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Expanding newborn screening programmes and strengthening informed consent

De uitbreiding van de hielprik en het versterken van geïnformeerde toestemming
(met een samenvatting in het Nederlands)

Proefschrift

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Introduction

Every year millions of newborns throughout the world are subjected to a 'heel prick': a drop of blood is taken from the heel and subsequently tested for a variety of diseases. In some countries, such as the Netherlands, this procedure is on a voluntary basis. Of course this does not mean that the child involved gives permission, but rather that its parents give an informed consent; they are given an opportunity to refuse the procedure. In practice, however, the screening is conducted as a matter of routine. Over time, different screening programmes have expanded to include more and more diseases, and as technology advances, further expansions are to be expected.

From an ethical perspective, newborn screening for congenital diseases is a seemingly unspectacular topic. Unlike issues such as enhancement, xenotransplantation and genetic manipulation, it does not involve intuitions about the future of mankind or the boundaries of what is 'natural'. Unlike topics such as third world poverty or the ethics of warfare, it does not involve issues of extreme injustice, nor does it spark heated societal debates, such as in the cases of euthanasia, abortion, gender inequality or animal rights.

The procedure for newborn screening is simple and relatively painless. The diseases screened for are very rare, and therefore few people will be affected by the results. It is often offered as a matter of routine. The general attitude among the public is that newborn screening is part of the standard care offered to new parents and their child. Yet, as is apparent from the title of this thesis, I believe it was worthwhile to devote my PhD research to the topic of informed consent for newborn screening. Before commencing my discussion I will briefly explain why.

What put me on the track of the topic of this thesis was a short editorial written by Joan Austoker. In it she argued, or rather, presumed, that screening needs to be accompanied by a thorough informed consent procedure, particularly if the screening may convey harms as well as benefits.

> "[S]creening, like most medical interventions, has harms as well as benefits. All the more reason therefore to ensure that patients undergoing screening are fully aware of both the benefits and the harms. Failure to obtain truly informed consent for many current preventive interventions is clearly unethical."[1]

[1] Austoker (1999), p. 722.

The thought seemed to be that informed consent is a necessary requirement for any medical intervention, especially when participation may have adverse consequences for the individual involved. Although to me this itself seemed far from a clear proposition, let alone evidently true, I noticed as I continued my research that this presumption is widely shared. There is a general tendency in academic and societal debate to emphasize the need for proper informed consent for screening. Austoker's claim refers to screening in general, but, as noted, I believe that it is particularly interesting when applied to the expansion of newborn screening. This expansion is deemed to be a reason for redirecting our attention to the requirement of informed consent. As I will show in chapter 1, in the debate on this expansion an important argument is that expansion increases disadvantages relative to the advantages, which leads to the claim that expanded screening programmes necessitate strengthened informed consent.[2] I will call this claim the 'SIC claim' (the Strengthening Informed Consent claim). This is the claim I will address in this thesis: I will focus on the question of whether and under what conditions the requirement of informed consent should be strengthened as the newborn screening programmes expand. To answer this question, I will analyse the theoretical presuppositions of this claim. Before I begin, however, I will explain what is interesting about the SIC claim. Why should one want to devote a thesis to the question of strengthening informed consent in relation to newborn screening?

First, informed consent for newborn screening merits ethical analysis because it prompts discussion on the role of such screening practices within a broader societal context. Newborn screening, although it is only a minor intervention, affects a lot of people. Therefore, minor increases of the disadvantages of testing are still likely to have a significant impact on the population. This means that expansions should not be introduced without reflection on the impact that such expansions have on society. A critical scrutiny of the debate on the expansion of screening programmes hopefully contributes to a legitimate and defensible screening practice. Second, my choice of topic offers an opportunity to consider a variety of themes which have larger implications than merely for newborn screening programmes. In discussing these themes I will touch upon some issues which are both important to modern society and interesting from a theoretical perspective: informed consent, public health, the ethics of screening, parental authority and epistemic rights. These issues lie at the very

[2] I should mention here that, contrary to Austoker and others, I will speak of 'advantages' and 'disadvantages' of screening, rather than 'harms' and 'benefits'. The reason for this is that 'harms' and 'benefits' are more theoretically laden and further analysis is required before we can apply them to the discussion on informed consent. As I will argue in part II, a specific conception of harms and benefits is necessary in order for these concepts to relate to the requirement of informed consent. Therefore whether the mentioned advantages and disadvantages of expanded newborn screening constitute benefits and harms is an issue which I will have to postpone until later, specifically chapter 8.

core of our thinking about the role of medicine in society and the limits of governmental intervention. In the course of the last decades, they have more and more been acknowledged as being in need of an ethical analysis and have therefore been increasingly debated upon. Also their interrelatedness needs to be thought through if we are to find a response to the way in which they affect all of our lives. I want to briefly mention some of these issues in order to give an indication of the debates in which I take a position in this thesis. I will say more of substance on the different issues in the course of this thesis.

The first and foremost subject that this thesis addresses is the concept of informed consent.[3] Without a doubt this is one of the most discussed concepts in medical ethics. Informed consent has played a pivotal role in the rethinking of the classic understanding of the role of doctors as exclusively well-doers. Against this predominantly paternalist perspective, the concept of informed consent provided the opportunity to empower patients and emphasize autonomous decision making. However, there has also been a lot of criticism of the blind application of the principles involved. A thoughtless or fanatic application of the principle can lead to situations where the patients are *not* respected as autonomous decision makers, for example when patients are confronted with choices they would rather not make. Therefore some have argued that the overly enthusiastic hailing of informed consent as a panacea requires downplaying. The issues surrounding informed consent require a balancing act: on the one hand authors are justifiably reluctant to let go of the achievements of earlier generations that secured patient choice, on the other it has to be acknowledged that the principle of informed consent is not sacrosanct. In any case, it is important that the principle does not defeat its own purpose, which is to empower patients.

The issue of informed consent becomes all the more pressing when we consider that newborn screening is a collective enterprise; this leads me to the second theme of this thesis, public health.[4] Public health ethics is an exciting and relatively new field of research. Its objects are interventions that aim for the health of the public, rather than specified individuals. Examples are screening, the promotion of safe sex, vaccination, smoking policy and dietary education. Characteristic of these interventions is a pro-active stance towards diseases; the focus is on prevention instead of on cure. Many questions arise with regard to public health interventions; some are very similar to those in medical ethics, others are quite different. Our approach towards these questions may have substantial implications for society as a whole, in particular the role of health care in society and the

[3] See chapters 2, 3 and 4 for literature relevant to the issues mentioned here.
[4] See chapter 5.

limits of state intervention. The relevant framework and even definition of public health are still in development. This thesis is – amongst other things – an attempt to contribute to the ongoing debate on public health care. In the context of the issues surrounding the heel prick, the debate on the ethics of screening is of course of particular interest.[5] Since Wilson and Jungner proposed ten criteria for population screening in 1968,[6] it has become widely acknowledged that screening is an activity that raises moral concern and should be the object of scrutiny. Screening is not something that needs to be pursued at all costs. Yet, all too often, we find that physicians and public health professionals merely see the public as consisting of people who need to be persuaded of the benefits of prevention. This, perhaps technology driven, attitude requires a vigilant stance from ethicists, of whom one might expect a critical perspective on technological and medical developments. Not all scientific progress necessarily leads to social progress. To narrow the point down to screening: not every addition to the screening programme is a blessing. There may be adverse consequences involved and it is important not to close one's eyes to this fact. A major theme in debates on the ethically justified implementation of screening programmes is the accompanying informed consent procedure. Particularly if screening involves potential harm, informed consent is considered to be of importance to the justifiability of these public health interventions. However, much current work on informed consent focuses on the clinical or research context. It is not self-evident that the requirements of informed consent can be translated unmodified into the public health context.

