ‘Appropriate Medical Care’, which was also published in 2000, the wording was even more clear-cut: ‘Even the least whiff of suspicion that guidelines, under the guise of quality improvement, would actually be focused on cost control, has to be avoided at all cost.’⁷⁴

This is extraordinarily relevant, for the debate on implementation, as the Health Council observed, ‘is partly conducted in the light of the pursuit of cost control.’⁷⁵ As medical professionals are ‘ideally placed’ to exert influence on cost development in healthcare with their decisions, this was not inconceivable, yet the Council nevertheless considered ‘that in the development of guidelines efficiency aspects should come second.’⁷⁶ This was, with a view to the willingness of physicians to actually implement these guidelines, a logical recommendation, yet it was slightly at odds with the ‘MTA policy’ of Borst-Eilers.

On the other hand, the NHG standards – other than the guidelines for specialists – fitted in very well with the pursuit of cost control. This was not so much caused by efficiency aspects being decisive, as by the central role that was assigned to the principle *in dubio abstine*. The NHG propagated the message that ‘needless acts destroy more than was dear to you.’⁷⁷ In her dissertation on changes in professional ethics of GPs and surgeons, Jolanda Dwarswaard concludes that GPs, with their cautious policy, were ‘in a certain sense, allies of the government.’⁷⁸

72. Interviews with Assendelft, Bossuyt, Knottnerus, Offringa, Rigter and Thomas; J. K. Helderma et al., *Dike-Reeve of the Health Care Polder* (Nijmegen, Institute for Management Research Radboud University, 2014), pp. 65-8; G. Schrijvers, ‘NICE is Niet zo Nice en Toch’, *Medicalfacts*, 1 March 2010, available from: <http://www.medicalfacts.nl/2010/03/01/nice-is-niet-zo-nice-en-toch/>

73. Gezondheidsraad, *Van Implementeren naar Leren*, p. 32.

74. De Neeling, *Passende Medische Zorg*, p. 21. See also, for example: Boer, *Onderzoek op Maat*, pp. 149-62.

75. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 19-20.

76. *Ibid.*, pp. 20, 32.

77. Cited in: Dwarswaard, *Dokter en Tijdsgeest*, pp. 80-1; See also: Rutten & Thomas, *NHG-Standaarden voor de Huisarts I*, p. 6.

78. Dwarswaard, *Dokter en Tijdsgeest*, on pp. 1180-19 and also on p. 123.

Yet from her analysis of successive volumes of the journal *Huisarts en Wetenschap* it becomes clear that GPs noticed a significant obstacle for this cautious policy, namely *the patient* – and thus a fourth impeding factor is identified. A recurrent subject of debate during the 1990s was the tension between ‘the frame of reference of the GP (sensible and economical) and that of patients (they are capable of and know everything).’⁷⁹ The expectations of patients were often too high and they sometimes even made ‘excessive demands’, as a result of which a GP came under pressure to refer them to a specialist or set up a specific treatment, while the GP did not consider this to be necessary based on the knowledge of the GP – and the NHG standards. With a view to the preservation of a good physician-patient relationship, it regularly occurred that GPs gave in to patients’ wishes after all. This was referred to as ‘a climb-down’ and ‘defensive practice’ in *Huisarts en Wetenschap*.⁸⁰

This debate on the patient as an impeding factor in the application of the recommendations from the NHG standards illustrates a fundamental problem of evidence-based medicine, which was addressed by the professor of clinical and health psychology, Jozien Bensing. She argued that EBM is a ‘*doctor-centred*’ approach. In the 1990s, however, virtually simultaneously with evidence-based medicine, an almost opposite ‘paradigm’ emerged strongly: ‘*patient-centred medicine*’. While interest in *both* movements increased rapidly, according to Bensing they were rarely related to each other or considered in conjunction with each other, so that they largely remained ‘*separate worlds*.’⁸¹

Following on from this, the sociologist David Armstrong made a connection between these two ‘*separate worlds*’ and the issue of clinical autonomy. His starting point was that evidence-based medicine constituted a defensive strategy enabling the medical profession ‘to resist at least some of the challenges to its traditional autonomy’. In Armstrong’s view, the success of this strategy depended on the degree of success in attempts to discipline individual physicians, in such a way that they allowed their behaviour to be partly influenced by, for example, evidence-based guidelines. Against this background, he considered EBM to be an example of ‘*intra-professional formalisation of control*’, which mainly served to ensure ‘the maintenance of the autonomy of the profession as a *collectivity*’. Yet little came of this in practice, as Armstrong concluded from the qualitative research he had conducted into ‘the ways in which general practitioners change their clinical behav-

79. De Melker, ‘Invloed van Juridisering’, p. 575.

80. All this, including all citations, is derived from: Dwarswaard, *Dokter en Tijdgeest*, pp. 81-8, 131-6. See also: De Melker, ‘Invloed van Juridisering’; Van der Weijden, *Richtlijnen in de Spreekkamer*, pp. 7-8; D. Willems & M. Veldhuis, *Wegen in de Zorg: Dilemma’s, Keuzen en Afwegingen in de Spreekkamer* (Assen: Van Gorcum, 2002), pp. 31-45.

81. J. Bensing, ‘Bridging the Gap. The Separate Worlds of Evidence-Based Medicine and Patient-Centered Medicine’, *Patient Education and Counseling* 39 (2000), pp. 17-25. See also, for example: J. R. T. C. Roelandt, ‘De Dilemma’s van de Cardioloog’, *Medisch Contact* 55: 27/28 (2000), pp. 1024-7.

ieur'. His most important finding was that British GPs emphatically claimed they used a 'patient-centred approach' and that, due to this 'rhetoric of patient-centeredness', they managed to preserve a good deal of their individual autonomy. In this context, Armstrong spoke of 'an alternative *individualised* autonomy that seems inimical to the logic of evidence-based medicine'.⁸²

Yet the contrast between standards and patient preferences, or that between evidence-based medicine and patient-centred medicine, is not an absolutely unbridgeable and immutable given. Precisely from Dwarswaard's study it appears that the tension between the cautious policy of the NHG standards and the empowered patient evaporated after 2000. On the one hand, she accounts for this on the basis of the space available for 'deviating in a rational fashion' from the standards and meeting the demands of patients. On the other hand, she mentions the possibilities GPs had to communicate with patients, thus convincing them of the accuracy of the recommendations from the NHG standards.⁸³

That the problem of the tension between the cautious NHG standards and the demanding patient was largely resolved around the millennium, is confirmed by research from 1999 into the implementation of the NHG standards, which showed that the recommendations from the standards to *omit* certain treatments score highest: nearly 80% of these recommendations were followed up. In a report from 2000, the Health Council labelled this high score with regard to precisely the omission of treatments 'remarkable' and 'very encouraging'.⁸⁴

This latter 'ray of hope' does not alter the fact that all the literature on the implementation problem and on the complex of impeding factors raises serious questions as to how much impact evidence-based guidelines have actually had.⁸⁵ The Dutch epidemiologist, Geert van der Heijden, argues that the influence of evidence-based guidelines may best be compared to a leaking pipeline.⁸⁶ The first 'leak' is located at the level of the evidence: for many clinical questions there is no evidence available, or the evidence is not very robust, is not convincing or is even conflicting, is interpreted differently by various experts or is difficult to generalise. The second 'leak' occurs in the production of guidelines. By no means all the available evidence is 'factored in' by guideline developers, for example because they do not know it or do not know how to trace it, or because there is a bias with regard to evidence produced in the country or discipline of origin. It is also possible

82. Armstrong, 'Clinical Autonomy, Individual and Collective'. TB's italics.

83. Dwarswaard, *Dokter en Tijdgeest*, pp. 85-8.

84. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 25-6.

85. See n. 69 above.

86. Personal communications between Van der Heijden and TB, d.d. 10 November 2011. The metaphor of the pipeline is also used by Van der Heijden (and others) in: *Het Tafelblad: van Kennis naar Praktijk*. Uitgave over Kennistafels van de Regieraad van de Zorg, januari 2011 (Den Haag: Regieraad Kwaliteit van Zorg, 2011).

that, during the interpretation of and debates and consensus building on the evidence – an inherent part of guideline development – there is leakage of a great deal of knowledge. This is followed, in the stage of distribution and implementation of guidelines, by countless forms of leakage as a result of numerous impeding factors. This begs the question of how much water still flows out at the end of the pipeline, or: how much evidence-based practice remains after all the ‘leakage’?

It would be rash, however, to conclude that EBM has led to virtually nothing, as this assumes the idea that the degree of implementation of evidence, in particular in the form of guidelines, is an objective in itself, and moreover the yardstick by which the impact of EBM may be measured. Precisely with regard to this, ideas started to change around 2000. This emerged, for example, from the report ‘From Implementing to Learning’ (Dutch: ‘Van Implementeren naar Leren’), which was published by the Health Council in 2000.

In the request for advice that minister Borst-Eilers submitted to the Health Council in 1999, she took the developments in the field of MTA as a starting point. In the opening sentence, she referred to ‘the speed at which new scientific insights and results from medical technology assessment become available these days’. Yet the big question, the minister went on to say, was ‘how to *establish the bridge between knowledge and practice*’. Guidelines formed a good way of bridging this gap in themselves, yet ‘they often proved to influence everyday practice at too slow a pace and to an insufficient extent’. The minister asked the Health Council to issue an opinion on the possibilities for improving this ‘*poor level of implementation*’.⁸⁷

According to the committee that set to work on it under the guidance of the Rotterdam professor of Policy and Public Healthcare, Tom van der Grinten, this request for advice was infused with ‘MTA policy thinking’.⁸⁸ This ‘MTA policy thinking’ included ‘the view that application of the results of MTA – increasingly established in guidelines for professional practice – is the proper way of optimising the quality of healthcare’.⁸⁹ The committee thought this vision was too limited and therefore decided not so much to provide the advice the minister requested as to plead for a ‘reorientation on the implementation issue’⁹⁰ – in fact, Borst-Eilers, the primary responsible person for ‘Medical Practice at a Crossroads’ (see chapter 8), was given a dose of her own medicine!

Van der Grinten and his fellow committee members rather explicitly distanced themselves from the request for advice by critically assessing three ‘presuppositions’ of ‘MTA policy thinking’. The *first* point they mentioned concerned the special, probabilistic character of the knowledge obtained from clinical-epidemiological research (which they con-

87. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 58-9. See also p. 19.

88. See a.o.: *Ibid.*, pp. 7, 16-17.

89. *Ibid.*, p. 7.

90. See also on this report: Bal, ‘Van Beleid naar Richtlijnen’.

sidered MTA to be part of as well). Because the EBM movement, with its ideas on ‘levels of evidence’, had strongly focused on clinical-epidemiological knowledge, according to them ‘a debate had broken out on the tension between “casuistry” and “statistics”, or on the question: ‘to what degree does a certain patient resemble the average patient in clinical research?’ Partly under the influence of this debate, attention was focused more on the ‘limitations of generic, epidemiological information when specific, clinical decisions are to be taken’. According to Van der Grinten and co-authors, it was ‘clear that clinical-epidemiological data are not always self-evident.’⁹¹

This was not to say that they rejected EBM and practice based on clinical-epidemiological ‘evidence’. In their view, good epidemiological data certainly offered an ‘interpretative framework’, also for the assessment of *specific* cases. In this respect, they subscribed to the ‘broader description’ that was now given to evidence-based medicine, where it concerned the integration of epidemiological data, pathophysiological knowledge, clinical experience and preferences of patients. The use of epidemiological evidence – whether or not in the form of guidelines – in clinical practice, required making *trade-offs*, where *coherence* was created *between different types of data* which was *meaningful* to the specific situation’.⁹² Here, medical professionals ‘preferred deterministic lines of argument based on pathophysiological insights and personal experiences’. Probabilistic data also played a role, but was mainly used ‘in order to avoid risky procedures’. From this it followed that the generic and the probabilistic mainly played a *preconditional* role in clinical practice, in which the specific nevertheless remained the ‘compass’.⁹³

The *second* ‘presupposition’ about which Van der Grinten and fellow committee members expressed doubt, was the ‘vision of professional practice’, which implicitly came to the fore in the request for advice by the minister. They wrote about this: ‘It is expected that (medical) professionals, in their daily practice, naturally apply scientific data packaged in guidelines, which is obtained in a methodologically proper fashion and carefully organised.’⁹⁴ Yet this was open to a great deal of debate. Firstly, guidelines were ‘more than just “packaging” for research data.’⁹⁵ Guideline developers made *judgements* and formed *opinions*, for example about what had been ‘adequately’ scientifically researched, or about how pros and cons of a certain intervention had to be balanced against each other. Secondly, the *application* of guidelines was ‘rarely a matter of pressing a button’.⁹⁶ Medical-professional reasoning and decision-making processes were marked by great

91. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 32-33, 47.

92. *Ibid.*, p. 33.

93. *Ibid.*, pp. 34-5. See also on this: H. Maassen, ‘Kansen voor Patiënten: de Waarde van Probabilistische Informatie’, *Medisch Contact* 56: 43 (2001), pp. 1567-9.

94. Gezondheidsraad, *Van Implementeren naar Leren*, p. 47.

95. *Ibid.*, p. 48.

96. *Ibid.*, p. 30.

time pressure, conflicting and incomplete data, changing circumstances of patients, the involvement of professionals who were often from various disciplines and had varying views of the relevant case, et cetera. This meant that physicians could never simply follow the recommendations from guidelines, but always needed to make a *'translation'* to the specific practical situation. According to the committee, it followed from this that *skilful* use of (evidence-based) guidelines required *competence*.⁹⁷

The *third* 'presupposition' that was challenged in 'From Implementing to Learning', was 'the image that professional practice occurs *in an own and rather static world as it were*'.⁹⁸ Healthcare professionals, however, faced both scientific and social dynamics. As far as the scientific dynamics are concerned, the committee pointed to the advance of the information technology and the rapid development of epidemiological research. From more sides than ever before, healthcare professionals were confronted with data. The integration of all these various data was usually 'not an easy task'.⁹⁹ With regard to the social dynamics, Van der Grinten and associates pointed to the call from patients, government authorities and insurers for 'transparent medicine' and the increasing pressure put on physicians to pursue efficiency with a view to cost control of healthcare. In addition, they identified an 'increasing interconnectedness of healthcare practices'; the development of 'medical-specialist companies', the emergence of health centres and initiatives in the field of transmural care demonstrated that healthcare processes became increasingly embedded in larger organisational contexts. Physicians were furthermore faced with 'patients who were increasingly informed and empowered', partly under the influence of 'the information culture' and the 'modern means of communication'.¹⁰⁰

According to Van der Grinten and peers, these reservations about 'MTA policy thinking' underlined 'the importance of broadening the approach to the implementation issue'.¹⁰¹ This broader approach was necessary because implementation of new scientific insights was *not an objective in itself*, but just a means of ensuring good patient care. In addition, the few implementation studies in which it had been investigated whether following guidelines actually had a favourable outcome for patients showed a varying picture: sometimes, but not always, there was a positive effect. For these reasons, the committee did not select implementation as such, but the optimisation of patient care as its 'point of orientation'. As a result, all manner of other issues appeared in the field of vision which, *besides* guidelines on the basis of MTA knowledge, were of importance for the quality of the healthcare process.¹⁰²

97. Ibid., pp. 30-4, 48.

98. Ibid., p. 47.

99. Ibid., pp. 21-3, 48-9.

100. Ibid., pp. 21-2, 37-8, 48-9.

101. Ibid., p. 47.

102. Ibid., pp. 7-8.

In this context, the committee pointed to the international literature in which the ‘narrow vision of implementation’, which was characteristic for research that focused on the impeding and promoting factors in the implementation of guidelines, gradually made way for ‘pleas for a broadening of this vision by incorporating insights from social sciences [...], educational studies and organisational studies’. This resulted, among others, in the emergence of a new ‘generation’ of guidelines. The ‘first generation’ of guidelines in the 1980s, which were predominantly created via the consensus method, had made way in the 1990s for the ‘evidence-based guidelines’ of the ‘second generation’, in which scientific data were centre stage. In the meantime, however, ‘third generation guidelines’ were developed, in which, much more so than before, the objectives of the developers and the trade-offs made were explicated and distinguished from the scientific substantiation. In addition, the objectives in these ‘latest’ guidelines had been broadened, which appeared, among others, from the efforts to integrate data on patient values and cost components.¹⁰³

According to the committee, the ‘broader’ approach to implementation above all meant that the focus needed to be shifted ‘from implementing to learning’. As expressed in this title, the main message of the report was that not so much the following of the guidelines themselves, as the *learning process* of both individual physicians and care organisations needed to be central to the quality policy. In complex daily medical practice, physicians had to develop a ‘translation’ from generic scientific knowledge to patient-specific characteristics and location-specific circumstances. According to the committee, this required skills that had to be *acquired*. This is why the report paid a great deal of attention to the concept of the ‘learning professional’. There was talk, moreover, of the ‘learning organisation’, in particular with a view to the ‘social dynamics’ of increasing interconnectedness of healthcare practices and empowering patients. For organisations and networks of professionals this meant that they needed to learn to cooperate, both with each other and with patients.¹⁰⁴

In order to be able to add depth to the notions of the ‘learning professional’ and the ‘learning organisation’, it was necessary, according to the committee, to involve insights from knowledge domains other than medicine itself. Reference was made here to the input of educational studies, organisational studies and the professional socialisation theories from the social sciences, which focused attention on the interactive, reflexive and dynamic character of successful learning and change processes. Put somewhat schematically, the ‘narrow vision’ of implementation assumed there was *one-way traffic* between science and practice – in the form of the impact of new insights in practice and the fol-

103. The committee, by the way, pleaded for reticence with regard to integrating cost components in guidelines. Efficiency aspects had to ‘come second place’. For the rest, the commission was very positive about the rise of ‘third generation’ guidelines. See n. 104 below. See for more on the ‘third generation’ guidelines: Berg, Bezemer & Van den Burg, ‘Normatieve Aspecten’, pp. 12-13.

104. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 9-10, 33-6, 39-42, 48-9.

lowing of guidelines – while the Health Council, according to the subtitle of the report, put the emphasis on: ‘the importance of *two-way traffic* between practice and science in healthcare’.¹⁰⁵

The impact of this advice by the Health Council was great, as was argued in 2006 by Roland Bal, a researcher at the Institute of Health Policy and Management at Erasmus University in Rotterdam. Referring to several large-scale ‘improvement programmes’ for the hospital and healthcare sector, he stated: ‘The concept of the “learning professional” and the “learning organisation” developed rapidly in numerous places’.¹⁰⁶ That the report by the Health Council resonated in the ‘field’, is not surprising as the committee that wrote it was largely composed of prominent representatives from this ‘field’. The committee members included, among others, Wim Schellekens, the then general director of the CBO, and Richard Grol who, as professor of Quality of Care in Nijmegen and Maastricht and, as an international authority in the field of implementation research, maintained close links with the NHG.¹⁰⁷

The extent to which the plea of this committee for a reorientation on the implementation issue fit in with what was happening in this area in the Netherlands may be illustrated with several examples. For example, there was the programme ‘Effective Implementation’ of ZON, one of the main subsidy funds for health research in the Netherlands. The first product of this programme, which launched in 1999, was a literature study into the state of affairs in the field of implementation. It included recommendations that were entirely in line with the advice of the Health Council, which was published some time later. There was a plea, among others, for a theoretical broadening in the approach to the implementation issue, with two ideal-typical approaches to implementation being juxtaposed: the ‘rational model’ and the ‘participation model’. The rational model tied in with the ‘MTA cycle’ and assumed a linear and ‘top-down’ implementation process. As a result, there was little focus on the diversity of needs in practice. These requirements of practice, as well as the communication and feedback between professionals in practice, formed the very ‘driving force’ within the ‘participation model’. As both models had their advantages and drawbacks, the authors of the ZON report were not in favour of the total replacement of the rational model with the participation model, but they opted for a ‘combination strategy’.¹⁰⁸

105. Ibid., pp. 8, 35, 40, 48-9.

106. Bal, ‘Van Beleid naar Richtlijnen’, p. 88. This was also manifest in a publication of ZonMw (The Netherlands Organisation for Health Research and Development) from 2006, on the ‘lessons learned’ by ZonMW about implementation: J. Ravensbergen & J. Zandvliet (eds.), *Dat Verandert de Zaak! Geleerde Implementatie-lessen van ZonMw* (Assen: Van Gorcum, 2006), see in particular pp. 16-18.

107. See for a list of the members of the committee: Gezondheidsraad, ‘Van Implementeren naar Leren’, pp. 60-1.

108. ZorgOnderzoek Nederland, *Effectieve Implementatie: Theoriën en Strategieën* (Den Haag: ZON, [2000]). See also the report of 2006 by ZonMw (the successor of ZON): Ravensbergen & Zandvliet, *Dat Verandert*

From the word go, such a ‘combination strategy’ was typical for the way in which the NHG approached its standards programme. It nevertheless seems very much that the ‘softer’ side of implementation and thus the ‘participation model’ became somewhat more prominent over the course of time. An indication for this is the difference between the first edition of the ‘standards book’ (part I) which the NHG published in 1993, and the second, entirely revised edition from 1999. In the first edition of this book, the NHG standards were already explicitly placed in a broader perspective. This occurred, among others, by focusing extensively on the possibility for GPs to deviate from the standards in a rational manner, based on the input of the patient and their personal, professional insights with regard to the concrete, specific situation.¹⁰⁹ In the second edition from 1999, this perspective was further broadened, for example in a new chapter entitled: ‘Balancing Between Science and Story.’ In this almost philosophical chapter, the standards were approached from an ‘unusual angle’, namely ‘as special texts with a message, as stories’.¹¹⁰ Thus, a constructivist stance was explicitly taken here:

‘Due to the rhetoric surrounding ‘evidence-based medicine’ it is easily forgotten that the transformation from medical, scientific facts into guidelines requires a *translation* with important arbitrary elements. In the form of a text, standards create an ideal reality that *invites the reader to engage in interpretation and criticism*’.¹¹¹

In the view of the authors of this chapter, the *translation* that needed to be made according to this quotation also meant that ‘all considerations that formed the basis of the choices made’ during the drawing up of a standard, ‘[needed to] be explicated to the greatest extent possible.’¹¹² This was also reflected in the revised guidelines in the second edition of the standards book, which included many features of the so-called ‘third generation guidelines’. In greater depth than in the book from 1993, the digressions on the ‘translation’ pointed to the way in which the standards and the complex, unruly reality of medical practice were ‘at odds with each other’. This is why the standards did offer a framework, but their application in practice was ‘left to the creativity of the GP’.¹¹³ GPs were invited by the standards as it were to construct – together with the patient and through ‘interpretation and criticism’¹¹⁴ – their ‘own version of the story’.¹¹⁵

de Zaak!. See also: R. Grol & M. Wensing, *Implementatie: Effectieve Verbeteringen van Patiëntenzorg*. 4th ed. (Amsterdam: Reed Business, 2011), pp. 28-38.