Third, the topic of this thesis touches upon the issue of parental authority.[7] If informed consent is given for newborn screening, this is generally done by the parents of the child. This raises the question of why they should be the ones to make such decisions. The issue of parental authority has been increasingly debated over recent years. In a strongly individualized society the question arises of what the responsibilities of parents, government and others are with regard to children. This question touches upon a wide variety of controversies, ranging from child abuse to vaccination. There are two related reasons why, particularly in the past few decades, parental authority is deemed of interest. The first relates to the heightened complexity of society and the fact that 'liberal values' of pluralism and individuality seem to be ever more broadly embraced. This is likely to affect the way in which tension between the individual choices of parents and the interests of their offspring is perceived. The second is that the possibilities of influencing and intervening in the private sphere have increased. For example, developments in information technology enable more

5 See chapter 1.
6 Wilson & Jungner (1968).
7 See chapter 6.

efficient databases in which risk factors for families can be registered. Also, more and more information has become available on risk factors associated with 'lifestyle choices'. Risk profiling and increased awareness of the consequences of a particular lifestyle carry the promise of enabling the government to steer families more effectively in the direction of acting in the child's best interest. The question is, however, what interventions are desirable or acceptable? Many of the proposed measures may entail intervening in the structure of the nuclear family. The moral upshot of this is yet to be determined.

Fourth, there is the debate on what I would call 'epistemic rights'.[8] The actual heel prick is not very invasive. However, the information that may be obtained can have a substantial effect on people's lives. This raises the question of what rights individuals have with regard to the transfer of information. This issue plays an increasingly large role in different contexts as more and more information on us and our environment becomes available. In particular, in the context of genetics there has been an ongoing debate on 'the right to know' and 'the right not to know'. What does the individual have a right to know? Does he have a right to be protected from potentially harmful information? Whereas informed consent was initially conceived as relevant to physical interventions, the concept of a right not to know challenges our intuitions with regard to consent for information transfer. More fundamentally, this discussion raises problems of how to understand these epistemic rights and their consequences, not only in genetics but also in relation to other types of information dealing with risks and choices (think of, for example, risk assessments with regard to violent behaviour).

There are thus four contemporary debates from which the discussion on the role of informed consent in newborn screening derives its importance. Moreover, not only are these themes interesting and worthwhile discussing separately, there is also scientific value in discussing them in combination; informed consent for newborn screening is but one terrain where the discussions meet, but it is by no means the only one. Debates on for example child obesity, whole genome sequencing in the diagnostic context, consent in the context of addictive behaviour, direct-to-consumer genetic testing and mandatory vaccination all relate to a greater or lesser extent to the issues discussed here.

To be clear, I will not 'solve' all or perhaps not even one of these issues. What I will primarily set out to do is to bring more clarity to the debates briefly sketched above. The main motivation for this

[8] See chapter 7.

is that, despite the main focus of my attention being on the topics connected to these issues, I found myself increasingly dissatisfied with the conceptual framework within which the relevant questions were frequently asked. The answers often seemed reasonable enough, yet the way in which the argumentation was framed equally often seemed inadequate. Also, the frameworks used in the debate were often incompatible, leading to unnecessary confusion and misunderstandings. This thesis should primarily be read as an attempt to elaborate on the arguments which structure these debates, rather than being a specific policy recommendation. However, I will not refrain from stating normative arguments, mainly in the concluding chapters of this thesis.

At this point it is necessary for me to say something about my methodology. This thesis is an essay in applied philosophical ethics. As a consequence, its ambitions are both philosophical and practical. Studies with such a two-pronged aim face an inherent tension: it can be difficult to illustrate the practical relevance of philosophical contemplations, and, conversely, everyday experience tends to get messy and therefore its proper application in abstract discussions is not always apparent. The fact that this tension exists, however, does not imply that applied philosophical ethics necessarily fails in either its theoretical or its practical ambitions. In fact, in recent years this branch of philosophy has been very successful in demonstrating its relevance to both philosophy and policy. Applied ethicists are being taken seriously by policy makers and have earned their place globally in advisory institutions and commissions. However, encroaching on the field of applied philosophical ethics requires caution and subtlety. I will now give a brief sketch of my theoretical principles, in an attempt to pre-empt common misunderstandings.

Philosophy as I understand it is an academic discipline which does not directly depend on empirical data. The primary tools of philosophy are conceptual analysis and rational argument. By philosophical ethics I mean the branch of philosophy that focuses on questions of right and wrong in the context of action and policy.[9] Applied philosophical ethics in turn a sub-discipline of philosophical ethics and attempts to make a relevant contribution to actual problems that arise within a practical context. Engaging in philosophical ethics requires at least the presumption that there is a meaningful way to speak of issues of right and wrong that transcends mere opinion. At the core of any substantial position in ethics on what is right or wrong is either a declared conviction or a normative theory. A declared conviction can be any explicitly expressed intuition or belief that is

[9] Concerning issues on policy, there is an overlap between philosophical ethics and political philosophy. One way to distinguish the two is that the emphasis in the latter is, in general, more on just institutions, whereas philosophical ethics addresses political questions from the perspective of right action.

not backed by further philosophical argument. Philosophical ethics reflects on such explicitly declared convictions, which can either be scrutinized and revised or considered as assumptions. By normative theory I mean a comprehensive theory of right and wrong. Normative theory plays a justificatory role within ethics, although this role is deeply contested. Contrary to declared convictions, normative theory aims to offer a theoretical foundation.

Although my approach is basically philosophical, this does not mean that in the course of writing this thesis I have abstained from empirical input. As mentioned in the foreword to this thesis, philosophical ethics was one of the two disciplines involved in the research project of which this thesis was a part, the other being social science. Specifically, our research team has conducted 'focus groups', a method of qualitative social science.[10] These studies have provided material for me to work with. Input was given on how newborn screening policy might affect those involved and how different stakeholders assessed the developments in newborn screening. The influence of these focus groups on my thesis has, however, been indirect: my conclusions do not depend on empirical data for their justification.[11] The role of empirical input is on two levels: assessing and describing the practical problem and determining how the philosophical argument might affect practice.

With respect to my methodology, two things are important to keep in mind when reading this thesis. First, I interpret the central claim of this thesis – the SIC claim – as a normative ethical claim which calls for ethical analysis. That is, I try to make sense of the policy recommendation to strengthen informed consent requirements from the perspective of what is morally required. In daily practice it is all too often assumed that informed consent is generally necessary or beneficial, but it is an ethicist's job to investigate the normative arguments that underlie a claim. This thesis is an attempt to examine the issue of informed consent for newborn screening at a general level. Its justification will therefore not be valid if it refers merely to tradition, existing laws, personal preference or convenience. Second, I approach the conceptual questions in a critical manner, by which I mean that my analysis has revisionary ambitions: I found myself unsatisfied with the theoretical and conceptual frame of the issue of informed consent for newborn screening, and I will attempt to critically assess this frame in order to improve on it. This means that the resulting conceptual framework is likely to deviate on some points from the use of the concepts in everyday language.

[10] See Detmar et al. (2007) and Detmar et al. (2008).

[11] See Nijsingh & Düwell (2009) for a more elaborate discussion of the relation between qualitative social science and applied ethics.

The criteria for success of such a revisionary project are coherence, conceptual clarity and the usefulness of the analysis to address the problem at hand.

The claim which I will be addressing is the SIC claim: informed consent for newborn screening requires strengthening as the programme expands. In order to assess this claim, I will dissemble it into parts. In doing so, I will assume that informed consent for newborn screening is a meaningful and justifiable practice. This will enable me to determine under what conditions the SIC claim holds.

The structure of this thesis is as follows.

In **part I,** I offer context to the claim that informed consent requirements need to be strengthened to the extent that newborn screening conveys more disadvantages relative to the advantages. The only chapter of this part of the thesis, **chapter 1**, includes a discussion of the Dutch debate on expanding newborn screening. From this discussion it becomes apparent that the interpretation and application of the relevant screening criteria are disputable for an expanded programme. In the debate, opinions varied on what the appropriate expansion is, yet there was remarkable consensus on the point that expansion increased the importance of the informed consent procedure. The controversy surrounding expanded newborn screening is thought to provide reasons for a larger emphasis on thorough informed consent.

In order to assess the SIC claim, I develop in **part II** a framework to understand the normative role of informed consent. Part II consists of three chapters, in which I aim to answer the questions of what informed consent is, how it can be normatively justified, and how it establishes its normative purpose.

In **chapter 2**, I focus on the concept of informed consent. I briefly discuss the origins of informed consent in international law and argue that over a number of years we can identify a common core in the different ways in which informed consent is understood. I propose a conception of informed consent as the expression of practical authority that represents the authority of every individual person to make certain self-regarding decisions. I explain practical authority in terms of exclusionary reasons for action. Exclusionary reasons involve a surrender of judgement to the authority, in this case the subject of consent. I continue to defend the claim that on an institutional level different moral theories can acknowledge an understanding of informed consent as

autonomous authority.

In **chapter 3**, I proceed by examining the normative presuppositions of the principle of informed consent. I discuss and reject justifications of informed consent that refer directly to certain values or goods. The first variety of these direct justifications, the instrumental justification, holds that the purpose of informed consent requirements is that it produces the best decisions. This justification encounters the problem that there is no independent standard against which to determine what decisions are in fact best. The other direct justification, the intrinsic value justification, can give an independent standard, but only at the cost of limiting the role of informed consent to those decisions which affect the course of an individual's life. I argue for rights-based justifications of informed consent, which explain the autonomous authorization relevant to informed consent in terms of the waiver of rights. There are two possibilities for a rights-based justification, explaining rights from either a will theory or an interest theory of rights.

In **chapter 4**, I discuss the standards of informed consent in its institutional application. Under what conditions are the rights as described in chapter 3 best protected? I argue for a 'narrow' account, which focuses on accountability and lists a set of necessary and sufficient criteria for informed consent. This view is opposed to 'broad' accounts, which emphasize trust and the communicative context within the doctor–patient relationship. The main problem with broad accounts is that they insufficiently recognize the potential flexibility of the criteria of consent, and therefore unnecessarily complicate informed consent requirements.

In **part III**, I will look at three features of newborn screening that complicate the application of informed consent requirements in newborn screening procedures. All three features may affect the standards of the required consent.

In **chapter 5**, I discuss informed consent for public health interventions. I examine the tension that exists between the collective and the individual level of decision making in the context of public health. I argue that the authority of individuals to give consent for public health interventions cannot be brushed aside on paternalistic grounds. However, informed consent procedures for public health interventions can be limited on the non-paternalistic ground that it is sometimes impossible for the government to make neutral decisions. If there are relatively weak rights at stake, it may in some cases be justified to apply less exacting standards.

In **chapter 6**, I search for a justifying ground of parental authority. I argue that the child's rights are insufficient to justify parental authority in some decisions. The rights of the parents are inevitably part of a complete account of the discretion of parents to make decisions concerning their children. Next, I argue that, in isolation, the parents' rights have no justificatory power in this respect. I conclude that the rights of parents and those of children should be considered in their interrelatedness. I present a relational account of parental authority, based on the right of both parents and children to engage in intimate relations.

Chapter 7 focuses on epistemic rights: 'the right to know' and 'the right not to know'. I argue that these rights should be based on a notion of privacy. Next, I consider the specificity of the consent regarding epistemic interventions. I argue that this consent should not be aimed at choosing whether or not to receive specific information. Rather the informed consent that does justice to the privacy of individuals is likely to be a 'generic' consent.

Like part I, **part IV** also contains one chapter, **chapter 8**. In this chapter I return to the claim that informed consent procedures should be strengthened when the newborn screening programme expands. I examine ways in which this strengthening could be realized and how the claim could best be defended. I then argue that the SIC claim is not necessarily true, and that different forms of strengthening informed consent for newborn screening may be undesirable.

Part I Surveying the Terrain

In the introduction I have briefly described the claim that I will be investigating in this thesis, which is that informed consent requirements for expanded newborn screening need to be strengthened to the extent that this screening conveys disadvantages relative to the advantages (the SIC claim). In order to address the question of whether and to what extent this is a valid claim, I will break it into parts in this thesis. First, however, I will place the SIC claim in a broader context. Chapter 1 concerns the expansion of newborn screening and the role of the SIC claim in the debate on this expansion.

Chapter 1: Expanded newborn screening

In this chapter, I will explore the debate on expanded newborn screening programmes and, more specifically, the arguments in this debate that emphasize the need for a 'strengthened' informed consent procedure as the disadvantages of screening increase relative to the advantages. After briefly discussing the history and characteristics of newborn screening (1.1), I examine the Dutch debate on the possibilities for expansion and proceed to give a short overview of the criteria that are considered important (1.2). This gives us an indication of the possible advantages and disadvantages of expanding newborn screening and what considerations are deemed important in this respect. I then examine the claim that expansion of newborn screening calls for a strengthened informed consent procedure (the SIC claim) and give a first, tentative, interpretation of this claim (1.3). I suggest that this argument relies on the idea that the increased controversial character of the newborn screening programme calls for better or more thorough informed consent procedures.

1.1 Newborn screening

Newborn screening is the practice of systematic testing for inborn diseases in the first week after birth. Typically, newborn screening involves taking a drop of blood for testing, although other methods are available.[12] The blood is usually taken from the heel of the infant – which is why the procedure is also known as the 'heel prick' – and subsequently tested for a variety of conditions. The amount of blood required is dependent on the amount and type of conditions tested for. Different countries approach the logistical aspect of screening in various ways, but usually either a professional (typically a nurse or a physician) attends people's houses or a drop of blood is taken at the hospital. In some countries, parents will be contacted only when the test comes back positive, whereas in others parents always receive the results. In any case, newborn screening is generally performed as a matter of routine; it is considered a part of the standard procedure of care after birth. Newborn screening differs in this respect from screening of high-risk groups or other selective screening activities, such as cascade screening.[13]

Newborn screening was first introduced in the USA in 1962, and after that many countries followed.[14] Nowadays, screening is performed in, amongst other countries, Japan, Brazil, Australia,

[12] Other possibilities are the 'sweat test' and the use of urine samples (Zie Erbe & Levy (2002), pp. 581-2).

[13] I.e. "the systematically approaching of relatives of patients affected by genetic disorders" (Wert, de (2005a)).

[14] In 1962, a screening programme was implemented in Massachussetts; see Levy & Albers (2000). Pass (2000) dates the beginning of newborn screening as 1957, when a pilot study was conducted in California. See also Erbe &

South Africa and in most European countries. At first screening was performed solely in search of phenylketonuria (PKU), but as technology progressed, more and more diseases have been added to the different screening programmes. Over time the different screening programmes have been expanded in different ways, so that a wide variety of selections has emerged.[15] Some screening programmes aim at thirty or more diseases, whereas others contain only three or four. On the whole, however, the trend is towards expansion. Some countries have a partially or wholly mandatory programme, whereas others do not.

Large scale programmes such as newborn screening require the cooperation of many. The 'screening authorities' – an abbreviation for the collective of laboratories, advisory boards, public health officials, responsible politicians, involved physicians and other professionals who contribute to the screening programme – constitute a rather diffuse and complex network. As a consequence, the implementation of newborn screening is performed by way of a routine and standardized complex of different interactions between professionals rather than a single diagnostic test performed by a physician on a patient, as we would imagine a prototypical clinical scene. As I hope to show later, this has important implications for the normative dimensions of newborn screening.[16]

Newborn screening is, in another respect, fundamentally different from clinical, diagnostic testing. The initiative for screening is taken by the screening authorities, whereas diagnostic testing typically occurs because the patient visits the doctor with physical complaints. Screening mostly concerns *asymptomatic* individuals, who in general seem perfectly healthy.[17] In fact, as we will see below, the diseases concerned are so rare that the child tested more than likely *is* healthy. This too has important normative implications, to which I will return in chapter 8.