109. Rutten & Thomas, *NHG-Standaarden voor de Huisarts I*, pp. 8-22.

110. Geijer et al., *NHG-Standaarden voor de Huisarts I*, p. 23.

111. *Ibid.*

112. *Ibid.*, p. 27.

113. *Ibid.*, pp. 24-5.

114. *Ibid.*, p. 23 (see n. 110 above).

115. *Ibid.*, p. 27.

This type of reflections¹¹⁶ is indicative of a shift in emphasis in the approach to the implementation of NHG standards from ‘one-’ to ‘two-way traffic’, which was also expressed in the ‘Editorial Section’ of the second, revised version of the standards book, in which the then chairman of the NHG wrote:

‘Furthermore, it is about time that the NHG spreads its wings towards the GP in practice, not only to provide focused assistance in the implementation of our standards, but also to listen attentively, to become familiar with the needs of GPs or the issues they encounter [...]’¹¹⁷

Apart from in the standards policy of the NHG, the reorientation on the implementation issue pleaded for by the Health Council was also clearly evident in the final report of the KNMG project ‘Appropriate Medical Care’ from 2000. The aim of this project was to find out if guideline development could contribute the maximisation of the quality of care in the event of a given scarcity of resources. This was done experimentally in sub-projects in cardiology and psychiatry in which a serious attempt was made to arrive at the development and implementation of guidelines in which MTA knowledge on efficiency was integrated as well. Yet in the final report the project group concluded: ‘we did *not* succeed’.¹¹⁸ In retrospect, the project group argued this was due to the *way* in which they had attempted to rationalise medical practice: ‘What we attempted to implement was all in all [...] a strict and comprehensive, empirically based, quantitative rationalisation programme, which was also characterised by ‘a typical *top-down* approach’. This approach, which had even been described as *radical* by the project group, soon proved ‘not viable’ and ‘slightly naive’.¹¹⁹

The main obstacle was the ‘partially fundamental and insurmountable shortage of necessary data’¹²⁰ which even occurred in a discipline richly endowed with evidence such as cardiology. Here, just as the Health Council would do later that year, the KNMG project group pointed to the limitations that were inherent to clinical-epidemiological research and clinical-epidemiological evidence –with as bottom-line that, on the basis of this, only statements about *categories* of patients could be made, while medical practice was primarily focused on the well-being of *individual* patients. The observation was

116. See also, for example: Stoop, Berg & Dinant, ‘Tussen Afwijken en Afwijzen’, p. 8.

117. Geijer et al., *NHG-Standaarden voor de Huisarts I*, p. VII

118. De Neeling, *Passende Medische Zorg*, p. 35.

119. *Ibid.*, pp. 35-6.

120. *Ibid.*, p. 35.

added here that in particular knowledge about cost-effectiveness was still fraught with methodological challenges.¹²¹

In addition, the project group expressed doubts about the approach to implementation of guidelines as a top-down and linear process. A striking amount of attention was paid here to 'normative aspects': discrepancy between the normative considerations of care providers in practice and those of guideline developers proved a major obstacle to an effective implementation of guidelines. There was also a disparity, moreover, between the way in which medical practice was described in guidelines and how practising physicians experienced this. The guidelines presented the decision-making process in medical practice as: 'a series of steps that need to be followed one by one, with clear moments of choice and sharply defined criteria, on the basis of which decisions are to be taken.' This was at odds with the experience on the part of physicians of 'practice' as something which had a strongly 'situated' character, or was shaped 'in continuous interaction with a complex, specialist and social context' and, as a result, was characterised by 'flexibility and changeability'.¹²²

All this induced the project group to let go of the 'radical programme for the rationalisation of medical practice' for the benefit of a 'realistic programme'. This 'realistic programme' was characterised by a 'bottom-up' approach, 'two-way traffic', explication of the value judgements and *flexibility* of guidelines, so that they could be adapted to local circumstances and individual physicians were left enough room for discretion. All this moreover amounted to a shift in emphasis 'from implementing to learning'.¹²³ After 25 years of rather fruitless attempts to *implement* guidelines, it was time for a different approach: guideline developers as well as users had to go through 'a long-term and demanding joint *learning process* [...]'.¹²⁴

The distinction between a 'radical' and 'realistic' programme made by the project group of the KNMG is virtually identical to a distinction made several years later by Hutschemaekers and Tiemens, professor and senior researcher in the field of professionalisation in healthcare (in particular mental healthcare) respectively. They juxtaposed two models in an article from 2006: 'the guideline approach' and 'the heuristic approach'. Both approaches were closely linked to the EBM movement, which was evident from the intention 'to improve care by using scientific evidence'. In both cases, moreover, the avail-

121. Ibid, see in particular pp. 16-20. See also the studies underlying the final report of the KNMG project 'Appropriate Medical Care': E. S. Goes et al., *Passende Medische Zorg in de Cardiologie*. KNMG Project Passende Medische Zorg, Deelrapport A (Utrecht: KNMG, 2000); H. W. Tiemeier et al., *Passende Ambulante Zorg bij Depressie*. KNMG Project Passende Medische Zorg, Deelrapport B (Utrecht: KNMG, 2000); Berg, Bezemer & Van den Burg, 'Normatieve Aspecten'.

122. De Neeling, *Passende Medische Zorg*, pp. 16-20. See also: Berg, Bezemer & Van den Burg, 'Normatieve Aspecten'.

123. De Neeling, *Passende Medische Zorg*, pp. 35-41.

124. Ibid., p. 20.

able evidence was analysed using the same ‘levels of evidence’ as those formulated by the EBM movement. Thus, Hutschemaekers and Tiemens actually presented two ‘variants’ of evidence-based medicine, which, however, fundamentally differed from each other on a number of points. The guideline approach had a ‘top-down character’, because the available evidence itself was the starting point, and from there a movement was made towards practice. The ‘heuristic’ approach, on the other hand, had a ‘bottom-up character’, because a clinical problem from daily practice was used as a starting point. Phrased differently, the ‘guideline approach’ started with an answer and the ‘heuristic approach’ with a question. In the first approach, furthermore, the value of evidence was perceived as being more absolute than in the second approach, in which evidence from clinical research was integrated with the individual expertise of the physician and the personal experiences of the patient. In the ‘guideline approach’ the physician was ‘just the implementer’, while in the ‘heuristic approach’, he sought a solution to a problem.¹²⁵

All in all, broad support seems to have originated in the ‘field’ for the reorientation on the implementation issue, as advocated, among others, by the Health Council. This reorientation may be typified as a shift in emphasis from implementing to learning, from one-way to two-way traffic, from standard to story, from radical to realistic programme, and from ‘guideline approach’ to ‘heuristic approach.’¹²⁶ The question that presents itself is what this meant for the role and impact of evidence-based medicine in the Netherlands. It is difficult to provide a direct answer to this, yet some light may be shed on this with the help of the third ‘detour’ in this chapter: the debate over the past fifteen years on the

125. G. Hutschemaekers & B. Tiemens, ‘Evidence-Based Policy: from Answer to Question’, in J. W. Duijvendak, T. Knijn & M. Kremer (eds.), *Policy, People, and the New Professional: De-Professionalisation and Re-Professionalisation in Care and Welfare* (Amsterdam: Amsterdam University Press, 2006), pp. 34-47.

126. This ‘broad support’ for the reorientation on the implementation issue was manifest in the interviews by TB and can also be illustrated with lots of examples. See for only a selection of these examples: Berg, *Rationalizing Medical Work*, pp. 100-41; R. Crommentuyn, ‘De Opvoedkundige Waarde van Richtlijnen’, *Medisch Contact* 57: 47 (2002), pp. 1723-5; B. V. M. Crul, ‘Praten en Pillen, Pillen en Praten’, *Medisch Contact* 56: 49 (2001), p. 1795; Lemaire, ‘Richtlijnen met Elkaar in Strijd’; M. Levi, *Kansen voor de Inwendige Geneeskunde* (Amsterdam: Vossiuspers UvA), pp. 13-14; E. van Loon & R. Bal, ‘Uncertainty and the Development of Evidence-Based Guidelines’, *Valuation Studies* 2 (2014), pp. 43-64; H. Maassen, ‘Tussen Droom en Daad: Assendelft (NHG) and Van Barneveld (CBO) over Evidence-Based Medicine’, *Medisch Contact* 56: 49 (2001), pp. 1800-2; Offringa, Assendelft and Scholten, *Inleiding in Evidence-Based Medicine*, pp. 6-10 (see also the 4th edition of this text book of 2014, pp. 6-9); A. K. Offringa-Hup, ‘Ruimte rond de Richtlijn’, *Medisch Contact* 64: 11 (2009), pp. 453-5; Ravensbergen & Zandvliet, *Dat Verandert de Zaak!*; Roelandt, ‘Dilemma’s van de Cardioloog’; Schoemaker et al., ‘Grade Zet Bewijs om’; Stoop, Berg & Dinant, ‘Tussen Afwijken en Afwijzen’; J. G. P. Tijssen, M. L. Simoons & J. J. E. van Everdingen, ‘Landelijke Richtlijnen voor het Klinisch Handelen, een Methodologische Beschouwing’, *Nederlands Tijdschrift voor Geneeskunde* 142 (1998), pp. 2078-82; Van der Weijden, *Richtlijnen in de Spreekkamer*. See also for an example from abroad the plea for a ‘heuristic approach’ in: Kristiansen & Mooney, ‘Evidence-Based Medicine’, p. 5.

'opportunities' and 'threats' for a positive role for (the 'heuristic approach' to) EBM in Dutch medicine.

Detour 3: Opportunities and Threats

In the publications of the NHG, the KNMG and the Health Council discussed above, a certain optimism resounded on the possible effectiveness of the 'new' approach to the implementation issue – and, by extension, to evidence-based medicine. In the final report of the KNMG project 'Appropriate Medical Care', for example, not only was it argued that both guideline developers and users had to go through a 'long-term and demanding joint learning process' but also that the 'signs for a successful learning process' were favourable. From the literature, it became evident that the developers of guidelines '[were] fully prepared to face the shortcomings and potential dangers of guidelines.' This was also the experience during the project 'Appropriate Medical Care'. As, during the implementation of the project, there was a surfacing of all manner of presuppositions, implicit value judgements, confusion, inconsistencies, gaps in the available data and decision moments which were important for practice, many lessons had been learnt with regard to a more refined way of developing guidelines.¹²⁷

There was a similar optimism in respect of the learning process of the *users* of guidelines. The KNMG, the CBO, the NHG and the Health Council noted that there was widespread and growing support within the medical profession for the development and application of evidence-based guidelines, mainly due to the necessity of channelling the explosive growth of medical knowledge. The Health Council argued for example: 'That guidelines are good tools to synthesise and structure the rapidly increasing stream of medical-scientific data, *is actually no longer subject of debate*.'¹²⁸ Also 'within the framework of professionalisation' and 'in view of the necessity of making medical practice more transparent for third parties', the use of guidelines was a given to many medical professionals. The KNMG project group 'Appropriate Medical Care' therefore expressed the expectation 'that medical professionals and healthcare as a whole will increasingly prove capable of applying guidelines in practice.'¹²⁹

127. De Neeling, *Passende Medische Zorg*, pp. 19-20, 35-40. See also, for example: Tijssen, Simoons & Van Everdingen, 'Landelijke Richtlijnen' and most other references in n. 126 above.

128. Gezondheidsraad, *Van Implementeren naar Leren*, p. 18. See, with regard to the function of EBM in coping with the avalanche of medical information: S. Bakker, 'Automatisering van de Medische Literatuur- en Informatievoorziening', *Nederlands Tijdschrift voor Geneeskunde* 141 (1997), pp. 33-8; Levi, *Kansen voor de Inwendige Geneeskunde*, pp. 16-17; 'Standaarden + Medline = EBM', *Huisarts en Wetenschap* 42 (1999), pp. 589-90; J. Zaat, 'Worstelend met de Literatuur: Zoeken in Medline via Internet – een Vergeelijking van Vijf Zoekmachines', *Huisarts en Wetenschap* 42 (1999), pp. 11-17, see in particular p. 16.

129. De Neeling, *Passende Medische Zorg*, p. 21.

To a certain extent, the high hopes with regard to the learning process of both developers and users of guidelines seem to have come true. The methods and procedures for the development of guidelines, which were used by the NHG and, to an increasing extent, by the CBO and the scientific associations of medical specialists as well, decidedly improved over the course of time (although they still leave much to be desired, according to experts).¹³⁰ On the part of the users of the guidelines, resistance against the guidelines *as such*, which was still very much present in the 1990s, seems to have largely disappeared.¹³¹ Whether users went through a ‘learning process’ in respect of the use of guidelines is harder to indicate. An important given in this connection is that EBM and evidence-based guidelines slowly but surely earned a permanent (compulsory) position in medical education, training courses and further training.¹³²

Of course, the big question is what the (possible) learning process of drafters and developers actually produced for medical practice. Recent implementation studies show that there is still a considerable implementation problem.¹³³ Assuming a linear and ‘nar-

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130. Compare the introduction and chapters 6, 7 and 8 of the first edition of 2000 and the fourth edition of 2014 of the textbook: Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*. See, in addition: Van Everdingen, *Evidence-Based Richtlijnontwikkeling*, see in particular pp. XIII-XVII, 7-8, 15-17. Grol & Wensing, *Implementatie*, a.o. pp. 38-9, 155-87; Van Loon & Bal, ‘Uncertainty’; Ravensbergen & Zandvliet, *Dat Verandert de Zaak!*; A. de Rijk et al., ‘Betere Zorg door Inbreng Patiënten’, *Medisch Contact* 66: 40 (2011), pp. 2430-3; Scholten, *Hoe Sterk?*; Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 5.
131. See n. 130 above. See in addition, specifically about the increasingly broad acceptance of guidelines *as such* (in particular by GP’s): J. Braspenning, F. Schellevis & R. Grol, ‘Kwaliteit in Beeld’, *Medisch Contact* 59: 21 (2004); Broersen, ‘NHG Presenteert’; Evenblij, ‘25 jaar’; J. J. E. van Everdingen, ‘Een Hoop Gedoe, maar Wel de Moeite Waard’, *Medisch Contact* 58: 12 (2003), pp. 473-6; Idem, ‘Honderd NHG-Standaarden’; Grol et al., ‘Implementatie van NHG-Standaarden’; L. Goudswaard, K. in ’t Veld & R. Dijkstra, ‘Van Richtlijnen, de Dingen die Niet Voorbijgaan’, *Huisarts en Wetenschap* 53 (2010), pp. 51-4. Resistance against guidelines *as such* appears to have waned, but without disappearing completely. Every now and then criticisms did ‘resurface’. See for example: T. L. Th. A. Jansen, K. Went & P. W. Tanja, ‘Richtlijnen onder Vuur: Toename van Protocollen Leidt tot Kookboekgeneeskunde’, *Medisch Contact* 58: 7 (2003), pp. 233-5.
132. See the subsequent assessment reports of the medical curricula in the Netherlands, see for example: Stichting Quality Assurance Netherlands Universities *Onderwijsvisitatie Geneeskunde* (Utrecht: QANU, 2004), pp. 26, 55, 142; Idem, *Onderwijsvisitatie Geneeskunde: Faculteit Geneeskunde, Utrecht* (Utrecht: QANU, 2011), p. 21. See also the diary of a medical student in Utrecht, about the omnipresence of the term ‘EBM’ in medical education; Emma, ‘Evidence-Based Blaren’, *Medisch Contact* 60: 37 (2005), p. 1472. See, in addition, specifically with regard to general practice: Beljaards et al., ‘Veranderende Profiel’; Broersen, ‘NHG Presenteert’; Burgers, ‘Honderdste NHG-Standaard’; Van Everdingen, ‘Honderd NHG-Standaarden’; In ’t Veld & Grol, ‘Standaarden en Praktijkaccreditering’.
133. Broersen, ‘NHG Presenteert’; Van Dijk, Hooft & Wieringa-De Waard, ‘What are the Barriers?’; B. Dumas & M. Ludwig, ‘Te Veel Verschil in Behandeling’, *Medisch Contact* 68: 44 (2013), pp. 2260-2; M. A. H. Fleuren et al., ‘Richtlijnen Genoeg, Nu de Uitvoering Nog’, *Medisch Contact* 65: 7 (2010), pp. 306-8; Grol et al., ‘Implementatie van NHG-Standaarden’; Grol and Wensing, *Implementatie*, pp. 24-8; Lugtenberg et al., ‘Welke Barrières?’; Schoemaker et al., ‘Grade Zet Bewijs om’; Swennen et al., ‘Doctor’s Perceptions’; Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 7; Zwolsman et al., ‘Barriers’.

row view' of implementation, this would mean that the image of the leaking pipeline is upheld. The 'broader vision' of implementation, however, offers some room for a rosier picture, for the impact of evidence-based guidelines no longer needs to be measured against the extent to which the recommendations are followed. For example, it is not about applying clinical-epidemiological evidence one on one in practical situations, but it is about 'factoring it in' in the integration of various types of data. Thus, the clinical-epidemiological evidence, as the Health Council phrased it, functions as a 'frame of reference' that defines 'preconditions' for medical practice. Seen in this light, there is little doubt that the rise of EBM added an important new element to the heart of medical practice: on a larger scale and in a more systematic manner than ever, clinical-epidemiological evidence is *involved* in the decisions that physicians take regarding the treatment of their patients.¹³⁴

With delight, the Health Council concluded that this mainly favourably impacted the *omission* of unnecessary medical procedures.¹³⁵ Following on from this, Assendelft, former managing director of the Dutch Cochrane Centre and former head of the NHG standards programme, argued that the main role of evidence-based medicine is/was that of *abolition medicine*. According to him, randomised trials mainly proved effective in 'exposing' all manner of ineffective, inefficient and even harmful medical practices, which had sometimes been applied for decades based on routine, authority, 'beliefs' and pathophysiological reasoning. Assendelft argues that EBM was 'highly successful' in 'separating the wheat from the chaff'.¹³⁶ A similar view was taken by several others, including Trudy Van der Weijden who, in her inaugural speech as extraordinary professor of *implementation of guidelines* in Maastricht, noted: 'Due to Evidence-Based Practice, chances of ineffective treatments and medical failures have greatly decreased'.¹³⁷ This is also in line with Iain Chalmers's argument that the role of the Cochrane Collaboration and the EBM has been and still is primarily: combating *bad medicine*.¹³⁸

134. See a.o.: Gezondheidsraad, *Van Implementeren naar Leren*, pp. 34-35; Maassen, 'Kansen voor Patiënten'; Stoop, Berg & Dinant, 'Tussen Afwijken en Afwijzen'; Timmermans & Kolker, 'Evidence-Based Medicine', p. 108.

135. Gezondheidsraad, *Van Implementeren naar Leren*, pp. 25-6.

136. Cited in: M. Hordijk, 'Klinische Trial Krijgt Concurrentie', *Medisch Contact* 66: 35 (2011), pp. 2045-7. This was also elaborately discussed in the interview (by TB) with Assendelft.

137. Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 4. See also, for example: Grol & Wensing, *Implementatie*, p. 158; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*, p. 8 (also in 4th edition of 2014); Willems et al., *Passend Bewijs*, p. 21. See, in addition, the book *Medische Misvattingen ('Medical Fallacies')*. In the preface of this book immediately and explicitly the link was made between the 'current drive for evidence-based medicine' and the book's content of a huge amount of (exposed) fallacies and misconceptions in the recent history of medicine. See: C. J. E. Kaandorp & J. J. E. van Everdingen (eds.), *Medische Misvattingen: Nieuwe Inzichten in de Geneeskundige Praktijk* (Houten/Diegem: Bohn Stafleu van Loghum, 2002), p. XVI.

138. This was explicitly and elaborately argued by Chalmers at the short (summer) course 'History and Philosophy of Evidence-Based Healthcare', which was organized by the Centre for Evidence-Based Medicine

The elimination of ‘bad medicine’ is unmistakably of great importance, but with the comments by the Health Council, Assendelft, Van der Weijden and Chalmers an important limitation is given at the same time: the practice of ‘good medicine’ requires a great deal more than just the application of data from trials or other clinical-epidemiological research.¹³⁹ The reorientation on the implementation issue advocated by the Health Council does justice to this by stressing the necessity of a ‘translation’ from science to practice and of the integration of evidence with pathophysiological reasoning, clinical experience and the patient perspective. Yet at first sight, this seems to have little to do with what EBM ‘added’ to medicine, namely: rationalisation of medical practice with the help of, above all, clinical-epidemiological evidence. After all, physicians had always been involved in integrating pathophysiological reasoning, clinical expertise and characteristics of individual patients – and EBM was (initially) presented by its advocates as more or less the *opposite* of this.