The purpose of newborn screening is, in the first place, prevention. A distinction can be made here between primary prevention, secondary prevention and tertiary prevention.[18] *Primary prevention* has as its aim the prevention of a disease occurring. Although disease prevention in this sense plays a role in the background of newborn screening practices,[19] most diseases considered for screening are congenital diseases, and therefore primary prevention is not the aim of most programmes. In

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Levy (1997) for an overview of (the history of) newborn screening.

15 Rimoin (2002), Loeber et al.(1999).

16 In fact, this is a central topic of public health ethics. See chapter 5.

17 See for example Ross (2002), p. 226 and Clarke (1997), p. 108.

18 Verweij (1998), pp. 13-14. In practice these distinctions are not always clear.

19 For example, newborn screening may help to prevent the birth of future affected siblings, although one could argue that it is a stretch to say that this is actually *prevention*. Another theoretical possibility is the detection of susceptibilities for disease, for example diabetes.

screening for diseases such as, for example, PKU, MCADD and CH,[20] the main goal of newborn screening is generally *secondary prevention*, which is aimed at preventing adverse consequences of a disease. Damage to health may be prevented due to early detection and subsequent treatment. For most diseases that are currently part of the screening on offer, early detection can be vital, sometimes literally: timely intervention may save the infant's life. In the case of secondary prevention, the disease itself would not strictly speaking be *cured* in the sense that the 'causes' are eliminated, but still treatment would have a beneficial effect by reducing or even eliminating the symptoms. Thirdly, newborn screening may have *tertiary prevention* as its goal. Tertiary prevention aims not at preventing medical problems but at the creation of better conditions, for example, the adaptation of a house, or the choice of career of the parents of a child affected with the untreatable disorder Duchenne's muscular dystrophy (DMD).[21]

After this brief characterization of newborn screening, I will now focus on the true 'classic of newborn screening', PKU. In order to understand the background of the current expansions of the heel prick, a closer look at screening for PKU will help to clarify the context in which newborn screening was introduced. Screening for PKU is considered the paradigm of newborn screening: it was the first and also is among the least controversial of the diseases screened for.

PKU is an autosomal recessive genetic disorder, which means that if both parents are carriers, their child will have a one in four chance of being affected. If it is affected the child will almost immediately develop symptoms and if left untreated the child will face serious retardation, physical damage and possibly even death. Treatment is simple and effective, however: a diet that is low in phenylalanine will almost entirely prevent these symptoms from occurring.[22] The diet need not be strictly adhered to for the child's entire life, but if a woman who is affected with PKU becomes pregnant, non-compliance can lead to severe damage to the child. It had been known since 1954 that a diet containing little phenylalanine helps to prevent the retardation that otherwise may be the consequence of PKU. The problem was, however, to detect this disease early in order to prevent the manifestation of these symptoms.

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[20] As mentioned, PKU is the abbreviation for phenylketonuria. MCADD is medium-chain acyl-CoA dehydrogenase deficiency and CH is an abbreviation for congenital hypothyroidism. See appendix. All three are popular screening targets and relatively easy to treat.

[21] Shickle (1999), p.1.

[22] In practice this is a diet which is low in proteins.

Although other diagnostic methods existed,[23] the development of the blood spot analysis by Robert Guthrie caused a small revolution in the diagnostics of infant diseases. The main contribution of Guthrie, however, is generally not considered to be the blood spot test itself, but rather its implementation in a large scale screening operation: the birth of newborn screening. Starting from the early sixties, 'universal' screening'[24] for PKU gradually spread, first across the USA and then across many other countries.

In the Netherlands, PKU has a prevalence of 1 in 4,000.[25] Although this amounts to but a few dozen children a year, the screening for PKU is worthwhile. The costs of retardation and the cheap remedy to prevent this from occurring results in PKU screening being cost effective, even if only a few children are diagnosed per year. The blood spot analysis for PKU is reliable and cheap. The Guthrie test has been replaced by more efficient ways of testing, so that now the specificity and sensitivity[26] of testing for PKU is extremely high. The sensitivity of a test depends on the relative number of false negatives (affected children that were missed) and the specificity depends on the relative number of false positives (non-affected children that were falsely identified as being affected). These characteristics notwithstanding, newborn screening for PKU is not *entirely* uncontroversial. Diane Paul, for example, has argued that screening for PKU is not the success story it is proclaimed to be.[27] She argues that there is a real danger of adult female PKU patients not following their diet when pregnant. This leads her to assert the bold statement that "all the benefits of screening may be neutralized by the birth of retarded children to women who have ended the diet".[28] In itself this does not constitute an argument against screening. To establish that, one would have to suggest that it is preferable to prevent this potential damage to future generations rather than preventing the symptoms of PKU from occurring in newborns who already existed. Prioritizing potential and temporally distant damage over imminent danger in this way seems hard to defend, to say the least. Paul has some other notes of warning, however. For example, she points towards the large number of false positives in screening for PKU. As I have already remarked, this no longer applies to the screening for PKU and therefore this argument is now out-dated. However, it does apply to some other current newborn screening activities.[29]

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23 Erbe & Levy (2002), p. 581.

24 Universal screening is screening which is offered to *all* individuals in a certain group, such as all newborn individuals, all males or females above the age of 65 or simply all individuals of a population.

25 In 'non-western' countries PKU is far less common; for example in Japan (which also has a screening programme for PKU) the prevalence is approximately 1 in 100,000. Tada et al. (1984).

26 Schulze (2003). See section 1.2, p. 22.

27 Paul (1994), p. 324.

28 Ibid., pp. 324-5; see also Holtzman (2003).

29 In the Netherlands, screening for tyrosinemia type I was abandoned when it turned out that there were too

Despite the critique uttered by Paul, screening for PKU is generally considered worthwhile and justifiable. Paul's suggestion, however, is not that PKU screening is not justifiable. Rather her point is that "in PKU as in other screening programmes, some kinds of harm have been systematically ignored, thus exaggerating the benefits and understating the harms".[30] At the very least, this is a message worth remembering when considering the ethical dimensions of newborn screening. Her arguments, though not as conclusive as arguments against screening, give us reason for caution, particularly when considering expansion. On the whole, however, due to the obvious benefits of screening for PKU the participation rate has always been very high, even in countries with a non-mandatory offer.[31] In combination with the (current) specificity and sensitivity and the potential medical benefit, screening for PKU can be considered very successful.

The fact that screening for PKU was widely implemented created the opportunity for adding other diseases to the programmes: with the blood samples already being gathered and the logistic apparatus in place, it became possible and relatively easy to screen for other diseases than just 'the classic', PKU. This expansion is the focus of the next section.

1.2 Expansion: the Dutch case

In the previous section, I have introduced newborn screening and described what its initial aim was: screening for PKU. I now turn to the expansions of newborn screening. Many expansions of the screening programme will be relatively cheap, since the infrastructure and the samples are already there. As mentioned, since the introduction of newborn screening for PKU, quite a number of other diseases have been added to the screening programmes. Although this started out with the addition of two or three diseases, some programmes have now expanded to up to dozens of different afflictions. Furthermore, many countries have added very different types of conditions to the screening on offer. The offer may include treatable as well as untreatable conditions, very rare diseases, susceptibilities and carrier status.[32] As a consequence, the reasons for and against an expanded offer have become more complicated too.[33] I will now proceed to discuss the criteria that

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many false positives. See also footnote 43.

30 Ibid., p. 326.

31 See Detmar et al. (2007).

32 Examples of diseases currently screened for are congenital adrenal hyperplasia (CAH), MCADD, sickle cell disease, maple syrup urine disease (MSUD), homocystinuria, CF (cystic fybrosis) and DMD. Other possibilities for screening are Fragile X syndrome and neuroblastoma. See appendix.

33 For discussion on the desirability of expansions of newborn screening, see for example Bailey et al. (2005), Baily & Murray (2008), Wald (1998), Wilcken & Travert (1999) and the President's Council on Bioethics (2008).

are deemed relevant to these expansions.