This may be balanced, however, by another characteristic of EBM. Various pioneers of the clinical epidemiology and EBM movement in the Netherlands are of the opinion that EBM mainly represents a certain *attitude*. What had appealed to them most at the time in role models such as Sackett and Wulff was their (self-)critical mind set, which was expressed in their attitude towards authorities, habits and ‘beliefs’ as well as in the way in which they openly pointed out what they did *not* know or mentioned it when they were unsure about a certain clinical issue. According to them, in the educational approach, which EBM originally was first of all, it was also primarily about cultivating such an attitude. In ‘Medical Practice at a Crossroads’, the Health Council agreed with this by emphasising the necessity of a mentality change as well a behavioural change. In ‘From Implementing to Learning’ the Health Council expanded on this, by – as was also done by the NHG, the KNMG and other actors for that matter – emphasising the importance of the ‘learning process’, in which an important role was reserved for critical (self-)reflection and for explication of uncertainties, presuppositions, value judgements, choices and interpretations.¹⁴⁰

and Oxford University in July 2012. Chalmers was one of the tutors of this course, TB was one of the participants. See on this course: <http://www.conted.ox.ac.uk/B900-77>. This is also entirely in line with the approach in of the book *Testing Treatment* which is co-authored by Chalmers. See: I. Evans et al., *Testing Treatments: Better Research for Better Healthcare*. 2nd ed. (London: Printer and Martin, 2010). See also, in this respect: V. Prasad et al., ‘A Decade of Reversal: an Analysis of 146 Contradicted Medical Practices’, *Mayo Clinic Proceedings* 88 (2013), pp. 790-8.

139. See a.o. notes 136-138 above.

140. Gezondheidsraad, *Medisch Handelen op een Tweesprong*, see a.o. p. 12; Idem, *Van Implementeren naar Leren*. This change of mentality, attitude and mind-set was also explicitly mentioned in this sense in the interviews with Assendelft, Borst-Eilers, Bossuyt, Büller, Dekker, Van Gijn, Knottnerus, Offringa and Thomas. See also on this (and on the relevance/plausibility of this change of mentality), for example: A. Ankoné & S. Wildevuur, ‘“Onze Generatie is Anders”: Toekomstige Arts Opteert voor Teamwork’, *Medisch Contact* 48: 35 (1993), pp. 1029-34; Crommentuyn, ‘Opvoedkundige Waarde’, Mooij, *Polsslag*,

This would mean that the impact of EBM should not be measured by the extent to which guidelines were followed, as this impact rather consists of more subtle changes in the manner of professional practice. Yet the possible contribution of EBM to a change in mentality and behaviour is difficult to ‘prove’ – and there is certainly no ‘high-level evidence’ available. It may only be noted that representatives of the Dutch EBM and clinical epidemiology movement are generally quite satisfied with what has been achieved and mainly with how, over the last decades, the profession has worked on the rationalisation and quality improvement of medical practice.¹⁴¹

Yet they also perceive – following on from the international debate on the current ‘crisis’ that is allegedly experienced by the EBM movement¹⁴² – a number of considerable ‘threats’.

The ‘threats’ that are repeatedly identified in the EBM debate of the last years may roughly be divided into three categories. This first category of ‘threats’ relates to the *production of evidence*, the second category to the *handling of evidence* and guidelines by healthcare professionals and the third category to the *threats from the ‘outside’*.

With regard to the first category of threats, there is mainly a great deal of debate on the impact of industry on research and about the ‘publish-or-perish’ system. The interest of industry in generating favourable research results for their products and the interest of researchers and research groups in ‘scoring’ as high as possible with publications in high-impact journals purportedly form the root of three serious problems with regard to the ‘evidence-base’ of evidence-based medicine. In the first place, physicians are confronted with a virtually unmanageable ‘*information explosion*’, in the form of the enormous and ever-expanding volume of ‘evidence’ that is produced. Secondly, a great deal of this ‘evidence’ is believed to be *unreliable*, as a result of negligence, failing methods, conscious manipulations and ‘publication bias’.¹⁴³ Thirdly, a large part of the evidence produced is believed to be *hardly relevant* to medical practice, as the research agenda is purportedly

pp. 446-7; ‘Naar een Nieuw DKB-Pakket (5): De Implementatie’, *Huisarts en Wetenschap* 38 (1995), pp. 500-1.; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*, pp. 9-10 (and pp. 8-9 in the 4th edition of 2014); Pronk, ‘Kunst van het Opleiden’; Rasmussen, ‘Evidence-Based Medicine’; Spreeuwenberg, “Evidence-Based Policymaking”; K. in ‘t Veld & R. Helsloot, ‘Nieuw Kompas voor de Afdeling DKB: De Kwaliteitscirkel’, *Huisarts en Wetenschap* 42 (1999), p. 332.

141. Interviews with Assendelft, Borst-Eilers, Bossuyt, Büller, Dekker, Van Gijn, Knottnerus, Offringa and Thomas. See also notes 130-132 above.

142. See a.o. Greenhalgh, Howick & Maskrey, ‘Evidence-Based Medicine: a Movement in Crisis?’.

143. ‘Publication bias is well known phenomenon in clinical literature, in which positive results have a better chance of being published, are published earlier, and are published in journals with higher impact factors [than negative results]. Conclusions exclusively based on published studies, therefore, can be misleading’. This is a quote from: H. H. Dubben & H. P. Beck-Bornholdt, ‘Systematic Review of Publication Bias in Studies on Publication Bias’, *British Medical Journal* 331 (2005), pp. 433-4.

not determined by the questions from practice, but by said interests of industry and scientists.¹⁴⁴

These problems are nowhere near new. Already in 1994, for example, the statistician Douglas Altman – who had been involved with the Cochrane Collaboration from the outset – published an opinion piece in the *British Medical Journal*, entitled ‘The Scandal of Poor Medical Research’, with as conclusion: ‘As the system encourages poor research it is the system that should be changed. We need less research, better research, and research done for the right reasons.’¹⁴⁵ Twenty years on, in 2014, Altman, together with several other Cochranites, made an important contribution to a series of articles in the *Lancet*, entitled ‘Research: Adding Value, Reducing Waste’, in which it was argued that a considerable part of the astronomical sums of money spent on medical research was actually ‘wasted’.¹⁴⁶ This gave rise to a BMJ blog entitled: ‘Medical research – still a scandal’.¹⁴⁷

In the Netherlands, too, there has been a great deal of attention over the past years for the ‘failing system’ of science. Partly under the influence of a case of large-scale fraud – of which there was widespread media coverage – involving the fabrication of research data by the social psychologist Diederik Stapel, the debate was launched on the perverse consequences of the ‘publication factory’ that scientific research has become,¹⁴⁸ and there is an explicit call for reconsideration and change.¹⁴⁹ In this context, Zon-Mw, a key funder of health research in the Netherlands, launched the project ‘system failure’ in 2013, with the aim of providing an insight into the nature, scope and origin of system failure across the entire spectrum of health research, creating awareness about it and offering possible directions in which solutions are to be sought.¹⁵⁰

The relevance of all this for evidence-based medicine is great. The *excess* of evidence that is produced perhaps constitutes the main explanation for the rise of EBM, which may be regarded as a necessary adaptation to the ‘information explosion’ in medicine. With this *adaptation* to the information explosion, however, the cause of this – the continu-

144. See for example: B. V. M. Crul, ‘Evidence-Based Medicine is Niet Zaligmakend’, *Medisch Contact* 56: 11 (2001), p. 399; J. Heilbron, M. van Bottenburg & I. Geesink, *Wetenschappelijk Onderzoek: Dilemma's en Verleidingen* (Amsterdam: KNAW, 2000); E. Pronk, ‘Twijfels over de Wetenschap’, *Medisch Contact* 56: 39 (2001), pp. 1404-7; J. Visser, ‘Industrie heeft Invloed op Behandelrichtlijnen’, *Medisch Contact* 64: 44 (2009), p. 1800; Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 4.

145. Altman, ‘Scandal’.

146. *The Lancet*-series ‘Research: Increasing Value, Reducing Waste’, published January 8, 2014, available from: <http://www.thelancet.com/series/research>.

147. R. Smith, ‘Medical Research – Still a Scandal’. *BMJ blogs*, 31 January 2014. Available from: <http://blogs.bmj.com/bmj/2014/01/31/richard-smith-medical-research-still-a-scandal/>

148. See a.o.: R. Abma, *De Publicatiefabriek. Over de Betekenis van de Affaire-Stapel* (Nijmegen: Van Tilt, 2013).

149. See a.o. the ‘Science in Transition’ initiative that was launched in 2013. See for the website: <http://www.scienceintransition.nl>. See also: Miedema, *Science 3.0*.

150. The start document of the Zon-MW project ‘Systeemfalen’ is available from: <http://www.zonmw.nl/nl/themas/thema-detail/implementatie/buikbaar-onderzoek>.

ous production of too much evidence – is *not* removed. This ‘drying out a flooded room without turning off the taps’ seems to increasingly turn itself against EBM, as shown by the comment by Greenhalgh et al. in 2014 in the *British Medical Journal* that ‘the volume of evidence, especially clinical guidelines, has become unmanageable’.¹⁵¹

Thus, following on from the overproduction of scientific evidence, there appears to be an overproduction of clinical guidelines, while these very guidelines are supposed to ensure that the abundance of evidence for practising physicians is reduced to manageable chunks. In the Netherlands, too, where the ‘overproliferation’ of guidelines seems to have taken on less serious proportions than in some other countries, there has been an increasing focus on the *excess* of guidelines over the past years. Reference is made here to an ‘enormous mountain of guidelines’, making any attempt at evidence-based practice ‘pointless’.¹⁵² Physicians are even believed to be growing ‘sick and tired’¹⁵³ of the ‘forest of guidelines’,¹⁵⁴ which has not been conducive to compliance with them needless to say.¹⁵⁵

The problem of the *excess* of evidence is compounded by that of *unreliable* evidence. How seriously the latter is taken by representatives of the EBM movement, was perhaps most explicitly expressed in an article from 2014, entitled: ‘How Evidence-Based Medicine is Failing Due to Biased Trials and Selective Publication’.¹⁵⁶

In addition, there is the problem of the *lack of relevant* evidence. This was, for example, discussed in an article in *Huisarts en Wetenschap*, in which the ideal of a fruitful cross-fertilisation between NHG standards and research was set against the difficult situation in practice: ‘Attempts by the NHG to structurally exercise influence on the research agenda [have] not always been as successful as we hoped. This agenda is also determined by the interests of universities, research institutes, researchers, financiers and patients’. As a result, ‘important areas of research remained underexposed, in particular where

151. Greenhalgh, Howick & Maskrey, ‘Evidence-Based Medicine’.

152. L. Blume, N. van Weert, & H. Kerckamp, ‘Ruim Twaalfhonderd Richtlijnen Is Te Veel’, *Medisch Contact* 68:10 (2013), pp. 546-8. In this article, it was observed that Dutch hospitals had to adhere to no less than 1200 guidelines. The authors pleaded for *much less* guidelines: no more than 20 out of the 1200 guidelines had to be prioritized, according to them.

153. P. Spronk, ‘Artsen zijn Doodmoe van Regels en Richtlijnen’, *Trouw*, 11 November 2013, p. 23.

154. M. Wymenga et al., ‘Weg met het Woud van Richtlijnen’, *Medisch Contact* 67: 37 (2012), pp. 2010-11.

155. Many examples could be added to those in notes 152-154 – too many to sum up here. But just to add a few typical examples, see also: Lemaire, ‘Richtlijnen met Elkaar in Strijd’; Lugtenberg et al., ‘Welke Barrières?’; H. Maassen, ‘“Richtlijnen Zijn Niet Altijd Even Logisch”’, *Medisch Contact* 65: 14 (2010), pp. 621-3.

156. S. Every-Palmer & J. Howick, ‘How Evidence-based Medicine Is Failing Due to Biased Trials and Selective Publication’, *Journal of Evaluation in Clinical Practice* (2014) doi:10.1111/jep.12147. See for a Dutch example: the consequences of the scientific fraud committed by the Dutch internist Poldermans (the Poldermans affair was ‘hot’ in the news in 2011) for the reliability of several ‘evidence-based’ guidelines. See: S. Broersen, ‘Kwestie-Poldermans Heeft Gevolgen voor Richtlijnen’, *Medisch Contact* 69: 4 (2014), pp. 122-3.

it concerns everyday complaints, as a result of which some 'gaps in the *evidence base* of standards' continued to exist.¹⁵⁷

Of course, the EBM movement is not to blame for the apparent malfunctioning of science. Precisely due to their focus on the 'evidence base' of medicine, several proponents of EBM and the Cochrane Collaboration belong to those who most sharply defined the problems and also proposed possible solutions. Yet it could be simultaneously argued that the rise of EBM did not exactly bring the realisation of these solutions any closer. The EBM movement (initially) placed a great deal of emphasis on RCTs. As discussed in part 2, the performance of RCTs was attractive to clinical researchers in terms of high-impact publications and research funds generated. Over the last years, within the EBM movement too, there has been a call for a *broader* research agenda, which would be required to build up a more clinically relevant evidence base for medicine. The RCT is the 'golden standard' for intervention research – and therefore EBM mainly seems to have contributed to a better substantiation of therapeutic practice – but the most important questions rather seem to lie in the area of diagnostics, prognostics, prevention and care. This (partly) requires other research methods, including qualitative research.¹⁵⁸ The big question, however, is who wants to and is able to finance this broader research agenda, and if (top)researchers are interested in performing research that does not yield any high-impact publications.¹⁵⁹

With regard to the issue of the relevance of the 'evidence base' for medicine, an even more fundamental problem occurs. The privileged position allocated to the RCT in the EBM philosophy was based on certain ideas about objectivity and scientific knowledge, where in particular the elimination of 'bias' and 'subjectivity' was the primary concern. Reliable evidence was, first and foremost, 'impersonal' evidence. According to several science philosophers, this '*doctrine of scientific rigour*' led to a 'methodological trade-off', where the great importance attached to criteria such as 'generality' and 'precision', came at the expense of criteria such as 'realism'.¹⁶⁰ It is also frequently argued that the emphasis on the

157. J. Dekker, 'Standaarden en Onderzoek voor en door Huisartsen', *Huisarts en Wetenschap* 53 (2010), pp. 47-50, on p. 48. See also, for example: 'Toponderzoek', *Medisch Contact* 58: 51 (2003), pp. 1978-82; In 't Veld & Grol: 'Standaarden en Praktijkaccreditering'.

158. Interviews with Assendelft, Bossuyt and Vandenbroucke; Bossuyt, 'Evidence-Based Medical Testing'; D. Djulbegovic & A. Paul, 'From Efficacy to Effectiveness in the Face of Uncertainty: Indication Creep and Prevention Creep', *JAMA* 305 (2011), pp. 2005-6; Greenhalgh, Howick & Maskrey, 'Evidence-Based Medicine'; I. Hernández-Aguado, 'The Winding Road towards Evidence Based Diagnoses', *Journal of Epidemiology and Community Health* 56 (2002), pp. 323-5; Hordijk, 'Klinische Trial'; Kristiansen & Mooney, 'Evidence-Based Medicine', p. 5; W. Köhler, 'Goed Kijken Mag Weer', *NRC Handelsblad*, 6 June 2009, section 'Wetenschap', pp. 8-9; A. Loonen, 'De Prijs van EBM', *Medisch Contact* 64: 26 (2009), pp. 1170-2.

159. See a.o. Miedema, *Science* 3.0.

160. This is paraphrased from: Ho, 'Medicine, Methodology, and Values'. But see also: Borgerson, 'Bias and the Evidence Hierarchy'; N. Cartwright, 'The Art of Medicine: A Philosopher's View of the Long Road from RCTs to Effectiveness', *Lancet* 377 (2011), pp. 1400-1; Dehue, 'Dutch Treat'; Kelly and Moore, 'Jud-

greatest possible internal validity of clinical research came at the expense of the external validity (generalisability) and thus also of its clinical relevance.¹⁶¹ In a certain sense, the EBM philosophy thus *contributed* to the gap between science and practice, while the EBM movement rather wanted to bridge it. It is precisely for this reason that Van der Weijden, in her oration as professor of Implementation of Guidelines, made critical comments in respect of EBM. Her main message here was: ‘We need to be wary of putting the *strength* of the evidence from experiments before the *relevance* of the evidence.’¹⁶²

The second category of threats for EBM relates to the way in which evidence and guidelines are *dealt with* by medical professionals. The Health Council and various other parties pointed to the necessity of a translation from science to practice, where integration occurred between clinical-epidemiological knowledge, pathophysiological reasoning, clinical experience and the wishes and characteristics of patients. Although the EBM philosophy clearly evolved in this direction as well, it offered (and offers) too few starting points to flesh this out. In the report ‘From Implementing to Learning’ the Health Council wrote about this: ‘When the theme of ‘translation’ is discussed, matters seldom progress beyond relatively vague indications.’¹⁶³ The authors refer to various articles here which ‘advocate a more structural approach to what is often so loosely termed “the translation”’¹⁶⁴

At this stage, it does not appear that this ‘more structural approach’ has actually been able to develop within the EBM movement – despite several initiatives in this direction.¹⁶⁵ Hutschemaekers and Tiemens therefore also had reservations about the ‘heuristic approach’ of which they were proponents. Especially the manner in which ‘practice knowledge’ and ‘experience-based knowledge’ was to be ‘integrated’ in evidence-based medical practice, remained unclear according to them. They argued that ‘the way in which this knowledge should be evaluated and used within the EBM heuristic is too vague and so complicated that it is hard to perform in daily practice.’¹⁶⁶

gement Process’; R. L. Kravitz, N. Duan & J. Braslow, ‘Evidence-Based Medicine, Heterogeneity of Treatment Effects, and the Trouble with Averages’, *Milbank Quarterly* 82 (2004), pp. 661-87; Loonen, ‘Prijns van EBM’; P. Rothwell, ‘Treating Individuals I. External Validity of Randomised Controlled Trials: “To Whom Do the Results of this Trial Apply?”’, *Lancet* 365 (2005), pp. 82-93; Sehon & Stanley, ‘Philosophical Analysis’.

161. See n. 160 above.

162. Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 4. See also: Crul, ‘Evidence-Based Medicine is Niet Zaligmakend’.

163. Gezondheidsraad, *Van Implementeren naar Leren*, p. 33.

164. *Ibid.*, p. 35.

165. For example GRADE, see chapter 3 and: Schoemaker et al., ‘Grade Zet Bewijs om’. See also: <http://www.gradeworkinggroup.org>.

166. Hutschemaekers & Tiemens, ‘Evidence-Based Policy’, pp. 46-7. See also the observation in 2014 by Van Loon and Bal in their paper ‘Uncertainty and the Development of Evidence-Based Guidelines’, on p.

This problem may partly be traced back to the genesis of EBM, Bossuyt argued in 2011. As EBM originated from clinical epidemiology – a scientific-methodological discipline – and critical appraisal of the medical literature, it focused, in his view, ‘first and foremost’ on the ‘evidence’ and not on the decision.¹⁶⁷ He supported this claim using the five steps of evidence-based practice. Plenty of books have been written by representatives of the EBM movement about the first, second and in particular the third step – the formulation of a clinical question, finding relevant evidence in the literature and the critical evaluation of this evidence respectively. Yet about the fourth step – the application in practice – little more may be found in the EBM literature than some general statements on the integration of evidence with expertise and patient preferences. ‘In all fairness’, as Bossuyt wrote, ‘it must be said that none of the EBM-textbooks actually described how in step 4, the decisions about the care of individual patients should be made.’¹⁶⁸

Due to this ‘disregard’ of step 4 of evidence-based practice – which precisely pertained to the ‘translation’ and ‘integration’ which were considered to be so important – it is highly questionable to what extent the implementation problem is actually solved or bypassed due to the reorientation on the implementation which became apparent around 2000. Since then too, publications have continued to appear on the failing implementation of guidelines and all manner of impeding factors which played a role here. The degree of implementation of the NHG standards is still high, compared to that of the guidelines for specialists as well as from an international perspective, but seems to have been ‘stuck’ at approximately 70% for years. The 30% of ‘deviations’ from guidelines does not only result from a *desired* ‘flexible’ handling of standards. In general medicine and (even more so) outside of it, there is still an ‘*undesired* inter-physician variation’ on a large scale, because physicians *irrationally* deviate from guidelines or simply do not know or use them.¹⁶⁹ The questions presents itself of how much has changed since the Health Council identified countless causes for irrational or inefficient medical practice in ‘Medical Practice at a Crossroads’ in 1991, including lack of time, bad communication, an uncertain or traditional attitude, demarcation problems between disciplines and the perverse incen-

58: ‘Guideline developers are very aware that they need experiential knowledge from healthcare practitioners, patients and specialised experts to create guidelines. There are, however, still great challenges in including this knowledge in ways that move beyond the overly “impressionistic.”’

167. Bossuyt, ‘Evidence-Based Medical Testing’, p. 18.

168. *Ibid.*, p. 12. Essentially the same point is made in: Kristiansen & Mooney, ‘Evidence-Based Medicine’, pp. 5-6. The argument of Bossuyt (and of Kristiansen and Mooney) seems to be valid, judged by browsing EBM text books such as: Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*, several editions; Sackett et al., *Evidence-Based Medicine*; Straus et al., *Evidence-Based Medicine*.

169. See n. 133 above.

tives created by the remuneration system. Most of these issues, as Borst-Eilers indicated herself as well, do *not* seem to have been removed.¹⁷⁰

Besides by the ‘old’ problem of physicians who insufficiently comply with the guidelines, over the past years, the ‘implementation debate’ has been increasingly dominated by the ‘new problem’ of physicians who follow the guidelines ‘too much’: regular warnings are provided against too *dogmatic* a handling of guidelines and the EBM philosophy with regard to, for example, the levels of evidence. Where, in the 1990s, EBM pioneers tried to convince their peers to start working in an evidence-based way, several of them are now inclined to apply the brakes. They have the impression that some physicians do not treat the results of trials or evidence-based guidelines critically enough, as a result of which they too unthinkingly apply them in practice. Furthermore, too many physicians allegedly think that if there is no ‘high-level evidence’ for something, it is *therefore* not ‘evidence-based’ and *therefore* not good. The critical mind, the ‘independence of thought’ and the anti-authoritarian mentality which, to many of these pioneers, constitutes the core of EBM, they do not see sufficiently reflected in their ‘epigones’.¹⁷¹ Not only were such concerns voiced in the Netherlands, but overseas as well.¹⁷² Ross Upshur for example, a Canadian physician who was trained at McMaster, wrote in 2005:

‘The data show a vast majority of clinicians and trainees are not interested in EBM at all! What they want is to be told where to go and what to look for, and they want others to do this work for them.’¹⁷³

170. Interview with Borst-Eilers. Especially, the (perverse) financial incentives of the remuneration system are singled out as important obstacle for a more efficient medical practice. For example: that the costs of Dutch healthcare continue to grow almost uncontrollably was attributed mainly to this factor in a report by the Dutch ‘Forum for Economic Research’ NYFER from 2012. See: L. Berenschot & L. van der Geest, *Integrale Zorg in de Buurt: Meer Gezondheidsresultaat per Euro* (Utrecht: NYFER, 2012). It seems that many GP’s attribute a negative role here to the marketisation of healthcare, especially after the introduction of the new Dutch healthcare system in 2006. According to these GP’s, marketisation makes it more difficult to uphold the cautious approach of the NHG-Standards. To a certain extent the same seems to apply for Dutch surgeons. See on this: Dwarswaard, *Dokter en Tijdgeest*, pp. 119-23, 143-50, 215-20; Goudswaard, In ‘t Veld & Dijkstra, ‘Van Richtlijnen’, p. 54.

171. See a.o.: B. V. M. Crul, ‘Redactionele Vrijheid onder Druk’, *Medisch Contact* 54: 45 (1999), p. 1540-2; Hijdra et al., *Vernieuwingen in de Neurologie*, p. 16; Van Loon & Bal, ‘Uncertainty’, pp. 52-3; Loonen, ‘Prijzen van EBM’; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*, p. 8 (p. 7 in the 4th edition of 2014); Offringa-Hup, ‘Ruimte rond de Richtlijn’; Y. M. Smulders, *Hoezo, Bewijs?* (Amsterdam: Vrije Universiteit/VU Medisch Centrum, 2008); Y. M. Smulders et al., ‘De Rol van Epidemiologisch Bewijs in de Zorg voor Individuele Patiënten’, *Nederlands Tijdschrift voor Geneeskunde* 154 (2010): A1910; E. Stolpers et al., ‘Intuïtieve Kennis is Volwaardige Kennis’, *Medisch Contact* 66: 46 (2011), pp. 2815-17.

172. See a.o.: Kristiansen & Mooney, ‘Evidence-Based Medicine’, pp. 16-18; Rasmussen, ‘Evidence-Based Medicine’, p. 158. See also n. 173 below.

173. Upshur, ‘Looking for Rules’, p. 485.

Both the 'old' implementation problem and the 'new' problem of 'dogmatism' raise the question of to what extent the educational and reflective handling of guidelines – as advocated by the Health Council in 'From Implementing to Learning' – will materialise. It looks very much as though the Council presented an ideal image of which the existing practice (still) falls short by a long way. Yet, judging from the debates of the past years, this does not form the main 'threat' for the 'broad approach' to implementation which is desired so much.

In the eyes of many physicians and medical associations, the biggest threat is 'external' – or from the *third* category of threats. This is associated with a number of important developments in healthcare policy in the Netherlands. In chapter 8, it was outlined how, in the 1990s, during minister Borst-Eilers's term in office, the 'symbiosis' between government and medical profession was restored.¹⁷⁴ In the 2000s, however, this 'symbiosis' was disrupted again, because the incremental policy of the preceding decade ended. Borst-Eilers herself set this policy change in motion in the last year of her ministry, when she published the memorandum 'Healthcare on Demand' (Dutch: 'Vraag aan Bod') in 2001. Core of the memorandum was a commitment to make the switch from a supply-driven approach to a demand-driven approach in healthcare in the short term, where a new insurance system would have to be introduced as well.¹⁷⁵

That the minister eventually considered a system change to be necessary after all, could be interpreted as an acknowledgment that her 'non-regret policy', which, among others, was geared towards an efficiency increase at the micro-level, had been insufficiently effective. It could be concluded from this that the impact of the introduction of EBM, as a means of controlling the cost of healthcare, was more limited than Borst-Eilers had hoped. At the same time, it should be noted that the announcement of a system change in 'Healthcare on Demand' did not really mark a break in the policy of the minister. This policy may have been 'incremental', but it did gradually lead towards a new insurance system which, in line with the report of the Dekker Commission from 1987, was characterised by regulated market forces.¹⁷⁶

Various scholars have demonstrated that, even after the 'failure' of the Simons plan, the officials at the Ministry of Health continued to work 'behind the scenes' on the creation of the right preconditions for regulated competition in healthcare. All manner of 'administrative-technical' matters were arranged, which brought a successful introduction of the new system closer. Almost unnoticed, the minds, too, grew increasingly ripe for this. The various parties in healthcare became increasingly familiar with 'the logic of

174. This is also a paraphrase from: Gunning-Schepers, 'Solidair Zolang het Werkt', p. 130.

175. Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 592, 842, 848; Helderma et al., *Dike-Reeve*, pp. 35-8; Vonk, *Recht of Schade*, p. 324.

176. See a.o.: Companje, *Tussen Volksverzekering en Vrije Markt*, p. 821. See also n. 177 below.

regulated competition' and 'both health insurers and healthcare providers anticipated a more market-oriented environment', which was expressed, among others, in a wave of mergers of healthcare institutions and of insurers. To a certain extent, what the literature refers to as 'path dependency' applies here. The longer the path of regulated market forces – which was tentatively embarked upon in the Netherlands in 1987 – was followed, the more 'rigorously' this course was followed by the policy and the more difficult it became to deviate from it.¹⁷⁷

This partly explains why one of the successors of Borst-Eilers, the conservative-liberal minister Hans Hoogervorst, succeeded in implementing the new healthcare system with noticeable ease. This new healthcare system was a fact in 2006, when two new laws entered into force: the Health Insurance Act (Dutch: *Zorgverzekeringswet (Zvw)*) and the Health Care Market Regulation Act (Dutch: *Wet marktordening gezondheidszorg (Wmg)*). No longer was there a distinction between health insurance fund and private insurance. This distinction was replaced with an entirely private insurance system including a basic package of insured healthcare of which the content was legally prescribed by the government. The insurers could compete with each other in terms of the price of the (nominal) premium they charged for this basic package as well as in terms of all manner of additional insurances they could offer.¹⁷⁸

Apart from the above-mentioned 'path dependency' and 'administrative-technical preconditions', the literature mentions various other factors that contributed to the 'success' of Hoogervorst.¹⁷⁹ It would go too far, however, to outline the realisation of the new healthcare system in detail here – and others have extensively published on this. It is mainly of importance here that in the EBM and implementation debate, the period after 2006 is often referred to as a distinctively new era.¹⁸⁰

177. Bottenburg, De Vries & Mooij, *Zorg tussen Staat en Markt*, pp. 181-4; Companje, *Convergerende Belangen*, 300, 304, 310-11; Idem, *Tussen Volksverzekering en Vrije Markt*, pp. 605-9, 821-2, 865-6; Helderma et al., *Dike-Reeve*, pp. 35-41; J. K. Helderma, G. Bevan & G. France, 'The Rise of the Regulatory State in Healthcare: a Comparative Analysis of the Netherlands, England and Italy', *Health Economics, Policy and Law* 7 (2012), pp. 103-24, on pp. 114-16, 119-21; E. Schut, 'Marktordening met Beleid', in J. K. Helderma, P. Meurs & K. Putters (eds.), *Orkestratie van Gezondheidszorgbeleid: Besturen met Rationaliteit en Redelijkheid* (Assen: Van Gorcum, 2006), pp. 47-53, on pp. 51-2. Vonk, *Recht of Schade*, pp. 317-33, see in particular p. 324.

178. Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 595-6, 602-3; Helderma et al., *Dike-Reeve*, pp. 38-9; Vonk, *Recht of Schade*, pp. 324-6.

179. See n. 177 above.

180. See a.o.: Van Everdingen, 'Honderd NHG-Standaarden'; Goudswaard, In 't Veld & Dijkstra, 'Van Richtlijnen', p. 52; Offringa, Assendelft & Scholten, *Inleiding in Evidence-Based Medicine*. 4th edition., pp. 7-8 (and compare this with the first edition of this text book from 2000, p. 8!); P. Smeets, 'Marktwerking is Zorgvershraling', *Medisch Contact* 64: 49 (2009), pp. 2057-9; P. Vos & J. Kasdorp, 'Advies en Beleid: RVZ', in J. K. Helderma, P. Meurs & K. Putters (eds.), *Orkestratie van Gezondheidszorgbeleid: Besturen met Rationaliteit en Redelijkheid* (Assen: Van Gorcum, 2006), pp. 94-107, on pp. 102-3.

In the view of many physicians and medical associations, this era signified a threat to the self-regulation by the medical profession. The greatest danger here was said to come from the insurers, who were assigned a 'directing role' in healthcare in the new system. This was not a novelty in itself, as there had been talk about such a role for insurers for decades, among others by Borst-Eilers. Yet little came of this in the 1990s and early 2000s for all sorts of reasons.¹⁸¹ However, the introduction of the new healthcare system in 2006 appeared to be capable of bringing about a change here. While it is nowhere near clear yet if and in what manner insurers are 'directing' healthcare to a greater extent, it is indeed a fact that their dominant position has been considerably strengthened.¹⁸²

Besides about the increased power of insurers, physicians are apprehensive about a more directive government. At first sight, this seems to be in contradiction with the introduction of increased market organisation in healthcare. In an advice from 2004, however, the Council of State (Dutch: 'Raad van State') already expressed great doubts whether the intended market organisation was feasible at all and whether there would not just be a situation of 'bureaucratically *simulated* marketisation'.¹⁸³ In any case, everyone in the Netherlands, including the greatest advocates of marketisation, realised that healthcare is not an 'ordinary' market and therefore has to be *regulated*. As a result, the introduction of market mechanisms by no means led to less bureaucracy. Bureaucracy did change in character though. In the words of Dols and Kerkhoff, the *consultation bureaucracy*, which had typified the 1970s and 1980s, made way for 'a new bureaucracy of supervisory and monitoring bodies'.¹⁸⁴ The political scientist Trappenburg characterised this new bureaucracy of control and supervision as an expression of 'societal neurosis in health care'. According to her, the new healthcare system was accompanied by 'hyper-control', which had

181. Berg, Bezemer & Van den Burg, 'Normatieve Aspecten', pp. 18-21; Van den Burg & Ter Meulen, 'Prioriteiten', pp. 47-8; Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 822, 850-857; B. V. M. Crul, 'Meer Verstand van Verzekeren', *Medisch Contact* 53: 5 (1998), p. 147; H. M. Dupuis, 'Achter de Ideologie van de Gezondheidszorg', in J. C. Gerritsen & C. P. van Linschoten (eds.), *Gezondheidszorgbeleid: Evaluatie en Toekomstperspectief* (Assen: Van Gorcum, 1997), pp. 105-12, on p. 111; Van Herk, *Artsen onder Druk*, pp. 44-5, 166; Hulst & Tiems, 'Geïntegreerde Zorg'; P. Visch, 'Prof. Dr. W. P. M. M. van de Ven: "Artsen en Verzekeraars Samen Verantwoordelijk voor Doelmatigheid"', *Medisch Contact* 49: 41 (1994), pp. 1275-7; J. Visser, 'Het Vertrouwen van de Verzekeraar', *Medisch Contact* 55: 38 (2000), p. 1318-20; Werner, 'Voor-treffelijke Gezondheidszorg', p. 68.

182. See a.o. Companje, *Tussen Volksverzekering en Vrije Markt*, pp. 869-70; Vos & Kasdorp, 'Advies en Beleid', p. 100

183. Regeling van een Sociale Verzekering voor Geneeskundige Zorg ten behoeve van de Gehele Bevolking (Zorgverzekeringwet): Advies Raad van State en Nader Rapport, *Kamerstukken II 2003/ 4*, 29763-4. Available from: <https://zoek.officielebekendmakingen.nl/kst-29763-4.html>. TB's italics.

184. See for this: Companje, *Tussen Volksverzekering en Vrije Markt*, p. 898, see also pp. 595-6, 870. See also: Vos & Kasdorp, 'Advies en Beleid', pp. 104-6.

become typical of the entire public sector in the Netherlands ever since the government started to pursue a neo-liberal course.¹⁸⁵

This is in line with the international literature in the field of political and social science, in which it is argued that the reign of neoliberalism (which pleads for ‘deregulation’) has paradoxically led to ‘the making of a new regulatory order’ and that ‘the era of neoliberalism is *also* the golden era of regulation.’¹⁸⁶ From this perspective, Helderma, Bevan and France characterise the recent developments in Dutch healthcare (policy) as ‘the rise of the regulatory state in health care’, a move ‘towards a model of “regulated” competition’, and a ‘gradual transformation from a predominantly corporatist governed system towards a regulatory health-care system’. They explicitly relate these shifts to ‘the creation and introduction of quasi-market arrangements.’¹⁸⁷

In the eyes of medical association and many physicians, this ‘new regulatory order’ in Dutch healthcare, consisting of both the directive role of insurers and the new bureaucracy of control and supervision, brought closer the danger of improper ‘external’ interference with the implementation of (evidence-based) guidelines. The medical professional literature explicitly placed a number of recent attempts at such external control in the context of the ‘new era’ of after 2006.¹⁸⁸ This applied, for example, to the establishment of the Dutch Regulatory Council for Care Quality (Dutch: ‘Regieraad Kwaliteit van Zorg’) by the Ministry of Health, Welfare and Sport in 2009. The main task of the Council, which consisted of independent experts who were appointed in a personal capacity, was ‘to ensure more structure and control in the development and implementation of guidelines.’¹⁸⁹ In 2014, the Council made way for the Institute for Health Care Quality (in Dutch: ‘Het Kwaliteitsinstituut’), which was integrated in the Health Care Insurance Board (Dutch Abbreviation: CVZ). It appears to have been the ambition of CVZ to develop into a Dutch version of NICE – the National Institute for Health and Care Excellence, which plays a pivotal role in British healthcare – or (to a lesser extent) the German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen IQWiG). This ambition was supported by the Ministry of Health, which, in 2011, appointed the chair

185. M. Trappenburg, ‘Societal Neurosis in Health Care’, in: J.W. Duyvendak, T. Knijn, & M. Kremer (eds.), *Policy, People, and the New Professional: De-professionalisation and Re-professionalisation in Care and Welfare* (Amsterdam: Amsterdam University Press, 2006), pp. 48-63. The quotes are from pp. 56 and 61.

186. These quotes are from the introductory article of a theme issue on all this of the journal of the American Association of Political and Social Science. See: D. Levi-Faur & J. Jordana, ‘The Making of a New Regulatory Order’, *Annals of the American Academy of Political and Social Science* 598 (2005), pp. 6-9.

187. Helderma, Bevan & France, ‘Rise of the Regulatory State’, pp. 114-16, 118-20.

188. See n. 180 above and notes 189, 193 and 198 below.

189. See on this the websites of the Dutch government (Rijksoverheid) and of Zorginstituut Nederland, respectively <http://www.rijksoverheid.nl/nieuws/2009/05/19/regieraad-kwaliteit-van-zorg-geinstalleerd.html>; <http://www.zorginstituutnederland.nl/kwaliteit/kwaliteitsinstituut/kwaliteit+van+zorg>. This was critically commented on in: Goudswaard, In ‘t Veld & Dijkstra, ‘Van Richtlijnen’, p. 52. See also: Maassen, ‘Richtlijnen Zijn Niet Altijd Even Logisch’.

of the CVZ, Bert Boer, 'quartermaster' of the new Institute for Health Care Quality. When the Institute was officially launched, on 1 April 2014, its 'host organisation' CVZ was renamed 'National Health Care Institute' (Zorginstituut Nederland).¹⁹⁰

Although some proponents of the Dutch EBM movement supported this development, there was also a degree of distrust towards the CVZ (now: Zorginstituut Nederland) and the Institute for Health Care Quality. Both institutes are considered instruments of the Ministry of Health to cut health care expenditures. What role the 'Dutch version of NICE' will fulfil is – partly in view of the limited budget the ministry set aside for this – still unclear. In a general sense, commentators point out that such an attempt at a more centralised control of the development and implementation of clinical guidelines could produce the side effect that physicians will be less inclined to adhere to the guidelines.¹⁹¹

The new 'Dutch NICE' is not the only actor that 'interfered' with the implementation of guidelines. In 2011, the Dutch Health Care Inspectorate (Dutch: 'Inspectie voor de Gezondheidszorg') emphasised in its multi-year policy plan for 2012-2015 that the promotion and monitoring of the compliance of standards and guidelines would become a major priority.¹⁹² With concern, it was concluded in *Medisch Contact* that the Inspectorate considered guidelines and standards to be 'mandatory requirements', mentioning them 'in one breath' with laws and regulations.¹⁹³

The greatest threat that many physicians perceive, however, does not come from this type of government agencies. They fear, most of all, that the *healthcare insurers* increasingly want to enforce compliance with guidelines (following the (dreaded) example of 'managed care' in the United States).¹⁹⁴ This fear is not only prompted by the 'directive role' that was allocated to the healthcare insurers in the new system, but also by the fact that they seem to enjoy the support of politicians for this attitude. In 2008, the then Minister of Health, Welfare and Sport, Ab Klink, wrote to the Dutch House of Representatives that, as far as he was concerned, 'evidence-based standards' should form the basis

190. See the link of Zorginstituut Nederland in n. 189 above. See also, a.o.: Helderman et al., *Dike-Reeve*, pp. 55-71.

191. See n. 71 above and see, in addition: Schrijvers, 'NICE is Niet zo Nice'.

192. Inspectie voor Gezondheidszorg, 'Meerjarenbeleidsplan 2012-2015: voor Gerechtaardigd Vertrouwen in Verantwoorde Zorg II (Utrecht: Ministerie voor Volksgezondheid, Welzijn en Sport, 2011). <http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2011/12/14/meerjarenbeleidsplan-igz-2012-2015.html>

193. Blume, Van Weert & Kerkkamp, 'Ruim Twaalfhonderd Richtlijnen', p. 546. See also, for similar comments: Goudswaard, In 't Veld & Dijkstra, 'Van Richtlijnen', p. 51-2; W. H. van Harten, 'Off-Labelgebruik van Richtlijnen', *Medisch Contact* 64: 12 (2009), pp. 514-16.

194. See for example: B. V. M. Crul, 'Niet op Mijn Stoel', *Medisch Contact* 60: 42 (2005), p. 1659; 'Hoogervorst: Autonomie Arts Niet van deze Tijd', *Medisch Contact* 60: 49 (2005), p. 1961; Smeets, 'Marktwerking in Zorgvershraling'; Spreuwenberg, 'Kloof tussen Theorie en Praktijk'. See also note 198 below.

for the contracts between healthcare providers and healthcare insurers.¹⁹⁵ In a certain sense, this policy line was followed by the CVZ, which advised the ministry on the composition of the statutorily insured package for insured healthcare. In a report from 2008, for example, the CVZ made the recommendation to impose ‘further conditions’ on the reimbursement of cholesterol-lowering medication. Here, the CVZ translated the clinical guideline Cardiovascular Risk management in reimbursement criteria for cholesterol-lowering therapy.¹⁹⁶

With this linking of clinical guidelines to conditions for reimbursement of care, as threatened to be imposed by healthcare insurers, the ministry or the CVZ, the mark is entirely missed according to critics. In their view a guideline is about the average patient, while reimbursement criteria are about the rights of *every individual* patient. The consequence of the latter is, according to Yvo Smulders, a Dutch professor of internal medicine, that ‘reimbursement criteria thus relate to what results from the *interaction of epidemiological evidence, clinical expertise and patient preference, every single time*.’¹⁹⁷ Thus, the message of Smulders and many others is clear: external interference with the implementation of clinical guidelines is at odds with the necessity of making ‘translations’ to specific situations and individual cases by ‘competent’, ‘learning professionals’. They therefore maintain that, while evidence-based medical practice is about the integration of various types of knowledge, it threatens to be *misinterpreted* or even *misused* by external parties that interpret clinical guidelines as bureaucratic rules that have to be consistently and mechanistically applied in practice.¹⁹⁸

Conclusion

With the above-mentioned fear among physicians of external monitoring of compliance with guidelines, this chapter seems to have come full circle, as it started with the question of to what extent the rise of evidence-based guidelines impacted the clinical autonomy of physicians, both at the individual and at the collective level. In the first instance, it does

195. A. Klink, *Een Dynamische Eerstelijnszorg*. Kamerbrief (Den Haag, 25 januari 2008), p. 20. This example is also given in: Smulders, *Hoezo Bewijs?*, p. 20. See also on the policy of Klink: H. Croonen & B. Crul, ‘Demissionair Minister Klink Evalueert Zijn Beleid: “Marktwerking is Geen Zaak van Alles of Niets”’, *Medisch Contact* 65: 10 (2010), pp. 428-31; W. J. Jongejan, ‘Marktdenken Bedreigt het Artsenvak’ *Medisch Contact* 65: 5 (2010), p. 212-14.