The purpose of this section is twofold. First, discussing these criteria will help position this thesis in the current debate on expanded newborn screening. Second, I want to present some of the complexities related to expanded screening; this leads to the observation that such expansions may not unequivocally be a blessing to the families involved. As I will show in section 1.3, the possible disadvantages of screening play a crucial role in the claim for strengthening consent. I will focus mainly, but not exclusively, on the Dutch situation. The Dutch expansion of the newborn screening programme and the debate that surrounded this expansion will serve as an illustration of the complexities of the issue at hand.

The Dutch newborn screening programme originates from 1973. As in other countries, at first this screening was limited to screening for PKU. In 1981, CH (congenital hypothyroidism) was added to the programme and in 2000, CAH (congenital adrenal hyperplasia). In 2005, the Dutch Health Council (Gezondheidsraad (GR)), an advisory board to the Ministry of Health, published a report, which was largely adopted following a governmental decision in January 2007, advising an expansion of the Dutch screening programme from three to eighteen diseases. The GR assumed five main criteria for newborn screening, the first three of which were inspired by the criteria of J.M.G. Wilson and G. Jungner in their 1967 World Health Organization (WHO) report.[34] According to the GR, the suitability for a disease to be added to the newborn screening programme depends on these five criteria:

> "The disorder should be clearly described, there should be a suitable detection method and the treatments should actually be available and accessible. Moreover, participation in screening is voluntary and participants should be properly informed."[35]

The first three of these criteria, which directly refer to the expansion, I will discuss in this section; I will return to the last two, which concern the accompanying informed consent procedure, in 1.3.

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[34] Although generally ethical advisory boards tend to place great value on Wilson and Jungner's criteria on screening, not all follow them. For example the Nuffield Council on Bioethics (1993) follows Lappé (1972). Interestingly, the GR does not mention the first criterion of Wilson and Jungner "*The condition sought should be an important problem*", which is often considered to be a necessary criterion. Although it has been suggested (e.g. by Shickle (1999)) that it is added to Wilson and Jungner's list for reasons of net utility, I believe that in that case a different formula would have been more appropriate. It is more likely that the criterion either demands that the disease screened for is very widespread *or* that the disease is a very serious one. On this reading, the principle sets a threshold for screening.

[35] Gezondheidsraad (2005), pp.20-1.

My purpose is not to defend any position on the justifiability or proper interpretation of the criteria used by the GR (or in the WHO report), but merely to sketch the considerations that are deemed important in the Netherlands in the discussion on the expansion of newborn screening. This will help me to frame the question on the relation between the expanding newborn screening programmes and the call for strengthened informed consent procedures. Since the GR appeals directly to Wilson and Jungner, I will occasionally refer to the original text of the WHO report when discussing the criteria of the GR.

"There should be a suitable detection method"

This criterion corresponds directly to Wilson and Jungner's fifth criterion ("*there should be a suitable test or examination*").[36] This criterion of the suitable detection method implies minimally that there should be a *reliable* test, in the sense that it produces information that is clear, relevant and correct. Obvious as this may seem, the implications are of significant practical relevance. A disease that is rejected for screening on the grounds of this criterion – as far as I am aware, worldwide – is Fragile X syndrome, a disease that causes a variety of mental impairments. There is no uncontroversial way to test for Fragile X.[37] Such screening has been proposed but not implemented, the reason being that the test only gives indirect information on the chance of being affected.

The need for the test to be reliable also has implications for the question of to what extent it is able to isolate all and only those people who are affected. Any screening programme is bound to have false negatives and false positives.[38] The obvious problem of false negatives is that affected children do not receive a timely diagnosis. False positives are considered a problem for the newborn screening logistics and might lead to anxiety for parents.[39] The sensitivity of a test depends on the number of true positive test results in relation to the number of patients actually being affected. A relatively large number of false negatives therefore mean the test is low in sensitivity. The specificity of a test is derived by relating the number of true negative test results to the total number of those without the disease (true negatives plus false positives). This means that a relatively high

36 Wilson & Jungner (1968), p 27.
37 Bailey et al. (2001), Bailey et al. (2008).
38 Shickle (1994).
39 Gurian et al. (2006).

number of false positives indicate a low specificity.

For quantitative tests, the specificity and sensitivity partly depend on the choice of the cut-off point. The cut-off point is a chosen point of deviation from the average of what is measured; anything beyond this point is considered a positive result. Roughly, if this point is low, then consequently a larger number of children will be considered positive; conversely if the cut-off point is higher a larger number of cases will come back negative.[40] Of course this in itself is not to say that these are *false* positives and *false* negatives, but since there is a margin of error it may be held that a high cut-off point correlates with a larger number of false positives and a low cut-off point with a larger number of false negatives.[41] Since technologies such as tandem mass spectrometry (MS/MS; see appendix) are very reliable methods of testing, the number of false positives and false negatives is estimated to be very low for most diseases that are currently being screened for. However, there are two things to note here. First, for extremely rare diseases, even if the test has a high specificity, the 'positive predictive value' (the proportion of patients with a positive test result who are correctly diagnosed) of the test can still be very low.[42] Second, not all diseases considered for screening can be detected by way of MS/MS and some which can are significantly harder to detect in a reliable manner.[43]

Another complication concerning the suitability of the test is that some screening programmes deliver results on diseases not sought or give additional information on carrier status, implying that the child has the genetic predisposition to transmit a disease to the next generation without being affected himself. An example of the first is where screening for MCADD delivers results on the related – but much more rare – disease, MADD.[44] An example of the second is that screening on CF can deliver the result of people being merely carriers.[45] This 'unsought' information is often considered to be an undesirable side effect of those screening programmes,[46] which raises the

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40 President's Council on Bioethics (2008), p.13.

41 A complication which we will encounter shortly is that the answer to whether something is to be regarded a false positive or a false negative depends partly on the definition of that disease. Furthermore, if a deviant value is measured, this could deliver a false positive for one affliction, but that in itself does not imply that this value does not point to another malfunction. In such a case, it may be possible that something is found other than that which one is looking for.

42 Ibid.

43 For example, tyrosinemia type I (a disease that causes liver malfunction). This disease was initially added to the expanded newborn screening in the Netherlands, this decision was temporarily revoked when it turned out that there were too many false positive results. The reason that this test is unreliable is that the symptom – a high level of tyrosine – can point to more than just one cause. In 2008 tyrosinemia type I was again added to the programme.

44 Multiple acyl-CoA dehydrogenase deficiency, also known as glutaric acidemia type II (GA-II). See appendix.

45 Gezondheidsraad (2005).

46 See, however, Parsons et al. (2003). In some cases unsought information can also be seen as a positive side

dilemma of whether or not to communicate this information to those involved. If the unintentional finding is communicated to parents, this means *de facto* a further expansion of the screening programme. Not only are they now informed about whether a child has, for example, CF, but also of their child's carrier status for CF. If, however, this information is withheld this means discarding potentially relevant information on an individual's health status.

The criterion of the suitability of the test should not be mistaken for a directive purely based on efficiency: the value of this criterion is strongly connected to the idea that it is wrong to subject people to tests that are unreliable or deliver ambiguous or unsought results. This criterion presents policy makers with complex and problematic choices: at a certain point it has to be decided which cut-off point is optimal, whether the test is sufficiently accurate and whether other aspects of the test (such as the possibility of finding information not sought) can be considered acceptable.

The first criterion of the GR raises the question of when a test is considered sufficiently reliable. What number of false positives and false negatives is acceptable for a specific test? What balance can be struck between the two? Also there is the issue of what to do with unsought information. Given their problematic character, these issues are likely to be the topic of debate as the newborn screening programme expands. Its application and interpretation is open to dispute.

"The disorder should be clearly described"

According to the GR, this principle means that it should be known what the natural course of the disease is,[47] but also knowledge of the variation of the seriousness of the condition and prevalence are also required. This seems to be a common sense requirement of proper policy and scientific, methodological purity: one should formulate the goals of screening clearly before commencing. I interpret this criterion as implying that it should be clear what constitutes a positive test result. Two points ought to be noted.