196. P. I. Polman & M. A. den Haan, *Pakketadvies 2008*. Publicatienummer 256 (Diemen: College voor Zorgverzekeringen, 2008), pp. 12, 17, 31-2. This example is also given in: Smulders, *Hoezo Bewijs?*, p. 20.

197. Smulders, *Hoezo Bewijs?*, p. 21. TB’s italics.

198. Smulders, *Hoezo Bewijs?*, pp. 18, 20-1; Smulders et al., ‘Rol van Epidemiologisch Bewijs’. See also: Grol & Wensing, *Implementatie*, p. 160; Van Harten, ‘Off-Labelgebruik’; Jongejan, ‘Marktdenken Bedreigt’; Offringa-Hup, ‘Ruimte rond de Richtlijn’; Rasmussen, ‘Evidence-Based Medicine’, p. 158; Van der Weijden, *Richtlijnen in de Spreekkamer*, p. 1; Willems et al., *Passend Bewijs*, pp. 32-7, 40-1, 47-8.

not seem as if the clinical autonomy was seriously threatened (at both levels). In 2004, the sociologists Timmermans and Kolker therefore argued that the issue of the impact of guidelines on the autonomy of medical professionals was actually not that interesting. The literature did, for example, extensively dwell upon the question of *by whom* the guidelines were developed, but this appeared to be a 'non-issue'. Most guidelines were developed by health professional organisations, and in cases where other agencies took the lead, they still left the actual drawing up of guidelines to members of the medical profession. According to Timmermans and Kolker, the relevance of clinical guidelines to the daily practice of clinicians was furthermore overestimated. They typify the 'optimism' about the impact of guidelines as 'a form of technological determinism' which is far removed from reality: 'Clinical practice is often much messier and complex than suggested by this form of theoretical reductionism'.¹⁹⁹

The reservations of Timmermans en Kolker are justified in themselves, but do not take away the fact that there are certainly good reasons to reflect on the relationship between guidelines and professional autonomy. Justified or not, physicians were rather worried about the possible erosion of self-regulation and the freedom of clinical practice. Fear of this seems to have been one of the reasons why physicians and medical associations started making serious efforts towards the development and implementation of guidelines. This allowed them to show that they took responsibility themselves for the quality of medical practice, so that non-medical parties would see less cause for interference in this respect. Important here was that EBM and evidence-based guidelines were experienced as something of, for and by physicians themselves – while, for example, MTA was rather considered to be something external.

The theme of self-regulation and professional autonomy is also relevant with regard to the implementation of guidelines. For example, the relatively great willingness of GPs to work with the NHG standards was partly due to the space they felt there was and which they were given to deviate from them. In the words of Van Herk, 'respecting the clinical autonomy of every GP' was a prerequisite for the acceptance of the NHG standards. In all this, recent developments show that the preservation of autonomy is not self-evident. While initially the self-regulation of the medical profession seemed to have been safeguarded, it came under renewed pressure with the introduction of the new healthcare system in 2006, because insurers were given more power and a new bureaucracy of control and supervision was set up.

From the perspective of the implementation problem, it is possible to view this current situation in several ways. On the one hand, it could be argued that the prediction made by the Health Council in 1991 in 'Medical Practice at a Crossroads' has come true: if the medical profession would not put its affairs in order, others would take over the

199. Timmermans & Kolker, 'Evidence-Based Medicine', the quotes are from p. 186 and 187.

initiative. Medical associations did try to put their 'affairs in order', among others through the development of guidelines, but due to the implementation problem, the impact of this on the behaviour of individual physicians was limited. Perhaps this lack of 'internal control' contributed to the increased threat of 'external control' of the implementation of guidelines by insurers, the Inspectorate and the 'Dutch NICE'. In view of the persistence of the implementation problem on the other hand, it is highly questionable if effective external control is actually possible. If medical associations were not even capable of keeping their followers 'in line', why would government agencies and insurers be able to do so? From analyses of the impeding factors of implementation, it emerges that physicians are less willing to work with guidelines if they do not perceive them as being 'theirs'. They moreover generally strongly oppose the use of clinical guidelines as instruments of cost control. In short, the government and insurers may well encounter the 'obstructive power' of the medical profession in this respect.

The *reorientation* on the implementation issue, which occurred in the field around 2000, sheds another light on the issue. This reorientation may be interpreted as a strategy prompted by professional interests, as the 'broad approach' advocated, among others, by the Health Council, the KNMG and the NHG ill accorded with external supervision on, or the top-down enforcement of the application of guidelines. The pleas for 'two-way traffic' between science and practice, for a heuristic bottom-up approach, and for a reflective, flexible, and educational handling of guidelines implied that evidence-based guidelines should rather be used as educational than as normative quality instruments.

However, it would demonstrate too limited a vision of professionalisation processes if the reorientation on the implementation issue were only explained in terms of the defence of professional interests and professional autonomy.²⁰⁰ The pleas for a 'broader approach' were also inspired by *substantive* motives. It was argued that the complexity of everyday practice was simply at odds with a consistent, mechanistic application of guidelines. Such an attitude may undoubtedly be partially prompted by professional interests. In this context, Van Herk speaks of the opportunity for 'professional representatives' to convince 'non-medical parties that the greater part of medical practice is of an undetermined character and that [therefore] the self-regulation of the medical profession offers the most advantages to all parties'.²⁰¹

On the other hand, he argues that *factors other* than such a promotion of interests were probably more decisive for the preservation of self-regulation. He first of all mentions *the nature of the activity to be regulated*. Medical practice *is* indeed very complex and, as a result, in the terminology of Van Herk, 'undetermined' to a large extent. This

200. See, for example: Timmermans & Kolker, 'Evidence-Based Medicine', pp. 188-90; Weisz et al., 'Emergence of Clinical Practice Guidelines', p. 692.

201. Van Herk, *Artsen onder Druk*, p. 41.

forms a major limitation for the possibilities of capturing medical practice in rules. In addition, he points to the great value citizens attach to health and healthcare, which is also why they, as 'care consumers' impose high demands or have high expectations. In the light of these factors, Van Herk argues that 'the weight of the promotion of interests as explanation for the self-regulation of the medical profession decreases'.²⁰²

Without entirely dismissing the role of the promotion of interests and the concern for the preservation of professional autonomy, the conclusion seems to be justified that the 'reorientation on the implementation issue' was first and foremost inspired by a recognition of the complexity of medical practice. Partly for this reason, the shift 'from implementing to learning' offers a new perspective of the possible role and impact of EBM in the twenty-first century. The rather dismal image of the 'leaking pipeline', which is associated with a focus on implementation and 'one-way traffic' between science and practice, makes room here for (opportunities for) a more positive interpretation.

In this respect, a certain comment by Timmermans and Kolker is appropriate. They wrote that the 'American medical professionalization literature', through its preoccupation with the theme of professional power and autonomy, '*missed what is truly peculiar about the turn to evidence-based medicine*'.²⁰³ This, according to Timmermans and Kolker, was '*the move from pathophysiology to epidemiology*'.²⁰⁴ It is beyond dispute that, under the influence of EBM and evidence-based guidelines, physicians involve systematically collected clinical-epidemiological data in the decisions they take in everyday medical practice to a greater extent and in a more structural manner than in the past. As the Health Council formulated it, clinical-epidemiological knowledge mainly imposed *preconditions* on medical practice here. The significance of the rise of EBM therefore mainly seems to lie in the contribution made to 'abolition medicine', or the countering of 'bad medicine'.

A second important role that may be ascribed to EBM is that of the adaptation to changed circumstances. This may be illustrated with the report 'From Implementing to Learning', in which the Health Council pointed to the 'scientific and social dynamics' in which medical practice occurred. The Council observed here that EBM and in particular evidence-based guidelines, formed a useful and necessary adaptation to the 'information explosion' in medicine, to the ICT age and to the social call for more transparency. Partly for this reason, the use of clinical guidelines was not or barely a subject of debate.

202. Ibid., p. 47. This conclusion fits in well with the sociological literature of the last decades, in which there appears to have been a gradual trend away from the 'power and control approach' that originally formed the main framework for analysing professions and professionalisation processes. Illustrative is the remark of Timmermans and Kolker that the American sociological literature has far too long been 'preoccupied with the question of whether the medical profession is overall gaining or losing power'. See: Timmermans & Kolker, 'Evidence-Based Medicine', p. 188.

203. Timmermans & Kolker, 'Evidence-Based Medicine', p. 188. TB's italics.

204. Ibid. TB's italics.

The 'reorientation on the implementation issue' moreover added another adaptive element to this. Part of the social dynamics was the increasing importance of the 'patient perspective', which was focused on more within the 'broad vision' of implementation, than within the 'narrow vision'. In a certain sense, this was expressed in the efforts to combine evidence-based medicine – originally highly 'doctor-centred' – more effectively with 'patient-centred medicine'.

In addition to 'abolition medicine' and 'adaptation to changing circumstances', a third possible effect of EBM may be identified, as it seems plausible that the rise of evidence-based medicine (to a greater or lesser extent) contributed to a mentality and behavioural change among physicians. Part of the 'reorientation on the implementation issue' is the strong emphasis placed on the *learning process* and the 'learning attitude' of both professionals and organisations. An important part of this process was learning to *explicate* choices, value judgements, presuppositions and trade-offs. At this point, the 'reorientation on the implementation issue' fits in well with the importance that the pioneers of evidence-based medicine have always attached to a (self-)critical attitude and the origin of EBM as *educational* approach. It does not seem implausible that this aspect impacted the way in which (new generations of) physicians were trained in the Netherlands, for EBM gradually managed to acquire a permanent place in the medical curricula, training courses and programmes for further training.

Yet the debates of the past years on the threats to EBM demonstrate that it is not self-evident that EBM may (continue to) fulfil the roles described above. Paradoxically enough, in countering these threats, the EBM movement mainly seems to benefit from putting its own 'importance' into perspective. The most conspicuous innovative aspect of EBM – the systematic involvement of clinical-epidemiological evidence in the medical decision-making process – especially made a contribution to 'abolition medicine', but is far less decisive for 'good medicine'. With a view to this 'good medicine', EBM proponents have regularly pleaded for a broader research agenda over the past years, effectively acknowledging the limitations of the RCT. This also raises questions on the (mal)functioning of the system of scientific research and the possible role the EBM movement has played in it. Furthermore, while systematic reviews and evidence-based guidelines are admittedly presented as useful tools for medical practice, at the same time it is argued that physicians should not allow themselves to be guided by them too much, too uncritically, or 'dogmatically'. This is because the translation that needs to be made from guidelines to practical situations is believed to require a heuristic, flexible and reflective use of guidelines. Needless to say, this viewpoint is incompatible with any attempt by insurers or government agencies to impose or enforce compliance with guidelines.

This 'putting into perspective' of EBM may largely be traced back to one issue. This issue pertains to what the Health Council identified in 2000 as: the tension between statistics and casuistry, between the generic and the specific, or between epidemiological data

and medical decisions on the care for an individual patient.²⁰⁵ The EBM movement has never really been able to dissolve this tension, as argued by the historian George Weisz:

'Among EBM's greatest failings is its inability to distinguish between doing the greatest good for the individual patient and doing the greatest good for all patients, collectively.'²⁰⁶

Weisz concludes that, partly due to this limitation, the EBM movement has nuanced and moderated its philosophy over the course of time. There has been an increasing emphasis on the integration of clinical-epidemiological evidence with pathophysiological reasoning, professional expertise and the patient perspective. The reorientation on the implementation issue discussed in this chapter dovetailed well with this. There are threats, however, partly because this reorientation seems to have disregarded the government and the insurers. Perhaps it will be possible to convince these non-medical parties – and, for example, research subsidisers as well – of the *limitations* of EBM and clinical research, so that they, too, let go of the 'radical programme' and switch to a 'realistic programme' and a 'broad', 'heuristic approach'. In this case, there would be a useful, positive role for EBM in the twenty-first century. Admittedly, the paradigm shift and revolution as announced in the early 1990s would not materialise then, but Weisz's prediction below may come true:

'It is possible that EBM will lose its ideological and programmatic edge and become just one routine part of practice, among many others.'²⁰⁷

205. This point is made by many authors, see a.o.: Djulbegovic & Paul, 'From Efficacy to Effectiveness'; Hijdra et al., *Vernieuwingen in de Neurologie*, pp. 16-18; R. S. G. Holdrinet, 'Alleen Meer Dokters Opleiden Helpt Niet', *Medisch Contact* 56: 45 (2001), pp. 1653-6; Levi, *Kansen voor de Inwendige Geneeskunde*, pp. 13-14; Maassen, 'Kansen voor de Patiënt'; Smulders, *Hoeho Bewijs?*, p. 12-13; Smulders et al., 'Rol van Epidemiologisch Bewijs'; Tonelli, 'Limits of Evidence-Based Medicine'; J. P. Vandenbrouce, 'De Cochrane Collaboration en "Evidence- Based Medicine"', *Nederlands Tijdschrift voor Geneeskunde* 139 (1995), pp. 1476-7; Wiersma, *Twee Eeuwen*, pp. 262-297.

206. Weisz, 'From Clinical Counting', p. 387. See also p. 389.

207. *Ibid.*, p. 389.



Overall Conclusions

A Doctor's Order: Two Aspects of EBM

What actually *is* evidence-based medicine? It was one of the main objectives of this study to arrive at an answer to this question from a historical perspective. Or, put differently: to interpret or typify the phenomenon of EBM focusing on its history. This objective was based on the fact that EBM has many facets, various stakeholders sometimes give widely differing meanings to it, and EBM itself has undergone a number of substantial changes over the course of time. For the same reason, it is almost impossible to capture the phenomenon of EBM in a (concise) characterisation. Nevertheless, an attempt to this end is made here, on the basis of the title of this dissertation: *A Doctor's Order*. This literally means 'a doctor's prescription or advice', but here, this title refers to two essential aspects of evidence-based medicine, which from the central threads of this dissertation.

The first aspect is contained in the title word 'order', which, among others, has the connotation of 'arrangement', 'structure' or 'regulation'. In this sense, the word 'order' refers to EBM as a mechanism of control, or as an instrument for 'ordering' (regulating, formalising, rationalising, standardising) medical practice. This aspect of the phenomenon of EBM ties in with the theoretical 'coat rack', as it was discussed in the introduction. Guiding principles here were Theodore Porter's theoretical ideas on a shift from disciplinary to mechanical objectivity, which has occurred in numerous domains, professions and disciplines over the past two centuries.¹ According to Porter, this shift, which was generally accompanied by quantification, was the result of a professional response to external pressures in many cases. He maintains that these 'external pressures' were related to the rise of democratic mass societies in the West, which was accompanied by an increasingly strong call for transparency and accountability, as well as to the increasing necessity for regulation and cost control of the welfare state, which had developed in many Western countries. Along with the social-scientific literature on professions and (de- or re-)professionalisation² and the work of the sociologist Gieryn on cultural maps of science and boundary work,³ these insights from Porter offer a useful handle for the interpretation of

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1. See on this: Porter, *Trust in Numbers*.
 2. See a.o.: Freidson, *Professionalism: the Third Logic*; Timmermans & Kolker, 'Evidence-Based Medicine'.
 3. See: Gieryn, *Cultural Boundaries of Science*.

the phenomenon of evidence-based medicine. From this 'theoretical coat rack', notions are derived of EBM as a mechanism of control, as a shift from disciplinary to mechanical objectivity, and as a professional response to external pressure.

On the basis of these notions, it is possible to place EBM in the context of the late twentieth century, the era in which, according to a broad consensus in the literature, the 'paradox of modern medicine' became visible. After the golden era experienced by medicine in the 1940s, 1950s and 1960s, a turnaround became noticeable around 1970. Besides the 'law of diminishing returns', several developments were responsible for this, including the burgeoning costs of the welfare state necessitating cutbacks, the negative sides of what is often referred to as 'medicalisation', and the increasing uncertainty of physicians who were confronted with an ever more complex practice and with an unmanageable or barely manageable explosion of medical knowledge. This 'paradox of modern medicine' and in particular the way in which both the medical profession and various non-medical parties attempted to get a grip on this, form the main themes of the Utrecht/Maastricht research programme 'Medicine in Transition', of which this dissertation forms a part. The subject of evidence-based medicine serves as a 'window' here, which offers a specific 'view' into this theme.

Yet these reflections derived from the title word 'order' are nowhere near sufficient to characterise the phenomenon of EBM. In the description and analysis of the Dutch case of EBM – or in the empirical 'floor' of this study – it emerged clearly how great and sometimes even decisive the role of local and especially personal factors was in the rise of clinical epidemiology and evidence-based medicine in the Netherlands. In order to do justice to this, the designation 'A Doctor's' in the title refers to a second aspect of EBM: the major input of individuals or small groups of medical professionals, who the historian Marks would refer to as 'therapeutic reformers'.⁴ With some goodwill, it could be argued that 'Marks' especially does justice to the second aspect of EBM, while Porter's work focuses on the first aspect. The perspectives offered by both historians seem to complement one another perfectly. Each one on its own probably provides too one-sided a picture, while an adequate interpretation of the phenomenon of EBM seems to result from the combination of the work of both.

The characterisation of EBM as 'A Doctor's Order' and the argument that 'Porter' and 'Marks' jointly shed an illuminating light on the phenomenon of evidence-based medicine are supported by the findings in this dissertation. The main outlines in respect of this will be summarised below, where the three parts of this dissertation will be discussed separately. Subsequently, a more detailed discussion will follow of why Marks's concept of 'therapeutic reformers' provides a useful *amendment* to the notion derived from Porter of

4. See: Marks, *Progress of Experiment*.

EBM as a shift from disciplinary to mechanical objectivity, as a professional response to external pressure and as a mechanism of control.

Part I: Evidence-Based Medicine in International and Historical Perspective

In part I, the applicability of the 'Porter scheme' for the history of EBM clearly came to the fore. The foundation for this was laid in chapter 1, in which evidence-based medicine was placed within the long-term perspective of the process of objectification and quantification in modern Western medicine, which can be traced back to the nineteenth century. Medicine was far from alone in this respect for that matter. Starting in approximately 1850, numbers, statistics and (mechanical) objectivity rapidly developed in numerous areas – and not least in government bureaucracies. The use of measuring instruments, figures and statistics here had consequences that reached much further than just the collection and processing of numerical data. A numerical approach required that phenomena be classified, that matters be measured in a specific way, and that procedures be standardised. As quantitative methods became ever more commonplace, they also increasingly influenced the way in which questions, problems or objectives were formulated. In short, the process of objectification and quantification greatly influenced the way in which 'modern' people began to look at the world.

With regard to medicine and healthcare, this was further explained using the work of Rosenberg on the 'specificity revolution'.⁵ In several publications, Rosenberg shows how, in connection with the process of objectification and quantification described above, the 'ontological' view of diseases as specific entities became dominant and subsequently became one of the most important ordering principles for medicine and healthcare in the twentieth and early twenty-first century. In this regard, he points to the 'bureaucratic imperative' of thinking in terms of specificity, which he supports with countless examples, referring, amongst others, to EBM.

In the words of the French historian La Berge, Rosenberg's work illustrates that 'numbers' embody the values of order, precision, rationalisation, standardisation and control.⁶ With this comment, the connection is established between the process of objectification and quantification on the one hand and, on the other hand, the work of Porter in which this process is linked to a shift from disciplinary to mechanical objectivity which, among others, facilitates regulation and control. In line with this, the placing of EBM against the

5. Rosenberg, 'Tyranny of Diagnosis'.

6. La Berge, 'Medical Statistics'.

historical background of the process of objectification and quantification in medicine corresponds well with the view of EBM as a mechanism of control.

Thus, chapter 1 outlined a framework for a historical interpretation of the phenomenon of evidence-based medicine. In chapter 2, this was further specified with a description of how, in the period following the Second World War, statistics, which had long enjoyed a low epistemological status within medicine, also gained considerably in importance and influence in this respect – where moreover inferential or mathematical statistics became properly accepted in medicine for the first time. The ‘statistical era’ that was thus heralded in medicine had two important ‘engines’.

The first ‘engine’ was the epidemiology of chronic diseases. Research into the relationship between smoking and lung cancer and into the risk factors for cardiovascular diseases, in particular, contributed to an entirely new health structure. The notion of risk factors that could be traced and calculated, almost naturally coincided with the conviction that they were controllable as well. In the second half of the twentieth century, all manner of new forms of preventative care were set up to reduce cardiovascular diseases and cancer. In addition to this, the acceptance of the ‘paradigm of risk factors’ was accompanied by the categorisation of people into subpopulations. The ‘risk’ that an individual ran was assessed on the basis of the available statistical-epidemiological data on the subpopulation to which this individual ‘belonged’. Following on from this, ever more refined statistical methods and techniques were developed in epidemiological research.

The second ‘engine’ of the statistical era in medicine was the Randomised Controlled Trial (RCT) which, over the course of the latter half of the twentieth century, developed into the gold standard for demonstrating the effectiveness of medical procedures. In chapter 2 it was argued, however, that the RCT is not the only self-evidently right method for the evaluation of the efficacy of medical interventions. Administrative and organisational factors, such as the efforts by the British Medical Research Council (MRC) to get a better handle on both the introduction and on the clinical testing of new medications, as well as on the behaviour of individual researchers, were of crucial importance to the coming about of the ‘very first’ RCT – the MRC-streptomycin trial of 1948.