One aspect of this criterion is that the question of whom we should consider a patient and whom not is not easily answered in relation to some diseases that are part of or candidates for newborn screening programmes. For example, Anne Kerr has shown that the question of what counts as an

effect, for example the detection of carrier status will be considered valuable information by some people.

[47] Gezondheidsraad (2005), p. 38. See also Wilson & Jungner's (1968) seventh criterion, p. 27.

instance of CF is to an extent dependent on 'a social construction'.[48] Apart from the problems of sensitivity and specificity mentioned earlier, this means that the answer to the question of who to treat as CF patients is to an extent a matter of decision: do we treat a patient with mild or unclear symptoms as a case of CF? If we do, we risk overtreatment. If we do not, the patient may suffer needlessly.

Secondly, some diseases suitable for screening – for example some amino acid deficiencies, such as the aforementioned MADD – are extremely rare and therefore not studied much. The development and prognosis of these diseases are often far from clear. The question arises of whether such lacunas in scientific knowledge add up to an argument against screening for these diseases. It may, on the contrary, be held that screening is a useful tool in finding out more about them. However, both the GR and Wilson and Jungner[49] seem to exclude screening for these largely unknown diseases.

Darren Shickle mentions that the dismissal of diseases where the natural course is not known should not be as strict as is sometimes suggested.[50] For example, in the case of AIDS, even when the natural history of the disease was still not adequately understood, that in itself does not seem to be a decisive argument against screening for HIV. In the case of genetic screening, however, we are dealing with non-transmissible diseases. Therefore, there may be a stronger case for the argument that we *should* be careful in implementing this specific type of screening, particularly when it is uncertain in what way and to what extent the disease will affect the life of the patient. At the very least, we need to be able to anticipate the possible consequences of screening in order to judge whether detection is meaningful.

The second criterion is based on the idea that screening only seems to make sense when we know what we are screening for and why. Like the criterion concerning the screening method, this is more than just a demand for efficiency. It seems irresponsible to search for information when we do not yet know whether and how it might benefit the subject. This criterion, too, is likely to be a topic for debate in its interpretation and application.

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[48] See Kerr (2000). See also Hedgecoe (2003) on the classification of CF. To an extent, the same goes for many of the diseases that are part of screening programmes. Also worth mentioning in this context is Fragile X (Shickle (1999), p. 19), where the seriousness and nature of symptoms emerging varies a lot.

[49] Wilson & Jungner (1968): "The natural history of the condition, including development from latent to declared disease, should be adequately understood."

[50] Shickle (1999), p. 12.

"The treatments should actually be available and accessible"

In considering an expansion of the screening programme, the treatability (which is not the same as curability) has long been one of the decisive criterion in newborn screening. The GR distinguishes three categories.

First, there are the treatable conditions ('type 1' diseases), where early detection and subsequent treatment can prevent physical damage. I have already mentioned PKU, but there are quite a few more. The GR lists seventeen diseases that fall into this category. What they have in common, apart from their treatability, is that the treatment is, for the most part, relatively cheap and easy. The second category ('type 2' diseases) is those where treatment is possible, but the medical value of early detection and treatment is equivocal, or at least controversial. An example is CF. Although in recent years impressive results have been made in the treatment of CF, it is still controversial whether or not newborn screening improves the health of the child. The symptoms of CF appear gradually, and therefore there is usually enough time to start treatment after a clinical diagnosis. The third category ('type 3' diseases) is that of conditions that are generally regarded as untreatable. For these diseases, the only possibility of 'prevention' is tertiary prevention. Examples are DMD and MADD.

The criterion of treatability, Wilson and Jungner themselves claim, is "perhaps most important".[51] Interestingly, this is also the principle that is currently most discussed and most controversial. As mentioned in the previous section, there are differing degrees of treatability among the diseases that have been mentioned as suitable for screening. Screening for the untreatable DMD has even been implemented in several locations in the world.[52] From this perspective it is remarkable that not only did Wilson and Jungner find this principle very important, they also found it very obvious: "For declared disease there is, *of course*, the ethical obligation to provide an accepted treatment".[53] I take this to mean that there is a duty not only to provide treatment when available, but also – since it is a criterion for screening – not to screen for diseases for which there is no treatment available. If we suggest screening for DMD we thus either have to reject this criterion or argue for a wider understanding of the term 'treatment'. This latter strategy is sometimes chosen.[54] For example it

[51] Wilson & Jungner (1968), p. 27

[52] One example is Wales, where extensive research has been done on the social impact and medical success of this screening programme. See for example Bradley et al. (1993).

[53] Wilson & Jungner (1968), p. 27.

[54] "Benefit to the family will also certainly benefit the child during his (her) life": Wilcken (2003). See also

has been argued that a positive test result for DMD enables people to make lifestyle adaptations and to adjust their expectations for the future, which may also benefit the child. Also, timely diagnosis may provide opportunities for counselling.[55] Furthermore, the family may be spared a 'diagnostic odyssey',[56] which can also be seen as indirectly beneficial to the child. It has also been remarked that early physiotherapy enables patients to deal with their affliction in a better way, which can be seen as a medical benefit. Lastly, early detection of DMD may have implications for reproductive decisions: when DMD is diagnosed early the parents know that there is a 25 per cent chance that a future sibling would be affected too. This enables the parents to avoid the birth of another child with DMD.[57] The advantage to the affected child, so it is argued, is that the parents have more time and resources to spend on it than in the case of them having two children with DMD.[58] All this, however, is *not* how Wilson and Jungner intended the criterion. They speak explicitly of treatment that affects the 'course and prognosis' of the disease.[59] There seems to be a presumption in Wilson and Jungner's approach that *medical* procedures need to have *medical* benefits.[60] Of course, we need not accept this assumption without an additional argument; in fact, this presumption has been increasingly challenged.[61]

A very different instance of screening, where there is no direct treatment available, is the screening for carrier status. For example, Tay-Sachs disease carrier screening (Tay-Sachs is an autosomal recessive disease which is considered to be virtually untreatable) has been implemented in different communities.[62] Information on a child's carrier status is of no medical benefit to that child. However, this knowledge does enable the child to make choices in reproduction when it reaches maturity.[63] This may be seen as a benefit (not having children that are born ill), but it cannot be called a treatment.

Bailey et al. (2008), Campbell & Ross (2003), Cornel et al. (2007), Schickle & Chadwick (1994).

55 See Mohamed et al. (2000).

56 Clarke (1997), p. 113.

57 Bushby et al. (1999).

58 Gezondheidsraad (2005), p.53.

59 Ibid., p.28.

60 We can see a correlation between the three criteria mentioned here, when interpreted in this way. All three criteria emphasize the importance of ensuring that an infant directly benefits from a certain screening procedure. For this benefit to be present it is necessary that there is an unambiguous result that is known to be of medical use. See Saxena (2003), who speaks of 'direct medical benefits'.

61 See Green (2006) and Ross (2006b). In the Netherlands the patient organization VSOP (Seldenrijk (2005)) explicitly challenged this presumption in response to the GR report. Oosterwijk & Meutgeert-Dekker (2007) argued that the criterion of treatability needs to be replaced with a terminology that does justice to the always shifting boundaries of medical knowledge and expertise, although it remained unclear how exactly this new terminology should be elaborated upon.

62 Kaback et al. (1993).

63 Dependent on the type of disease, there are different options: think of screening a person's partner for carrier status, embryo selection and prenatal testing.

As with the previous criteria, we can see that the criterion of treatability raises several issues that are open to dispute. This criterion is the most controversial of the three. Not all commentators agree on treatability as a criterion and, if they do, opinions still differ strongly on its interpretation. The general conclusion of my brief discussion of the three criteria is that although they are widely accepted, their application and interpretation are not. When considering the expansion of newborn screening, one needs to take into account that the disagreements run along different axes: there are different types of advantages and disadvantages of screening and different considerations to take into account.