The link between the ‘administrative and organisational factors’ and the statistical-epidemiological research design of the RCT is in line with Porter’s notions of ‘trust in numbers’, mechanical objectivity and a professional response to external pressure or even mistrust. This is further confirmed in that similar factors were relevant in the further development of the RCT into the ‘gold standard’. Porter himself argues in this context that the RCT became the ‘standard’ when, in many western countries, both public opinion and public officials lost trust in the claims of the pharmaceutical industry, the prescription practices of physicians and in the customary methods of evaluation of medicines based on ‘expert judgement’. He points to various factors underlying this loss of trust, such as the changes in the pharmaceutical industry from the early twentieth century, the

infrastructure of standardisation and regulation that developed as a result, and he singles out the Thalidomide affair of 1962.⁷

The epidemiology for chronic diseases and the RCT did not bring about a full-fledged 'statistical revolution' in medicine. The impact of epidemiology remained limited (for a long time) to the domain of public health, and the RCT mainly played an important role in the regulation of the market for medicinal products, while (initially) the methods of practising physicians were barely influenced by trial results. It was not until the 1980s – when clinical epidemiology experienced a breakthrough and the 1990s – when EBM was introduced – that 'statistical-epidemiological reasoning' advanced from the periphery to the centre of clinical medicine. This is probably also the most important innovation that the EBM movement has brought – together with the adaptation to and the use of the technological possibilities of the current *information era*.

The origin and development initially of clinical epidemiology and subsequently of evidence-based medicine were described in chapter 3, which addressed various elements that tie in with the word 'order' from the title of this dissertation and with the theoretical 'coat rack', which is mainly derived from the work of Porter. One of these elements is that of a professional response to external pressure. The pioneers of clinical epidemiology, including Feinstein and Sackett, were generally clinicians and/or clinical researchers, who were concerned about the extent to which medicine and medical science were dominated by basic biomedical laboratory research (and to a lesser extent epidemiological research in the 'population'), in which, moreover, *non*-medical specialists were calling the shots to an increasing extent. In the words of the sociologist Daly, in addition, clinical epidemiology originated 'during a time of ferment in healthcare and amid uncertainty about the processes of clinical decision-making'.⁸ The 'ferment' and 'uncertainty' from this quotation were also caused by the external pressure from the mounting criticism of medicalisation and iatrogenesis, an increasing call for transparency and accountability and the necessity for cost control. In addition to a micro dimension, evidence-based medicine has always had a macro dimension from the outset as well, which was focused on distributive justice in healthcare. This was mainly visible in the British 'root' of the EBM movement, which started with Archie Cochrane who, in the 1970s, was committed to creating a more effective and efficient *National Health Service* and was a source of inspiration to the systematic review movement, which led to the creation of the Cochrane Collaboration. It was also in Great Britain that, over the course of the 1990s, the concept of Evidence-Based *Healthcare* became a force to be reckoned with.

A second 'Porterian' element is that of the shift from disciplinary to mechanical objectivity and the associated notion of EBM as a mechanism of control. This aspect mainly

7. Porter, *Trust in Numbers*, pp. 199-209.

8. Daly, *Evidence-Based Medicine*, p. 25.

came to the fore in the shift that occurred within EBM from individual empowerment via critical appraisal to more collective products such as systematic reviews and (especially) clinical guidelines. In this context, chapter 3 pointed to an extensive article by Weisz et al. on the emergence of clinical guidelines, a development that the authors characterised as ‘a change in the method of *regulating* the quality of medical practice’ and as ‘a growing effort to bring *order* and coherence to a rapidly expanding and heterogeneous medical domain’.⁹

All in all, part I painted a picture with bold strokes, which largely confirms the relevance of Porter’s scheme and the ‘coat rack’ from the introduction. Yet at the same time, a few reservations were implicitly expressed here. To name one example: in chapter 2, it was argued that the origin and development of RCT into the ‘gold standard’ should not only be attributed to external pressure or mistrust, which originated, for example, as the result of the Thalidomide affair of 1962. In addition, the increasing heterogeneity of the medical profession was pointed out, which was accompanied, among others, by great mistrust on the part of ‘therapeutic reformers’ – usually academic medical professionals or officials at agencies such as the MRC – towards the, in their view, injudicious prescription behaviour of ‘average’ physicians.¹⁰

Both the relevance of ‘Porter’ and the necessity of expressing doubts here were more explicitly discussed in part II and part III.

Part II: The ‘Evidence Base’ of EBM: a History of Clinical Epidemiology in the Netherlands

Part II is entirely devoted to the history of clinical epidemiology in the Netherlands. The reason for this is that this discipline seems to have acquired a position in this country that is stronger than anywhere in the world. The foundation for this relative success of clinical epidemiology in the Netherlands was laid in the 1980s. During this decade, the academic research climate in the Netherlands underwent a radical transformation. This transformation was associated with international developments in research and, above all, with the research policy of the Dutch government which, besides drastic cutbacks, was aimed at a larger social relevance, better programming and increasing quality of research in the Netherlands. These policy objectives became tangible in the form of the austerity programmes, Task Division and Concentration and Selective Shrinkage and Growth, the introduction of conditional financing and a considerable shift in research funding from the ‘first flow of funds’ to the ‘second (or third) flow of funds.’ This meant that an end had

9. Weisz et al., ‘Emergence of Clinical Practice Guidelines’, p. 692. TB’s italics.

10. See a.o.: Marks, *Progress of Experiment*, pp. 2-3, 27, 40-1, 150-2, 230-1, 236.

come to an era in which clinical professors could pursue their own 'hobbies' in freedom and solitude. Those who wished to pursue an academic career needed to deliver value for their money, publish in high-impact journals, successfully engage in competition for research funds and try to connect with 'lines of research' and research schools.

Along several routes, this metamorphosis of Dutch academic science contributed to the rise of clinical epidemiology in the Netherlands. In the first place, 'population epidemiology', as described in chapter 4, managed to establish itself as an independent discipline at several medical faculties during the 1980s, often at the expense of the position of social medicine, which proved less able to cope with the changed circumstances than epidemiology. Some epidemiologists started to focus more on *clinical* epidemiology over time, and also received formal positions as professors of the clinical variant of epidemiology.

In the second place, as became evident from chapter 5, a powerful movement for clinical or patient-related research developed in the circumstances of the 1980s, prompted by alarming reports on the weak state of this type of research in the Netherlands. Within the context of the science and austerity policy of the 1980s, this also meant that major negative financial consequences were to be feared for clinical science and for clinical research groups. Representatives of the movement for patient-related research feared that medicine would become dominated even more by fundamental laboratory research, of which the agenda and execution was in the hands of non-medical experts to a significant extent. One of the exponents of this movement, Querido, stressed that medicine was an independent discipline, with its own questions and therefore its own methods. Querido and his kindred spirits found these 'own methods' in clinical epidemiology. The promise of clinical epidemiology, in other words, was renewed empowerment for clinicians and clinical researchers as well as a new 'distinctiveness' or 'identity'. Due to clinical epidemiology, moreover, it appeared that clinicians were able to 'get on' with conducting research. As appeared from chapter 6, clinical professors and research groups soon found that, due to the methodological input of clinical epidemiologists, they were able to publish in renowned journals and were successful in attracting research funds – for example from the Investigative Medicine Fund, which provided clinical epidemiology with a significant boost. It is above all because of this 'service-oriented role' with regard to clinical research which, under the changed academic research climate, was of crucial importance for (the survival) of academic clinical departments, that clinical epidemiology was able to advance so strongly in the Netherlands.

Thus, it seems justified to argue that the academic establishment of clinical epidemiology resulted from a professional response from clinicians, clinical researchers and directors of medical faculties and academic hospitals to the great pressure that had come about to deliver scientific results and to show that they were worth the research funds they received or tried to source.

However, such a 'Porterian' interpretation of the rise of clinical epidemiology in the Netherlands is rather one-sided and schematic. In part II, it repeatedly emerged how

important personal and contingent factors were. In chapter 4, it was discussed how the Finnish methodologist Miettinen more or less by chance, and via various personal contacts, regularly came to the Netherlands and through his famous courses, exerted a considerable influence on the theoretical and methodological mindset of generations of Dutch (clinical) epidemiologists. In addition, it was described how the department of epidemiology in Rotterdam formed a 'hotbed of critical minds' and was able to flourish due to the synergy between the small group of people that worked there. In chapter 5, it was emphasised that the representatives of the movement for patient-related research were not merely driven by professional and career interests, which were under pressure due to changed circumstances. Of importance too were the more substantive convictions, which manifested themselves in a great drive. This also came to the fore in chapter 6, in which, for example the Amsterdam internist Büller expressed, with an almost religious vocabulary, how much he had become captivated by the 'apostle' Sackett during his stay at McMaster and, once back in the Netherlands, devoted a great deal of his leisure time and energy to spreading the 'gospel'. Similar is the way in which the neurologist, Van Gijn, became inspired by the work of Wulff – he can still point out the chair in which he sat when he read it for the first time.

These and other examples not only point to the importance of the 'personal' in the history of clinical epidemiology in the Netherlands. In addition, they raise the question of where the initiative lay. Where disciplines in Porter's scheme *respond* to external pressure or mistrust, the protagonists from part II rather acted '*proactively*'. The representatives of the movement for patient-related research, the (clinical) epidemiologists and the pioneers of EBM tended to operate, to use Marks's words, as substantively and ideologically driven reformers. Striking here was that in all manner of forums, constantly the same people used their influence and networks to reform clinical research. Thus, there seems to have been a sort of vanguard, a reformist movement within the medical profession, which took initiatives that contributed to the success of clinical epidemiology in the Netherlands. It is an undeniable fact, however, that these reformers benefited from, and sometimes even consciously used, the major 'external pressures' that were created by the changing academic research climate.

Some caution is moreover required in declaring Porter's ideas applicable to all kinds of divergent developments. They will lose meaningfulness when their explanatory scope is stretched too wide. In part III, notions derived from Porter of EBM as a professional response to external pressure, as an example of a shift from disciplinary to mechanical objectivity and as a mechanism of control, were therefore related to the aspect of evidence-based medicine to which they seem most relevant: the development and implementation of clinical practice guidelines. Part II partly falls outside these frameworks, for science proves to have its very own dynamics, that should not be captured in a Porterian scheme in a forced way. Under the influence of, among others, the prevailing 'publish or perish' culture, medical research – including patient-related research – seems to have

become a self-referential system. This begs the question, however, regarding the extent to which evidence-based medicine is capable of bridging the gap between medical research and practice. The threefold problem of too much evidence, unreliable evidence and no or barely any clinically-relevant evidence, which was addressed in chapter 9, speaks volumes as far as this is concerned.

All in all, with the necessary goodwill, the relevance of 'Porter' was confirmed in part II, but at the same time it has to be said that this part falls somewhat outside the frameworks of the theoretical 'coat rack' of this dissertation. In order to be able to historically interpret the introduction of EBM in the Netherlands, the description of the rise of clinical epidemiology in the Netherlands did prove essential. However, the true test for 'Porter' and the 'coat rack' followed only in part III, for here, it was not the developments in medical research that were discussed, but matters such as the societal position and autonomy of the medical profession in relation to insurers and the government as well as the rationalisation and standardisation of medical practice with the help of guidelines.

Part III: EBM in the Netherlands: the Rise (and Fall?) of a Mechanism of Control

Part III opened with an extensive description and analysis of developments in the 1970s and 1980s, which formed the historical background– and in a certain sense the 'run-up' – to the introduction of evidence-based medicine in the 1990s. Largely in line with the Porter thesis, medicine came under considerable pressure in the 1970s and 1980s. However, this pressure cannot be attributed only to processes such as democratisation and bureaucratisation, upon which Porter mainly focuses. At least as important are the more substantive developments in the fields of medicine, healthcare and public health. Partly because of the high speed at which these changes occurred, in addition to new diagnostic and therapeutic possibilities, the upscaling and technological progress in medicine brought with it all manner of new questions and problems as well. The same applied to the political and social trends with respect to the way in which healthcare and the increasingly broadly and inclusively interpreted issue of (public) health was handled. That medicine and healthcare came under pressure must, in short, not merely be attributed to the process of modernisation in general, but also, and perhaps mainly, to the specific developments within these domains themselves.

In the 1970s, pressure on medicine did not lead to a situation where the medical profession resorted to more 'mechanical objectivity'. Rather, the initiatives that materialised most explicitly – those in the fields of peer review and continued training – were indicative of an attempt to boost trust in 'disciplinary objectivity' or in the professional expertise of physicians. In a general sense, the solutions to the problems of healthcare and medicine, pleaded for in the 1970s, fitted in with the specific circumstances in this

decade and the then prevalent 'zeitgeist'. The most significant examples of this are the emphasis on planning and structuring and attention to issues such as well-being and environmental health.

This changed under the influence of a number of developments in the 1980s. Under pressure from the economic recession of that time, but also from a changing vision of the welfare state, the emphasis in government policy shifted from planning and restructuring to cutbacks, increased efficiency and (later) marketisation. Budgeting, in particular, which was introduced in 1983 in connection with this policy, forced the medical profession to make a serious effort to achieve greater efficiency in medicine. However, for medical reasons too, *efficiency* was more and more often mentioned as being an essential part of the *quality* of medical practice. Initially, both individual initiators and medical professional organisations focused on the instrument of peer review here, but, in the course of the 1980s, they turned their attention to consensus guidelines and clinical decision analysis. In Porterian terms, a shift thus occurred towards more 'mechanical objectivity'. This shift may be attributed to a growing need, both with the government and with the profession, for more grip on medical practice. The combination of an explosive development in costs and the side-effects of the rapid medical progress of the latter half of the twentieth century, resulted in a situation where various stakeholders sought effective mechanisms of control for medicine.

However, the specific efforts in the field of consensus guidelines and clinical decision analysis were not without their problems. Partly as a result of this, there was still a certain openness to a new approach to the improvement of both the efficiency and quality of medical practice. This new approach emerged, in the early 1990s, in the form of EBM. The transition from consensus guidelines to 'evidence-based' guidelines and that from decision analysis to EBM was fluent. The persons and authorities that first tried to give shape to EBM in the Netherlands were often also the persons and authorities that had pioneered earlier with the consensus approach or clinical decision analysis.

The main reasons for the relatively strong and rapid rise of EBM in the Netherlands are thus identified. In the first place, the introduction of evidence-based medicine tied in seamlessly with developments that had been going on for some time within Dutch medicine. In the second place, EBM could benefit from the academic and institutional position that clinical epidemiology had acquired – academic departments of clinical epidemiology played an important (supportive) role in education in evidence-based medicine and in the production of systematic reviews and evidence-based guidelines. In addition, the Dutch Cochrane Centre found its home in an academic department of clinical epidemiology. Due to these two factors, EBM was able to get off to a 'flying start'.

In chapter 8, an 'additional explanation' was presented for the relatively strong influence that EBM acquired in the Netherlands. Developments in the healthcare policy of the government were found to have contributed significantly to an increased, accelerated, more coordinated and better organised production and proliferation of evidence-

based clinical guidelines. In short, the emphasis in government policy shifted from (attempts to implement) measures at the macro-level to the promotion of efficiency at the micro-level.

In the course of the 1980s, the debate on the boundaries of healthcare had become increasingly focused on the question of how to reduce the statutorily insured package for insured healthcare. In 1991, two important advisory reports were published on this. In the first report, that of the so-called 'Dunning committee', the system of a 'funnel' was proposed on the basis of which the statutorily insured package could be limited to forms of healthcare that were necessary, effective and efficient, and which could not be left at the personal expense and risk of the patient. In the second report, 'Medical Practice at a Crossroads', by the Health Council, a very different approach was opted for, as it argued that the key to the cost issue in healthcare did not so much lie with the statutorily insured package as with its application by healthcare professionals and in particular physicians, which was often incorrect, inefficient and superfluous. The Health Council therefore focused attention on the need to make medical practice more rational and, as a result, more efficient. This resulted in recommendations that could jointly be considered to be a plea for evidence-based medicine.

According to friend and foe alike, the impact of the report by the Health Council was far-reaching, not least because Els Borst-Eilers – who, as vice chairwoman of the Health Council, had exerted particular influence on 'Medical Practice at a Crossroads' – was Minister of Health, Welfare and Sport between 1994 and 2002. In addition, the approach of Borst-Eilers and the report by the Health Council fit in well with the political circumstances of the 1990s. In a general sense, the political wind blew in the direction of (efforts towards) a 'withdrawing government' and 'deregulation'. With regard to healthcare policy specifically, there was a great deal of support for Borst-Eilers's view that changes ideally come from below and from the inside. After the relationship between the government and the 'field' had deteriorated due to the severe austerity policy of the 1980s, this field – including the medical profession – proved able to exert a considerable 'obstructive power'. Partly as a result of this, Borst-Eilers's predecessor at the Department of Health, state secretary Simons, did not succeed in implementing a drastic system change. In addition, the attempts to apply 'Dunning's funnel' proved to yield little, while they did cause great political and social unrest. As minister, Borst-Eilers succeeded in largely restoring the 'symbiosis' between the government and the medical profession, partly due to her policy that was geared towards stimulating the production and proliferation of evidence-based guidelines from the inside and from below. It has been said that this political course was an admission of weakness on the part of politicians, who were incapable of making decisions in healthcare themselves, and therefore put the issue of the cost of healthcare on the plate of the medical profession. At the same time, it may be established that Borst-Eilers consistently and with substantive conviction followed the line of 'Medical Practice at a Crossroads'.

With this very report by the Health Council and the impact it had, the relevance of the Porter thesis as an explanatory framework for the rise of EBM seems to be more than established at first sight. The central message from the report to the medical profession was namely that the medical profession had to put its affairs in order 'now', for otherwise the government, the insurers or the hospital directors would take over the initiative. Put differently, under the external pressure of these non-medical parties, the medical profession was encouraged to embrace EBM. In chapter 9, it appeared that there were great concerns indeed within the medical profession in the 1990s – whether or not justified – about a possible adverse effect on the clinical autonomy of physicians. In the debates held about this, evidence-based clinical guidelines played a substantial role. On the one hand, there was some fear that clinical guidelines would bring external control closer, for they basically explicate and capture medical practice in rules. On the other hand – and above all – guidelines were embraced by medical associations and many individual physicians precisely as a way of defending or reinforcing their professional position and autonomy. This was most clearly visible in the guidelines for the GPs, the famous NHG standards, which were repeatedly presented as an instrument for the emancipation of GPs and the reinforcement of their professional position in relation to the specialists. In a more general sense, guideline programmes were presented as a way of 'retaining control in its own hands to the greatest possible extent'¹¹ and convincing governments and insurers that the monitoring and promotion of the quality of medical practice could be confidently left to the profession itself. This indicates that the rise of evidence-based guidelines could be typified, entirely in line with 'Porter', as being a form of further professionalisation of the medical profession, with which the trust of non-medical parties and of patients in the self-regulation of the medical profession could be preserved, and the demands of the time with regard to transparency and accountability were met as well.

Upon reflection however, the developments of the 1990s and the early 2000s raise several questions on 'Porter'. A first question is how great or real the external pressure actually was, as Minister Borst-Eilers and politicians in general seemed to think it fine to leave the efficiency issue to the self-regulation by the medical profession as much as possible. Only after the introduction of the new healthcare system in 2006, did the insurers actually also begin to pose a threat to this self-regulation (– where the future will have to prove how great this threat really is). It is interesting in this respect, that Bal, Bijker and Hendriks argue that the Health Council practised *future rhetoric* in 'Medical Practice at a Crossroads' with the warning that others would take over the initiative if the profession did not immediately put its affairs in order.¹² Thus, they suggest that the Council *exaggerated* the external danger in order to encourage the profession to implement the desired

11. This quote is derived from: Minderhoud, 'Passende Medische Zorg'.

12. Bal, Bijker & Hendriks, *Paradox*, pp. 99-100, 174-5.

reforms. The view of Bal, Bijker and Hendriks is all the more interesting because, from the early 1970s, the warning ‘we should act now or else others will do this for us’ was already being repeatedly used, almost like a mantra, in particular by representatives of professional associations who, for example, wanted to urge their ‘rank and file’ to make serious efforts in the field of peer review and protocol medicine. It looks very much as though such ‘reformers’ – to use Marks’s terminology – *needed* the external pressure – whether it existed or not – to achieve their objectives. This became evident, for example, in the 1980s, when the introduction of budgeting in particular put an end to the total non-committal approach that characterised all initiatives for the improvement of the quality of medical practice. The strong rise of evidence-based guidelines too, seems to have been driven in part by external pressure, but the question does present itself regarding the extent to which this pressure really existed, and to the extent to which it had been rhetorically ‘inflated’.

Following on from this, a far more fundamental point is that the scheme of a professional response to external pressure is implicitly based on the assumption that the medical profession and the ‘outside world’ are more or less separate domains. The prominent role Borst-Eilers played underlines how problematic this assumption is. As minister, she belonged to the ‘outside world’ of politics, but at the same time, she came from the medical profession. Representatives of the medical profession were very present in the ‘outside world’, not only in the person of the minister but, for example, also in that of important officials at the Ministry of Health, in influential advisory bodies, in public opinion and in the media. Conversely, the ‘outside world’ was extraordinarily ‘present’ within the medical profession. The study of successive volumes of *Medisch Contact* showed that the issues about which society as a whole was concerned, preoccupied the medical professionals as well. For example, criticism of the negative consequences of medicalisation, and of medical power and iatrogenesis by no means exclusively came from ‘outsiders’, but from medical professionals too. Moreover, a large part of the medical profession seemed to have internalised this criticism in the course of the 1980s. Rather than the clear-cut scheme of external pressures to which the profession subsequently responded, a much cloudier picture thus emerges in which it is not very clear where exactly the pressures came from, who responded to whom or what and with whom the initiative lay.¹³

Reservations may also be expressed in terms of the shift from disciplinary to mechanical objectivity. Evidence-based guidelines may in themselves be considered to be examples of mechanical objectivity, because the underlying evidence is collected and assessed on the basis of explicit criteria, and because they formalise and capture medical

13. See also on this the striking remark of Weisz et al.: ‘[The] proliferation of guidelines is the product of multiple groups of actors arrayed in novel permutations and combinations that cannot be reduced to a simple dichotomy between physician and administrator.’ See: Weisz et al., ‘Emergence of Clinical Practice Guidelines’, p. 692.

practice in rules. In practice, physicians only proved willing to apply guidelines when they were not mandatorily imposed and they were allowed to deviate from them in individual cases. In Van Herk's terminology, the guidelines therefore functioned not so much as normative quality instruments but rather as educational quality instruments.¹⁴ This trend was enhanced by a reorientation on the implementation issue which became evident across a rather broad spectrum in the 'field' around 2000, and which may be indicated as a shift in emphasis from implementing to learning, from 'one-way traffic' to 'two-way traffic', from standard to story, from radical to realistic programme, and from guideline approach to heuristic approach. This reorientation fitted in well with a nuancing of the approach to EBM in which clinical-epidemiological 'evidence' was presented to a lesser extent as the main foundation for medical practice and the emphasis tended to be placed on the importance of its integration with clinical experience, pathophysiological reasoning and specific characteristics and preferences of patients. The latter did require, however, as was emphasised by the Health Council among others, that a translation be made from guideline to practice, which required specific skills that had to be acquired. Guideline *developers*, moreover, also needed to go through such a learning process and learn specific skills. In fact, the introduction and proliferation of a form of mechanical objectivity, namely clinical guidelines, thus led to the development of *new forms of disciplinary objectivity* and the emphasis on the professional expertise required for the development and the proper application of clinical guidelines.