Debate on the proposed expansions

I have presented thus far three criteria of the GR: the disease should be well defined, there should be a suitable test and there should be a treatment available. For each criterion substantial – and sometimes controversial – considerations come into play in its interpretation and application. Of the criteria discussed, the last criterion received the most attention in the report: although the GR considers treatability to be an important criterion, they do not take a dogmatic stance on it, allowing for the possibility of screening 'type 2' and 'type 3' diseases. However, while the Dutch health council does not categorically rule out screening for ‘type 2’ and ‘type 3’ diseases, the advice emphasizes that currently the expansion should be limited to diseases in the ‘type 1’ category, with the sole exception of CF, which is categorized as a 'type 2' disease. The main consideration for the GR thus seems to be treatability. This leads the GR to recommend expanding the heel prick by adding fifteen diseases.[64] However, although these diseases share the feature of treatability, the GR acknowledges that “the severity and treatment of the diseases would vary more than in the present screening programme”.[65]

As mentioned, the Dutch government has largely adopted the views of the GR, and introduced an expansion of the heel prick in 2007 to a total of 17 diseases (that is, all of the recommended diseases with the exception of CF, which followed by in 2011). The report and the subsequent expansion provoked some public debate. Most of the responding authors acknowledged the

[64] They are, in alphabetical order: biotinidase deficiency, cystic fibrosis, galactosemia, glutaric aciduria type I, HMG-CoA lyase deficiency, holocarboxylase synthase deficiency, homocystinuria, isovaleric acidemia, longchain hydroxyacyl-CoA dehydrogenase deficiency, maple syrup urine disease, MCADD, 3-methylcrotonyl-CoA carboxylase deficiency, sickle cell disease, tyrosinemia type I and VLCADD (very-long-chain acyl-CoA dehydrogenase deficiency).

[65] Gezondheidsraad (2005).

desirability of expansion, although some did point out that it was not unequivocally a blessing. For example, Henriette Roscam-Abbing accused the GR of having an eye only for the positive sides of expansion while ignoring the darker sides. She worries particularly about (unsought) information without direct medical benefit, such as carrier status or diseases where treatment is difficult, and emphasizes that such information can be considered burdensome. Roscam-Abbing suggests that the GR has been guided by the technological possibilities, rather than by the question of what expansion is desirable.[66] Much of the debate, however, focused on the question of whether the extent of the expansion was sufficient. Although it is generally acknowledged that the credo 'the more, the better' does not apply here, many experts have a positive attitude towards the possibility of expansion, even beyond the proposed expansion. There are diseases that can be detected by way of MS/MS, but they have not been deemed to fit the criteria. In fact, this technology requires that certain information is consciously ignored in order to limit the findings to those diseases the screening was intended for. Some of this information concerns lesser known or untreatable diseases. To withhold this information, some argued, would be to close one's eyes to information that is readily available, thus withholding from the parents important information on the health of their child.[67] Another point that was brought forward was that DMD should be added to the programme because this would offer significant reproductive advantages, as well as sparing parents a long, tiresome diagnostic road. This argument constitutes a rejection, or at least stretches to an important degree, the third criterion of the GR, that of treatability.

This brief discussion shows that the expansion of newborn screening raises issues that are open to debate. The interpretation and application of the criteria are controversial. Not all possible expansions are unequivocally beneficial and there are many different considerations to take into account when considering these expansions. This leads me to the last two criteria of the GR of the five mentioned earlier, that the "screening is voluntary" and that the "participants should be properly informed".[68] These criteria do not relate directly to the desirability of expansion, but rather to the implementation of a specific offer.

On these criteria there was a remarkable consensus. Both proponents and opponents of expansion lauded the GR for stressing the necessity of informed consent for expanded newborn screening. Specifically, authors pleading for further expansions also argued for *strengthening* the informed

66 Roscam-Abbing (2006).
67 NRC Handelsblad (2007a), Volkskrant (2007), Seldenrijk (2005).
68 Gezondheidsraad (2005).

consent procedure, thus agreeing with the GR that there is an important relation between the moral requirement of informed consent and the expansion of the heel prick.[69]

1.3 The Strengthening Informed Consent (SIC) claim

In this section I give a first sketch of the claim that the expanded newborn screening calls for strengthened informed consent (the 'SIC claim'). Supporters of this claim argue that routine informed consent procedures (let alone a mandatory procedure) do not suffice for expanded newborn screening. I will interpret this primarily as a claim about standards of informed consent: the formal requirements that determine whether the informed consent is valid. The SIC claim holds that these should somehow be upgraded in comparison to the current less demanding standards.[70]

At first it may seem surprising that the biggest proponents of expanded screening are also fervent defenders of a thorough informed consent procedure. One could hold that if the relevant criteria are fulfilled, the question of informed consent becomes superfluous. If there is a case for expansion, why should we stress the importance of the option to refuse? Is the argument for expansion not based on the idea that screening can provide worthwhile information for children and their parents? A brief look at current international literature, however, reveals that the link between the possibility of expansion and the presumed necessity of informed consent is often made.[71] This thesis is for the most part dedicated to understanding and interpreting the SIC claim. For now I just want to look at the possible motives of the GR and others that subscribe to the claim that the question of expansion is closely related to that of the need for a stronger informed consent procedure.

The GR states that:

> "The expansion that the Committee recommends would mean that the severity and treatment of the diseases would vary more than in the present screening programme. This complexity necessitates providing more information while ensuring that it is still possible for parents to understand it. This involves providing information they reasonably require to take their decisions on screening."[72]

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69 Volkskrant (2007).

70 In this section I will only give a sketch of what this means. I will return to the question of how this strengthening is to be done in chapter 8.

71 See for example the quotes below and the quote by Austoker mentioned in the introduction. See also: Clayton (1992), Horn (1997) and Pelias & Markward (2001) .

72 Gezondheidsraad (2005), p. 24. Implicitly the report seems to suggest that the current standards of informed

This raises the following question: how does the observation that expansion of newborn screening leads to more complexity lead to the increased importance of informed consent procedures? One line of thought could be that it is *mere* complexity that calls for more intensified attempts to gather proper informed consent. At first sight, this seems to be the argument of the GR in the quote above. The argument could be that whereas all the relevant information was easy to grasp when the programme was limited to screening for just one or a few diseases, the diversity of the screening programme has vastly increased and that therefore the information supplied should be correspondingly diverse. It seems more likely, however, that what is meant here is that the importance of the informed consent procedure increases, and therefore subjects should not only receive *more* information, they should also be *better* informed. We can see this when focusing on a somewhat hidden assumption in the argument. The GR mentions information that parents *reasonably require*. In other parts they speak of diseases that differ in "relevant aspects". This raises the question: relevant for what? What makes the information that parents require *reasonably* necessary?

The argument implicitly assumes that as the reasons for dissent become more prominent the importance of a thorough informed consent increases. As we have seen, however, in the case of PKU there is little reason to stress the option to dissent. Screening for PKU is relatively uncontroversial. Every selection within an expanded screening programme will raise the question of whether the expansion is sufficient or, on the contrary, too expansive. Expansions will, in different ways, deviate from the paradigm case of PKU. Since there is a wide variety of possible expansions, this will raise more controversial questions on the desirability of expansion.

This points towards a slightly different argument: the argument that an expanded offer is more problematic and therefore cannot be assumed to be in accordance with everyone's wishes. In this argument the increased *controversy* (and not just *complexity*) of expanded screening offers a reason for strengthening the informed consent procedure. Look at the following quote:

> "As the benefit-to-risk ratio becomes less favorable, the moral necessity of seeking parental permission for screening increases as does the reasonableness of parents to refuse."[73]

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consent are insufficient for the present purposes too.

[73] Press & Clayton (2000), p.515.