This raises the question of how great the importance or impact of EBM as a mechanism of control actually is or can be. At the same time, the putting into perspective of EBM as outlined above, forms a possible answer to the persistent implementation problem or to rather too dogmatic an implementation of guidelines, as well as to the threat of too great an interference by regulatory agencies and insurers with the application of guidelines in medical practice. In particular this latter threat has, since the new healthcare system of 2006, become greater, which also demonstrates that, despite all the reservations above, 'external pressure' and a possible adverse effect on professional autonomy, remain important building blocks for a sensible interpretation of the phenomenon of EBM.

'Marks' as an Amendment to 'Porter'

Porter's ideas have more often been related to the rise of evidence-based medicine, also by representatives of the EBM movement itself. In this dissertation, it has become evident that Porter's scheme is indeed, to a large extent, applicable to the history of evidence-based medicine, but is, at the same time, not completely satisfying as an interpretive

14. Van Herk, *Artsen onder Druk*, pp. 177, 248.

framework for it. This is not to say that ‘Porter’ and the notion of EBM as a mechanism of control are to be rejected. It is necessary, however, to *amend* them with the help of Marks’s concept of ‘therapeutic reformers’.

Contrary to Porter’s work, that of Marks has not been used so explicitly before to characterise or interpret the EBM movement. This may in part be explained because at first sight, it is about an admittedly related yet different subject – the introduction of the Randomised Controlled Trial in the United States. Moreover, its focus is on the decades immediately preceding and following the Second World War, while the EBM movement did not originate until the end of the twentieth century. Nevertheless, in several ways, Marks’s concept of the ‘therapeutic reformers’ offers a useful addition to Porter’s scheme for a historical understanding of the phenomenon of evidence-based medicine.

In the first place, there are clear, substantive similarities between the ‘therapeutic reformers’ and the EBM movement. They both regarded the RCT as a guiding instrument for the rationalisation of medical practice. Marks described the ‘therapeutic reformers’ as ‘individuals who sought to use the science of controlled experiments to direct medical practice.’¹⁵ In the EBM philosophy, the RCT – despite subsequent nuancing – has always enjoyed a privileged position. In addition, the ‘therapeutic reformers’, according to Marks, were driven by ‘their belief in the power of science to unite both medical researchers and practitioners.’¹⁶ This ties in with the objectives of the pioneers of the EBM movement to make medical practice more scientific (‘turning the *art* of medicine into the *science* of medicine’) and to bridge the (growing) gap between science and practice. Philosophers of science would be inclined to say about both groups that they had a rather naive, positivist image of science.¹⁷

In the second place, these substantive similarities between EBM and the ‘therapeutic reformers’ show that evidence-based medicine did not come out of thin air in the 1990s. The protagonists from Marks’s book were mainly active in the first decades after the Second World War and were also, directly or indirectly, in contact with people who, as of the 1960s and 1970s, advocated RCTs, systematic reviews, clinical decision analysis, medical technology assessment (MTA), clinical epidemiology and clinical guidelines.¹⁸ Although Marks limits himself to the situation in the United States, his analysis shows that the international EBM movement has long historical roots. This is no different for EBM in the Netherlands. In many respects, its rise was a result of the introduction of peer review, health sciences, MTA, protocol medicine and (above all) clinical epidemiology in

15. Marks, *Progress of Experiment*, p. 2.

16. *Ibid.*, pp. 2-3.

17. See chapters 3 and 9.

18. Marks, *Progress of Experiment*, see in particular pp. 236, 244-245. See also: Ankoné, ‘Over de Vier Plichten.’

the 1970s and in particular the 1980s.¹⁹ It is striking here that EBM was regularly used as an umbrella notion, in which many of the other and previous frameworks were also included. Borst-Eilers for example, in her capacity as Minister of Health in the period 1994-2002, was inclined towards placing concepts such as clinical decision analysis, MTA and efficiency under the header of 'evidence-based healthcare'.²⁰

In the third place, it is very telling that Marks typifies the 'therapeutic reformers' as a '*political* community'.²¹ It is extraordinarily clarifying to also conceptualise the Dutch EBM movement as a '*political reform movement*'. Viewed in this light, the report 'Medical Practice at a Crossroads' by the Health Council, in which 'future rhetoric' was practised in order to inspire physicians and medical associations to action, had quite a few traits of a political pamphlet. The missionary work too, which was carried out by Borst-Eilers and the other authors of the report, fits well within this notion of EBM as a political reform movement. Not only with the Health Council, but with other representatives of the Dutch EBM movement, too, several examples may be found of 'future rhetoric' and 'missionary work',²² including: the cycles of lectures and debates which were organised by the people behind the guideline programme of the AMC; the NHG, which fell into debt so as to be able to send the first standards to all the Dutch GPs; and the way in which the KNMG introduced the project 'Appropriate Medical Care' to its followers, with one of the arguments being that this enabled the profession to retain control. It is not inconceivable that all these 'reformers' *exaggerated* the external pressure and the necessity of acting 'now' in order to *convince* medical professionals in the country of the necessity of their recommendations and activities.²³ This would, in any event, account for the contrast between, on the one hand, the repeatedly expressed message that the professional autonomy of medical professionals was at stake and, on the other hand, the finding that (for a long time) the government and the insurers had no intention of, nor were they capable of, interfering substantially in the self-regulation of the medical profession.

In the fourth place, Marks characterises the 'therapeutic reformers' as a 'disparate group' of people, consisting of medical and non-medical scientists, practising physicians, officials, directors and managers.²⁴ This is also applicable to the EBM movement for, apart from many (active) medical professionals, there were also agencies, directors, including Urbanus of the AMC in Amsterdam, officials and, last but not least, there was Borst-

19. See chapter 7.

20. See chapter 8.

21. Marks, *Progress of Experiment*, p. 2.

22. See for instance quotes from Urbanus, the chair of the board of the AMC in Amsterdam, arguing that physicians should keep 'the strings in hands' themselves instead of 'giving the wheel to politics, insurers and the patients', cited in: R. Otten, 'MTA-Mes'.

23. See also on 'the use of persuasion and power': Marks, *Progress of Experiment*, pp. 240-1.

24. *Ibid.*, p. 2.

Eilers in her capacity as vice chairwoman of the Health Council, who contributed to the introduction of EBM in the Netherlands. Thus, Marks's concept moreover offers the opportunity to let go of the problematic separation between profession and 'outside world' to some degree. The problematic aspect of the explanation of EBM as 'a professional response to external pressure' is that it does not do justice to the 'internal' and 'proactive' initiatives coming from the profession itself. At the same time, a strong case may be made for the fact that without 'external pressure', the quality policies of the various medical associations would not have materialised in quite the same way. Thus, a 'chicken or egg debate' begins, which may be circumvented with the view of the EBM movement as a heterogeneous group of reformers, consisting of medical professionals, but also of politicians, policymakers and institution directors.

In the fifth place, it should (nevertheless) be remarked that the EBM movement, as well as the 'therapeutic reformers' in Marks's book, did consist of medical professionals for the greater part. In addition, many directors, politicians and policymakers, who were committed to clinical epidemiology and EBM, had a medical background themselves. This certainly applied to Querido, Urbanus and Borst-Eilers. This forms an important explanation for the relatively great success of clinical epidemiology and EBM in relation to, among others, clinical decision analysis and MTA. The fact that EBM was considered to be something of, by and for physicians, was an important condition for its 'mainstream' acceptance within the medical profession. Incidentally, this simultaneously identifies a significant limitation of EBM: the characterisation of a 'Doctor's Order' is also applicable because EBM was (initially) highly 'doctor-centred' and not so much 'patient-centred', which could be problematic in its application in everyday practice.

In the sixth place and by extension, it may be argued that the concept of 'therapeutic reformers', as well as the title '*A Doctor's Order*', focuses attention on the 'medical content'. This is significant, for the rise of EBM should not only be placed in the broad context of modernisation and the 'democratic mass society' which, according to Porter, forms the historic background to processes of quantification and to shifts from disciplinary to mechanical objectivity. Furthermore – and perhaps above all – it was the more specific and substantive developments in medicine and healthcare themselves which encouraged 'therapeutic reformers' to perform methodological self-reflection.

In the seventh place, the conceptualisation of EBM as political reform movement links in well with the analysis from chapter 9 on the question of whether the 'guideline movement' led to 'stratification' and a shift from the professional autonomy of the individual physician to the profession as a whole. It was first of all argued that it was not implausible at first sight that this 'side effect' occurred. Like Marks's 'therapeutic reformers', many members of the Dutch EBM movement belonged to an elite or vanguard within the medical profession – academics and/or representatives of medical associations – who were concerned about the incompetent, irrational practice of 'peripheral physicians'. To a certain extent, they certainly wanted to impose a 'professional straitjacket' or an internal

mechanism of control on the 'average physician' in the country. In order to counter such undesirable matters as inter-physician variation, they tried to persuade the latter category of physicians to apply the standards and guidelines – which were drawn up by an elite of guideline developers, on the basis of systematic reviews that were produced by an elite of systematic reviewers.

In this respect, the Dutch case of EBM offers an interesting insight into the theme of the 'paradox of modern medicine'. With regard to this theme, it was discussed in the introduction to this dissertation that it 'has become busy in the consultation room' according to many commentators, because more and more non-medical parties have started to interfere with medical practice. In the foregoing, however, this 'standard image' of increasing interference by non-medical parties was somewhat put into perspective, while it has become clear that a vanguard of 'therapeutic reformers' attempted to combat inter-physician variation from the inside and (more or less) control 'average physicians', so that they would make more rational, effective and efficient decisions. In other words, interference and 'the straitjacket' not (only) came from 'strangers at the bedside', but (also) from certain segments within the medical profession *itself*.

It eventually turned out, however, that, partly due to the implementation problem, little was achieved with *internal* control by 'elites' of the practice of 'ordinary physicians'. It is partly for this reason that recently – after the introduction of a new healthcare system in the Netherlands in 2006 – the (feared) prospect of *external* control of medical practice by (semi-)governmental agencies and, in particular, insurers may have become closer to reality.

Incidentally, this is not to say that the introduction of evidence-based medicine in the Netherlands did not lead to anything. Chapter 9 pointed to the significant contribution that EBM made to 'abolition medicine', to the adaptation to the 'information explosion' in medicine and to changing circumstances, and possibly to a more subtle attitude and mentality change within the medical profession.

At the same time, several threats were mentioned, as well as the complexity of everyday medical practice, which always requires the development of a translation from the generic to the specific – or from guidelines based on probabilistic, clinical-epidemiological evidence to the concrete, specific patient and treatment situation. Partly in consequence of this, EBM has not brought the revolution or paradigm shift that was once proclaimed. In fact, if the medical profession wants to prevent governments and insurers from using EBM in an undesirable manner to impose bureaucratic rules, then EBM must be put into more modest perspective and the indeterminate character of medicine must be emphasised. Although evidence-based medicine still has a useful role to play here, it will remain difficult to actually get a grip on medical practice – and thus on the 'paradox of modern medicine'.

This relative powerlessness of the EBM movement too, is fully in line with the ‘therapeutic reformers’ from Marks’s book, as is evidenced by his remark – which forms a fitting final point of this dissertation:

‘Contemporary sociological studies [...] invest science with great power [...]. By contrast, *the sciences discussed in this book are weak, incapable of transforming the world of clinical practice as easily as reformers hope*.²⁵

25. Ibid., pp. 9-10. TB’s italics.



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- Jan Vandenbroucke, d.d. 24 May 2011
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Abbreviations

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| AWBZ | General Act on Exceptional Medical Expenses (Dutch: Algemene Wet Bijzondere Ziektekosten) |
| AMC | Academic Medical Centre, Amsterdam (Dutch: Academisch Medisch Centrum, Amsterdam) |
| AZU | University Hospital Utrecht (Dutch: Academisch Ziekenhuis Utrecht) |
| AZUA | Academic Hospital of the University of Amsterdam (Dutch: Academisch Ziekenhuis van de Universiteit van Amsterdam) |
| CBO | Central Supervisory Body for Peer Review; later renamed into: Dutch Institute for Healthcare Improvement (Dutch: Centraal BegeleidingsOrgaan voor de intercollegiale toetsing; later veranderd in: Kwaliteitsinstituut voor de Gezondheidszorg CBO) |
| CKB | Centre for Clinical Decision Analysis, Erasmus University Rotterdam (Dutch: Centrum voor Klinische Besliskunde, Erasmus Universiteit Rotterdam). |
| CVZ | Dutch Healthcare Insurance Board (Dutch: College voor Zorgverzekeringen) |
| EBRO | Evidence-Based Guideline Development (Dutch: Evidence-Based RichtlijnOntwikkeling) |
| KNAW | The Royal Netherlands Academy for Arts and Sciences (Dutch: Koninklijke Nederlandse Akademie van Wetenschappen) |
| KNMG | The Royal Dutch Medical Association (Dutch: Koninklijk Nederlandse Maatschappij tot bevordering der Geneeskunst) |
| LAD | National Association of Physicians in Employment (Dutch: Landelijke vereniging van Artsen in Dienstverband) |
| LHV | National Association of GP's (Dutch: Landelijke Huisartsen Vereniging) |
| LSV | National Association of Specialists (Dutch: Landelijke Specialisten Vereniging) |
| MTA/HTA | Medical Technology Assessment / Health Technology Assessment |
| NHG | Dutch College of General Practitioners (Dutch: Nederlands Huisartsen Genootschap) |
| NWO | Dutch Organisation for Scientific Research (Dutch: Nederlandse Organisatie voor Wetenschappelijk Onderzoek) |
| RAWB | Advisory Council for Scientific Policy (Dutch: Raad van Advies voor het Wetenschapsbeleid) |

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| RGO | Advisory Council on Health Research (Dutch: Raad voor Gezondheidsonderzoek) |
| SGO | Health Research Promotion Programme (Dutch: Stimuleringsprogramma GezondheidsOnderzoek) |
| STG | Steering Group on Future Health Scenario's (Dutch: Stuurgroep Toekomstscenario's Gezondheidszorg) |
| UMC | University Medical Centre (Dutch: Universitair Medisch Centrum) |
| Wet BIG | Dutch Individual Healthcare Professions Act (Dutch: Wet op de Beroepen in de Individuele Gezondheidszorg) |
| WGBO | Medical Treatment Agreement Act (Dutch: Wet op de Geneeskundige BehandelingsOvereenkomst) |
| Wmg | Health Care Market Regulation Act (Dutch: Wet Marktordening Gezondheidszorg) |
| WRR | Scientific Council for Government Policy (Dutch: Wetenschappelijke Raad voor het Regeringsbeleid) |
| ZON | Health Research the Netherlands (Dutch: ZorgOnderzoek Nederland) |
| ZonMw | The Netherlands Organisation for Health Research and Development |
| Zvw | Health Insurance Act (Dutch: Zorgverzekeringswet) |
| ZWO | Dutch Organisation for Pure Scientific Research (Dutch: Nederlandse Organisatie voor Zuiver-Wetenschappelijk Onderzoek) |

Dutch Summary – Nederlandse Samenvatting

Aan het begin van de jaren 1990 deed een nieuw begrip zijn intrede: Evidence-Based Medicine (EBM). Na een opmerkelijk korte tijd was EBM niet meer weg te denken uit de geneeskunde. Bovendien bekenden ook allerlei niet-medische disciplines in de gezondheidszorg, variërend van fysiotherapie tot geestelijke verzorging, zich tot de ‘evidence-based practice’. Zelfs buiten de gezondheidszorg raakte het nieuwe concept in zwang, bijvoorbeeld in de vorm van (pleidooien voor) ‘evidence-based management’ en ‘evidence-based policy’. Met enige overdrijving zou gesteld kunnen worden dat ‘evidence-based’ al snel uitgroeide tot een van de mantra’s van het huidige tijdsgewricht. Dit roept allerlei vragen op, bijvoorbeeld: Waarom sloeg het ‘evidence-based’ begrip zo aan, binnen en buiten de geneeskunde? Waar was het een antwoord op? De vraag die daaraan voorafgaat is echter: *Wat is evidence-based medicine eigenlijk?*

De meest gebruikte en invloedrijke definitie van EBM, die in 1996 werd geformuleerd, is: ‘het zorgvuldig, expliciet en oordeelkundig gebruik van het huidige beste bewijsmateriaal om beslissingen te nemen voor individuele patiënten’. Deze definitie is echter niet erg verhelderend. Het lijkt een open deur dat artsen hun beslissingen zorgvuldig dienen te nemen en daarbij zoveel mogelijk gebruik maken van de beschikbare wetenschappelijke kennis. In dit proefschrift is daarom getracht om niet aan de hand van een (vage) definitie, maar met behulp van een beschrijving van de historische ontwikkeling van dit fenomeen een antwoord te bieden op de vraag wat EBM eigenlijk is.

Deze vraag is des te relevanter doordat evidence-based medicine een ongrijpbaar fenomeen met vele gezichten is. EBM is omschreven als een onderwijsbenadering, een ideologische beweging, een tamelijk loze kreet en een kritische houding of mentaliteit. Wat de concrete vormen en ‘tools’ van EBM betreft, is het accent verschoven van ‘critical appraisal’ (kritische evaluatie) van de medische literatuur naar ‘systematic reviews’ (systematische samenvattingen van de onderzoeksliteratuur over specifieke onderwerpen) en klinische richtlijnen. Daarnaast blijkt EBM behalve een microdimensie ook een macrodimensie te hebben, dat wil zeggen: het is niet alleen een instrument om beslissingen te nemen over de zorg van individuele patiënten, maar wordt ook gezien als een leidraad voor het beleid in de gezondheidszorg, in het bijzonder voor het bereiken van verdelende rechtvaardigheid in een context van schaarste. Mede vanwege deze brede toepassingsmogelijkheden van EBM, is het concept door vele partijen omarmd, die er ieder echter hun eigen betekenis aan (willen) geven.

Al met al lijkt het onbegonnen werk om het fenomeen EBM te vangen in een (beknop-te) typering. Hier wordt daar toch een poging toe gedaan, aan de hand van de titel van dit

proefschrift: *A Doctor's Order*. Letterlijk betekent dit 'een doktersvoorschrift', maar hier verwijst deze titel naar twee wezenlijke aspecten van evidence-based medicine, die als rode draden door alle hoofdstukken van dit proefschrift heen lopen.

Het eerste aspect is vervat in het titelwoord 'order', dat hier verwijst naar EBM als beheersingsmechanisme, ofwel als een instrument voor het 'ordenen' (reguleren, formaliseren, rationaliseren, standaardiseren) van de geneeskundige praktijk. Dit aspect van het fenomeen EBM sluit aan bij de theoretische 'kapstok', zoals die in de inleiding wordt besproken. Leidend zijn daarbij de theoretische ideeën van de historicus Theodore Porter over een verschuiving van disciplinaire naar mechanische objectiviteit die zich in tal van domeinen, professies en disciplines heeft voltrokken gedurende de laatste twee eeuwen. Deze verschuiving, die in de regel gepaard ging met kwantificering, was volgens Porter in veel gevallen het gevolg van een professionele reactie op druk van buitenaf. Deze druk van buitenaf zou zijn toegenomen als gevolg van de opkomst van democratische massasamenlevingen in het westen, de daarmee gepaard gaande roep om transparantie en het afleggen van verantwoording, alsmede de toenemende noodzaak van regulering en kostenbeheersing van de verzorgingsstaat. Samen met de sociaal-wetenschappelijke literatuur over professies en (de- of re-)professionalisering en het werk van de socioloog Gieryn over 'culturele landkaarten van de wetenschap' bieden deze inzichten van Porter een zinvol handvat voor de duiding van het fenomeen van evidence-based medicine. Van deze 'theoretische kapstok' zijn de noties afgeleid van EBM als beheersingsmechanisme, als verschuiving van disciplinaire naar mechanische objectiviteit en als professionele reactie op druk van buitenaf.

Het fenomeen EBM laat zich aan de hand van deze noties goed plaatsen in de context van de late twintigste eeuw, het tijdperk waarin volgens een brede consensus in de literatuur de 'paradox van de moderne geneeskunde' zichtbaar werd. Na het gouden tijdperk dat de geneeskunde in de jaren 1940, '50 en '60 beleefde, tekende zich rond 1970 een kentering af. Naast de 'wet van de verminderde meeropbrengst' waren daar meerdere ontwikkelingen debet aan, waaronder de explosief stijgende kosten van de verzorgingsstaat die bezuinigingen noodzakelijk maakten, de negatieve kanten van wat wel wordt aangeduid als 'medicalisering' en de toenemende onzekerheid van artsen die werden geconfronteerd met een steeds complexere praktijk en met een niet of nauwelijks te hanteren explosie aan medische kennis. Deze 'paradox van de moderne geneeskunde' en vooral de wijze waarop zowel de medische beroepsgroep als tal van niet-medische partijen hebben getracht daar greep op te krijgen vormen de hoofdthema's van het Utrechts/Maastrichtse onderzoeksprogramma 'Medicine in Transition' waar dit proefschrift een product van is. Het onderwerp evidence-based medicine dient daarbij als een 'venster' dat de mogelijkheid biedt om een specifieke blik te werpen op deze thematiek.

Deze aan het titelwoord 'order' ontleende beschouwingen zijn echter niet toereikend om het fenomeen EBM te typeren. In de beschrijving en analyse van de 'Nederlandse EBM-casus' is nadrukkelijk naar voren gekomen hoe groot en soms zelfs doorslaggevend de rol is geweest van lokale en vooral persoonlijke factoren bij de opkomst van klini-

sche epidemiologie en evidence-based medicine in Nederland. Om hieraan recht te doen verwijst de aanduiding ‘A Doctor’s’ in de titel naar een tweede aspect van EBM: de grote inbreng van individuen of kleine groepen medici, die de historicus Marks zou aanduiden als ‘therapeutische hervormers’. Met enige goede wil zou gesteld kunnen worden dat ‘Marks’ vooral het tweede aspect van EBM recht doet, terwijl het werk van Porter de aandacht richt op het eerste aspect. De perspectieven die beide historici bieden lijken elkaar uitstekend aan te vullen. Ieder op zich geven ze wellicht een te eenzijdig beeld, terwijl uit de combinatie van het werk van beide een adequate duiding van het fenomeen EBM lijkt voort te komen.

De typering van EBM als ‘A Doctor’s Order’ en de stelling dat ‘Porter’ en ‘Marks’ gezamenlijk een verhelderend licht werpen op het fenomeen evidence-based medicine worden ondersteund door de bevindingen uit dit proefschrift, dat is opgebouwd uit drie delen van ieder drie hoofdstukken. In het eerste deel wordt het fenomeen evidence-based medicine in zowel lange termijn- als internationaal perspectief geplaatst. In hoofdstuk 1 wordt daartoe de bestaande historiografie afgezet tegen de wijze waarop EBM in dit proefschrift wordt gehistoriseerd. Terwijl in de medische literatuur de aandacht zich richt op ‘historische voorlopers’ en veel historische en filosofische literatuur zich concentreert op de ‘oneindige’ strijd tussen verschillende filosofische posities in de geneeskunde (theorie versus empirie), wordt hier voor een andere benadering gekozen. Evidence-based medicine kan namelijk, zo wordt in het eerste hoofdstuk betoogd, tegen de historische achtergrond worden geplaatst van een proces van objectivering en kwantificering in de geneeskunde dat al in de negentiende eeuw op gang kwam. Dit wordt onderbouwd aan de hand van het werk van Porter, Gieryn, Rosenberg en anderen, waarbij onder andere de link wordt gelegd tussen objectivering en kwantificering enerzijds en regulering, ordening, beheersing en standaardisering anderzijds. Aan het eind van hoofdstuk 1 worden zo de algemene contouren zichtbaar van de wijze waarop EBM historisch geduid zou kunnen worden. Hoofdstuk 2 richt zich vervolgens op de komst van ‘het statistische tijdperk’ in de geneeskunde in de tweede helft van de twintigste eeuw, aan de hand van de ontwikkelingen in de epidemiologie van chronische ziekten en de opkomst van de RCT – het gerandomiseerde klinische experiment – dat uitgroeide tot de ‘gouden standaard’ voor het vaststellen van de werkzaamheid van medische behandelingen. Daarmee wordt een belangrijke ‘schakel’ in de (voor)geschiedenis van evidence-based medicine aan de orde gesteld. EBM is namelijk een uitingsvorm van een hele *specifieke* vorm van objectivering en kwantificering, namelijk de toenemende invloed van probabilistisch, statistisch-epidemiologisch redeneren in de geneeskunst. Hoofdstuk 2 vormt zo als het ware de verbinding tussen hoofdstuk 1 en hoofdstuk 3, dat veel (beschrijvende) informatie bevat over de opkomst en de ontwikkeling van eerst klinische epidemiologie (de discipline waaruit EBM is voortgekomen) en vervolgens van EBM. Aan het eind van hoofdstuk 3 is de (internationale) geschiedenis van EBM in grote lijnen en grove trekken geschetst.

Om werkelijk historisch zicht te krijgen op dit fenomeen – en op de validiteit van de aan Porter ontleende duiding van EBM als beheersingsmechanisme – wordt in de delen II en III de ‘casus Nederland’ uitgewerkt. Deel II richt zich op de statistisch-epidemiologische ‘evidence-base’ van EBM, die voor een groot deel wordt geproduceerd door de klinische epidemiologie. De in internationaal opzicht opmerkelijk sterke academische positie die deze discipline in Nederland heeft verworven wordt in de historische context geplaatst van internationale en nationale ontwikkelingen in het medisch (en vooral: klinisch) wetenschappelijk onderzoek sinds de jaren 1970 – waaronder de verschuiving van ‘little science’ naar ‘big science’ en de toenemende druk op onderzoekers om zo veel mogelijk te publiceren, alsmede het wetenschapsbeleid van de Nederlandse overheid van de jaren 1980 en de metamorfose van het universitaire onderzoeksklimaat die daar het gevolg van was. Daarnaast wordt echter aandacht besteed aan de rol van specifieke individuen (‘therapeutische hervormers’) en lokale omstandigheden. Hoofdstuk 4 begint met een beschrijving van ontwikkelingen in de algemene of ‘populatie’ epidemiologie in Nederland, die tot op zekere hoogte de weg bereidden voor de latere opmars van de *klinische* epidemiologie. In hoofdstuk 5 volgt een analyse de ‘beweging ten behoeve van patiëntgebonden onderzoek’ die in de jaren 1980 een sterke lobby vormde voor versterking van toegepaste klinische wetenschappelijke onderzoek in Nederland en daarbij een sleutelrol zag weggelegd voor de klinische epidemiologie. In hoofdstuk 6 wordt de geschiedenis van vier lokale academische afdelingen klinische epidemiologie beschreven, om uiteindelijk aan de hand van deze ‘casussen’ de belangrijkste ‘succesfactoren’ van de klinische epidemiologie te benoemen, op persoonlijk, lokaal, nationaal en internationaal niveau.

In deel III verschuift de aandacht van de productie van ‘evidence’ naar de toepassing van ‘evidence’ in zowel de medische praktijk als in het gezondheidszorgbeleid. Vooral in dit deel worden de vooral aan het werk van Porter ontleende noties over EBM als beheersingsmechanisme, professionele reactie van buitenaf en voorbeeld van een verschuiving van mechanische naar disciplinaire objectiviteit ‘geconfronteerd’ met de specifieke bevindingen over de introductie van EBM in Nederland. In hoofdstuk 7 wordt eerst de historische achtergrond van de jaren 1970 en 1980 geschetst. Zowel de ‘druk’ op de geneeskunde en de medische beroepsgroep, als de wijze waarop artsen en artsenorganisaties daarmee omgingen komen daarbij aan de orde. Hoofdstuk 8 gaat vervolgens over de razendsnelle opmars die evidence-based medicine in de loop van de jaren 1990 in Nederland doormaakte. Dit wordt in verband gebracht met een aantal ontwikkelingen in het gezondheidszorgbeleid in Nederland en in het bijzonder met de rol van de minister van Volksgezondheid tussen 1994 en 2002, Els Borst-Eilers. Onder haar bewind verschoof het accent in het beleid van keuzes op macroniveau naar de stimulering van doelmatigheid op microniveau (met de ontwikkeling en implementatie van evidence-based richtlijnen als belangrijkste instrument). In hoofdstuk 9 wordt een tentatieve poging gedaan om inzicht te bieden in de betekenis en impact van evidence-based medicine in Nederland. De aandacht richt zich daarbij vooral op (het gebrek aan) de implementatie

van evidence-based klinische richtlijnen en de gevolgen daarvan voor, onder andere, de klinische autonomie van artsen. Tevens wordt het actuele debat over de belangrijkste kansen en bedreigingen voor EBM in de 21e eeuw in kaart gebracht.

De ‘Nederlandse EBM-casus’, die in deel II en III wordt beschreven, laat zien dat het schema van Porter enerzijds inderdaad in belangrijke mate van toepassing is op de geschiedenis van evidence-based medicine, maar daar anderzijds niet in alle opzichten een bevredigend licht op werpt. Dit betekent niet dat ‘Porter’ en de notie van EBM als beheersingsmechanisme verworpen dienen te worden. Wel is het nodig om ze te *amenderen* met behulp van Marks’ concept van ‘therapeutische hervormers’. In tegenstelling tot het werk van Porter, is dat van Marks nog niet eerder zo expliciet gebruikt om de EBM-beweging te typeren of duiden. Niettemin biedt Marks’ concept van de ‘therapeutische hervormers’ op meerdere manieren een zinvolle aanvulling op het ‘schema’ van Porter ten behoeve van een historische duiding van het fenomeen evidence-based medicine.

In de eerste plaats zijn er duidelijke inhoudelijke overeenkomsten tussen de ‘therapeutische hervormers’ en de EBM-beweging. Marks omschrijft de ‘therapeutische hervormers’ als ‘individuen die de wetenschap van gerandomiseerde experimenten wilden gebruiken om het medisch handelen aan te sturen’. Dit sluit aan bij de doelstellingen van de pioniers van de EBM-beweging om de medische praktijk (*geneeskunst*) meer wetenschappelijk te maken (*geneeskunde*) en de (groeïende) kloof tussen wetenschap en praktijk te overbruggen. Daarbij heeft bovendien het gerandomiseerde klinische experiment (de RCT) altijd een geprivilegieerde positie gehad in het EBM-gedachtegoed.

In de tweede plaats laten deze inhoudelijke overeenkomsten tussen EBM en de ‘therapeutische hervormers’ zien dat evidence-based medicine niet ineens uit het niets is opgekomen in de jaren 1990. Marks’ boek toont dat de (internationale) EBM-beweging lange historische wortels heeft. Dit is voor EBM in Nederland niet anders. De opkomst daarvan was in veel opzichten een voortvloeiende van de introductie van intercollegiale toetsing, gezondheidswetenschappen, Medical Technology Assessment (MTA), protocollaire geneeskunde en bovenal klinische epidemiologie in de jaren 1970 en 1980. Daarbij valt op dat EBM geregeld als een soort koepelbegrip werd gebruikt, waarin ook veel van de andere, en eerdere ‘frameworks’ als het ware werden opgenomen. Borst-Eilers was bijvoorbeeld, toen zij in de periode 1994-2002 minister van Volksgezondheid was, geneigd om onder andere beslisgeving, MTA en doelmatigheid te scharen onder de noemer ‘evidence-based gezondheidszorg’.

In de derde plaats is het zeer treffend dat Marks de ‘therapeutische hervormers’ typeert als een ‘*politieke* gemeenschap’. Het is buitengewoon verhelderend om ook de Nederlandse EBM-beweging als te conceptualiseren als een soort *politieke hervormingsbeweging*. In dit licht bezien had bijvoorbeeld het invloedrijke rapport ‘Medisch Handelen op een Tweesprong’ van de Gezondheidsraad uit 1991 – waarin ‘toekomstretoriek’ en ‘zendingswerk’ werd bedreven om artsen en artsenorganisaties tot ‘evidence-based han-

delen' aan te sporen – veel weg van een politiek pamflet. Ook andere vertegenwoordigers van de Nederlandse EBM-beweging vertoonden staaltjes van toekomstretoriek en zendingswerk. Daarvan zijn meerdere voorbeelden te geven, waaronder: de lezingencycli en debatten die door de mensen achter het richtlijnenprogramma van het AMC werden georganiseerd; het Nederlands Huisartsen Genootschap (NHG) dat zich in de schulden stak om de eerste NHG-standaarden naar alle Nederlandse huisartsen te sturen; en de wijze waarop de KNMG het project 'Passende Medische Zorg' introduceerde bij de achterban, met onder andere het betoog dat de beroepsgroep hiermee zelf de sturing in handen kon houden. Het is niet ondenkbaar dat al deze 'hervormers' de druk van buitenaf en de noodzaak om 'nu' te handelen hebben *overdreven*, om medici in den lande te *overtuigen* van de noodzaak van hun aanbevelingen en activiteiten. Hiermee zou in elk geval het contrast verklaard zijn tussen enerzijds de bij herhaling uitgesproken boodschap dat de professionele autonomie van medici in het geding was en anderzijds de bevinding dat de overheid en de verzekeraars (lange tijd) niet van plan of in staat waren om aanzienlijk in te treden in de zelfregulering van het medisch beroep.

In de vierde plaats typeert Marks de 'therapeutische hervormers' als een 'heterogene groep' mensen, bestaande uit medische en niet-medische wetenschappers, praktiserende artsen, ambtenaren, bestuurders en managers. Dit is ook van toepassing op de EBM-beweging, omdat behalve veel (actieve) medici ook instanties, bestuurders, onder wie Urbanus van het AMC in Amsterdam, ambtenaren en niet in de laatste plaats Borst-Eilers in haar hoedanigheid als vicevoorzitter van de Gezondheidsraad en minister bijdroegen aan de introductie van EBM in Nederland. Het concept van Marks biedt zo bovendien de mogelijkheid om de problematische scheiding tussen beroepsgroep en 'buitenwereld', die kleeft aan de Porter-these, enigszins los te laten. Het lastige van de verklaring van EBM als 'een professionele reactie op druk van buitenaf', is dat het geen recht doet aan de 'interne' en 'proactieve' initiatieven die vanuit de beroepsgroep zelf kwamen. Tegelijk is er veel voor te zeggen dat zonder druk van buitenaf het kwaliteitsbeleid van de verschillende artsenorganisaties veel minder van de grond was gekomen. Zo dreigt er een kip-of-ei-discussie, die ontlopen kan worden met de opvatting van de EBM-beweging als een heterogene groep hervormers, bestaande uit medici, maar ook uit politici, beleidmakers en instellingsbestuurders.

In de vijfde plaats dient (niettemin) opgemerkt te worden dat de EBM-beweging, evenals de 'therapeutische hervormers' in het boek van Marks, wel voor het overgrote deel bestond uit medici. Daarbij hadden ook veel bestuurders, politici en beleidsmakers die zich hard maakten voor klinische epidemiologie en EBM zelf een medische achtergrond. Dat gold niet in de laatste plaats voor Querido, Urbanus en Borst-Eilers. Dit vormt een belangrijke verklaring voor het relatieve grote succes van klinische epidemiologie en EBM ten opzichte van onder andere klinische beslistkunde en MTA. Dat EBM werd beschouwd als iets van, door en voor dokters, was een belangrijke voorwaarde voor de brede acceptatie ervan binnen de medische beroepsgroep. Overigens is hiermee tegelijk

een belangrijke beperking gegeven van EBM: de typering van een ‘Doctor’s Order’ is ook van toepassing omdat EBM (aanvankelijk) zeer dokter- en weinig patiëntgericht was, wat bij de toepassing ervan in de alledaagse praktijk problematisch kon zijn.

In de zesde plaats kan, in het verlengde hiervan, gesteld worden dat het concept van ‘therapeutisch hervormers’ evenals de titel ‘A Doctor’s Order’, de aandacht richt op de medische inhoud. Dat is van belang, omdat de opkomst van EBM niet alleen in de brede context moet worden geplaatst van modernisering en de democratische massasamenleving, die volgens Porter de historische achtergrond vormt voor processen van kwantificering en voor verschuivingen van disciplinaire naar mechanische objectiviteit. Ook – en wellicht vooral – zijn het meer specifieke en inhoudelijke ontwikkelingen in de geneeskunde en gezondheidszorg zelf geweest, die ‘therapeutische hervormers’ hebben aangezet tot methodologische zelfreflectie.

In de zevende plaats sluit de conceptualisering van EBM als politieke hervormingsbeweging goed aan bij de analyse uit hoofdstuk 9 over de vraag of de richtlijnbeweging leidde tot ‘stratificatie’ en verschuiving van de professionele autonomie van de individuele arts naar de beroepsgroep als geheel. Allereerst is betoogd dat het op het eerste gezicht niet onaannemelijk was dat deze ‘bijwerking’ zich voor heeft gedaan. Net als de ‘therapeutische hervormers’ van Marks, behoorden veel leden van de Nederlandse EBM-beweging tot een elite of voorhoede binnen de medische beroepsgroep – academici en of vertegenwoordigers van artsenorganisaties – die zich druk maakten over het onoordeelkundige, irrationele handelen van ‘perifere dokters’. Tot op zekere hoogte wilden zij wel degelijk een ‘professioneel keurslijf’, oftewel een ‘intern beheersingsmechanisme’, opdringen aan de ‘gemiddelde dokter’ in den lande. Om onwenselijke zaken als interdoktervariatie tegen te gaan, probeerden zij de laatstgenoemde categorie artsen ertoe te bewegen om de standaarden en richtlijnen toe te passen – die werden opgesteld door een elite van richtlijnmakers, op basis van *systematic reviews* die werden geproduceerd door een elite van *systematic reviewers*.

Wat dit betreft biedt de Dutch case of EBM een interessante inkijk in de thematiek van de ‘paradox van de moderne geneeskunde’. Ten aanzien van deze thematiek is in de inleiding van dit proefschrift besproken dat het volgens vele commentatoren ‘druk is geworden in de spreekkamer’, doordat steeds meer niet-medische partijen zich met het medisch handelen zijn gaan bemoeien. In het voorgaande is dat ‘standaardbeeld’ van toenemende bemoeienis van niet-medische partijen echter enigszins gerelativeerd, terwijl wel duidelijk is geworden dat een voorhoede van ‘therapeutische hervormers’ van binnenuit heeft geprobeerd om ‘gemiddelde dokters’ als het ware aan te sturen, zodat zij meer rationele, effectieve en doelmatige beslissingen zouden nemen. Met andere woorden, de bemoeienis en ‘het keurslijf’ kwamen niet (alleen) van niet-medische partijen, maar (ook) van bepaalde segmenten binnen de medische beroepsgroep zelf.

Uiteindelijk bleek echter dat er, mede vanwege het implementatieprobleem, weinig terecht kwam van een dergelijke interne controle. Mede daarom kwam recentelijk – na de

invoering van een nieuw zorgstelsel in Nederland in 2006 – het angstbeeld van externe controle op het medisch handelen door overheid en vooral verzekeraars dichterbij.

Hiermee is overigens niet gezegd dat de introductie van evidence-based medicine in Nederland tot niets heeft geleid. In hoofdstuk 9 is gewezen op de belangrijke bijdrage die EBM heeft geleverd aan de ‘afschafgeneeskunde’, aan de adaptatie aan de ‘informatieexplosie’ in de geneeskunde en mogelijk aan een meer subtiele attitude- en mentaliteitsverandering binnen de medische professie.

Tegelijk zijn echter meerdere bedreigingen benoemd, alsook de complexiteit van de alledaagse medische praktijk die altijd een ingewikkelde vertaalslag van het generieke naar het specifieke noodzakelijk maakt – ofwel van op probabilistische, klinisch epidemiologische evidence gebaseerde richtlijnen naar de concrete, specifieke patiënt en behandelsituatie. Mede hierdoor heeft EBM niet de revolutie of paradigmawisseling gebracht die ooit werd aangekondigd. Sterker nog, wil de medische professie voorkomen dat overheden en verzekeraars EBM op een ongewenste manier gebruiken om bureaucratische regels op te leggen, dan moet EBM worden gerelativeerd en de onbepaaldheid van het medisch handelen worden benadrukt. Voor evidence-based medicine is dan nog wel een nuttige rol weggelegd, maar het zal moeilijk blijven om werkelijk greep te krijgen op het medisch handelen.

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Curriculum Vitae

T. C. (Timo) Bolt (Arnhem, 1973) is a Dutch historian of science and medicine. After a (relatively short) career as an occupational therapist, he studied history at Utrecht University. After finishing his bachelor's (*cum laude*), he participated in the research master program (equivalent to MPhil level) Historical and Comparative Studies of the Sciences and Humanities (now: History and Philosophy of Science) at University Utrecht and graduated *cum laude* in 2009. As a historian/researcher, he has been working at the Research Institute for History and Culture (OGC) at Utrecht University (2007-2010). Between November 2010 and May 2015 he subsequently worked on his PhD research project on the history of evidence-based medicine, with professor of medical history, Frank Huisman, at the Medical Humanities department at the University Medical Centre Utrecht.

Timo Bolt has published (in Dutch) on the history of medicine, child psychiatry, ADHD, psychiatry, 'psychologisation', and time-concepts in various books and peer-reviewed journals, such as the *Nederlands Tijdschrift voor Geneeskunde* (the most important Dutch medical journal), *Low Countries Historical Review* (the official journal of the Royal Dutch Historical Society) and *Studium* (the official journal of GEWINA, the Belgian-Dutch Society for the History of Science and Universities). His book on the history of child psychiatry in The Netherlands, entitled *Kinderen van hun Tijd: Zestig Jaar Kinder- en Jeugdpsychiatrie in Nederland, 1948-2008* [*Children of their Time: Sixty Years of Child and Adolescent Psychiatry in The Netherland, 1948-2008*] (co-authored by Leonie de Goei) was awarded the Martinus J. Langeveld Prize of 2009 as "the Dutch book that has most inspiringly addressed the themes of the upbringing, education, and development of children and youths".

After finishing his PhD in 2015, Timo Bolt will be assistant professor at the history of medicine department (headed by professor Mart van Lieburg) at Erasmus Medical Centre in Rotterdam.