From the observation that there are advantages and disadvantages, it is concluded that informed consent grows in importance. Consider also the following quote of Adrian Edwards:

> "The ethics of screening require more [than full assessment]: the recipients (or in this case their parents) should be able to give informed consent to the tests. The potential seriousness and emotiveness of the conditions tested for (for example, cystic fibrosis, Duchenne muscular dystrophy) are such that specific pretest counselling and consent ought to be prerequisites."[74]

Here, it is the "seriousness and emotiveness" of a positive outcome that necessitates informed consent. Edwards refers to the fact that "not everyone will be reassured" by the outcome of the test and points out that there may be "enormous implications". It is this line of reasoning, which focuses on controversy rather than mere complexity, which seems to underlie the case for strengthened informed consent procedures for newborn screening.

The argument would have to go something like this. *Newborn screening up until recently has been a relatively uncontroversial public health intervention. Nowadays, however, possibilities for expanding the newborn screening programme have vastly increased. Though expanded screening may be considered desirable, there is by no means consensus on the question of what the content of the screening programme should be. There are reasons to deem the addition of a number of diseases to the programme desirable, but these reasons are not as straightforward as in the relatively simple case of PKU. For some of these conditions there are also good reasons against screening. Thus, there are mutually exclusive reasonable perspectives on the desirability of expanding newborn screening. For this reason it seems unjustifiable for the government to impose one specific perspective (i.e. one selection of diseases) on the entire population. Therefore individual citizens should be offered the opportunity to dissent as well as consent. This requires a better and more thorough focus on the informed consent procedure that accompanies this programme.*

The argument above is a rough sketch of the main argument for the Strengthening Informed Consent (SIC) claim. I will not straightforwardly address the argument until the last chapter, chapter 8. What I hope to have shown so far is that the debate on the expansion of newborn screening appears to raise questions about the proper accompanying informed consent procedure. These

[74] Edwards (1996).

questions relate to the heightened controversy of the newborn screening programme.

1.4 Conclusion

Since the introduction of newborn screening, the content of the screening programmes has expanded drastically. At first, screening was performed solely for PKU, but a great variety of diseases have been added to the programmes and more are being considered. At first these expansions included mainly diseases such as the 'success story', PKU, where it was manifest that early detection would provide the infant with clear medical benefits. Currently, more controversial diseases have been added to or considered as candidates for screening programmes. As I have shown in the case of the Dutch newborn screening programme, these (possible) expansions lead to a number of questions concerning which diseases are suitable for screening. I have illustrated the complexity of these questions by discussing the Dutch Health Council's (GR) criteria: the suitability of the test, the clarity of description of the disease, and treatability. These criteria have led the GR to recommend expanding the programme from three to eighteen diseases in the Netherlands, a policy which has now largely been adopted. Some have argued that these current expansions do not suffice and that more diseases could and should be added. However, the discussion seems to tend towards one point of consensus, which is that expansion calls for a strengthening of informed consent procedures (the SIC claim). I have considered this argument and suggested that it depends on the idea that the heightened controversy of expanded newborn screening necessitates a more thorough emphasis on the requirements of informed consent.

I will proceed by giving a general analysis of the concept of informed consent in part II of this thesis. In part III I will address three complications: the public health dimension of newborn screening, parental authority and informed consent for knowledge. Finally, in part IV I will return to the question that arose in this chapter: do the possibilities of the expansion of newborn screening call for a strengthened informed consent procedure?

Part II Informed Consent

In part I, I introduced the issue of the development of newborn screening. Due to their expansion, newborn screening programmes have come to include diseases that for a variety of reasons are more controversial than the initial screening for PKU. Referring to the Dutch case, I have argued that the current debate shows a tendency towards the idea that this development calls for thorough informed consent. I have tried to reconstruct this argument. In its most persuasive form it focuses on the increased controversy surrounding expanded screening; informed consent standards need to be strengthened to the extent that newborn screening becomes less of an undisputed blessing. If the advantages of screening are controversial and the disadvantages increase, people should at least be offered a choice, so the reasoning goes. In order to assess the conclusion of this argument, the SIC claim, it is necessary to analyse the concept of informed consent. In part II I develop a framework for the concept of informed consent, enabling me to apply this framework to the specifics of newborn screening in the remaining part of this thesis. Three questions need to be answered. First, of course, I will need to say what informed consent is (chapter 2). Further, informed consent is often presumed to be of both great legal and moral importance,[75] but in order to assess the SIC claim I will need to spell out exactly why it is of such great moral importance (chapter 3). Lastly I will have to expound on how it establishes its purposes in an institutional setting (chapter 4).

[75] A common presumption underlying the "doctrine of informed consent": "[...] Informed consent is seen as not merely a legal requirement, and not merely a formality: it is a substantial requirement of morality" (Freedman (1975)). See also the introduction to this thesis.

Chapter 2: The Concept of Informed Consent

Despite its history of only a few decades, the doctrine of informed consent has been very influential in the thinking about the morally justified behaviour of health care professionals. Although some authors tend to downplay the importance of informed consent,[76] it is safe to say that it is generally considered to be one of the central concepts in modern medical ethics. Despite this popularity, there are surprisingly few systematic philosophical accounts of the concept of informed consent.[77] In this chapter, I examine the concept of informed consent and develop an account of informed consent as autonomous authorization. In 2.1 I explore the history and international (legal) context of informed consent and suggest that a common core can be identified in the use of the concept of informed consent throughout the years. Central to the concept is the notion of authorization. In further elaboration on this point, I discuss the notion of practical authority in 2.2. In 2.3 I show how practical authority applies to informed consent. The requirement of informed consent entails abstaining from judgements 'on the merit' of a certain course of action.

2.1 Informed consent over the years

In order to set the stage for an analysis of informed consent this section gives a brief overview of the origin and common use of the concept. I will suggest that there is a permanent core in the concept of informed consent in its history of over six decades; informed consent should be understood as an authorization. I do not intend to make an empirical claim, but rather a normative one; my aim is to reconstruct the normative core of informed consent. The historical context serves as the background and starting point for my conceptual argument later in this chapter.

The origin of the informed consent doctrine in international law can be traced back to the 1947 Nuremberg Code.[78] Confronted with the WWII atrocities, or, more precisely, the sickening medical experiments which the Nazis conducted on human subjects before and during the war, a need arose for a new Code that was to bind medical professionals to certain ethical standards, beyond the

[76] See for example Dawson (2005b) and Manson & O'Neill (2007). I will discuss some criticisms of the modern-day emphasis on informed consent in the course of this and the ensuing chapters.

[77] The *locus classicus* is Faden & Beauchamp (1986). See also, for example, Brownsword & Beyleveld (2007), Dworkin (1988), Feinberg (1986), Katz (1984), Manson & O'Neill (2007), Vorstenbosch (1990).

[78] The notion of consent has been around longer than this, playing a prominent role in, for example, contractualist theories of the state (Manson and O'Neill (2007), p.3, Vorstenbosch (1990), p. 56). The specific use and content of the modern-day notion of 'informed consent' in a biomedical context, however, is usually traced back to the Nuremberg Code. See Faden & Beauchamp (1986) for a more elaborate account. See, however, Vollman (1996) for the claim that "the basic concept of informed consent was developed [in Germany] long before the second world war" and furthermore this "did not prevent crimes against humanity".

traditional 'Hippocratic' values, which were deemed insufficient to protect patients against the possible harms of research. As a prerequisite for consent, the Nuremberg Code states that "[the person involved] should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."[79] The Nuremberg Code particularly emphasizes the necessity of preventing fraudulent, coercive or deceitful conduct towards research subjects. According to Neil Manson and Onora O'Neill,[80] the 'volenti maxim' ('no injury is done when the subject is willing') was the guiding principle underlying the Code's emphasis on consent.[81] The role of consent was to provide "assurance and evidence that there has been no 'force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'".[82] This phrasing raises a lot of questions: is it impossible to harm someone when there is consent or are there exceptions? When is there enough "assurance and evidence" to establish whether a subject is 'willing'? In what cases does the requirement of informed consent apply – what is its scope? Under what conditions can the doctrine of informed consent be overruled? What are the adequate criteria to ensure informed consent? I will put aside these questions for now and return to them in chapters 3 and 4. In this chapter my focus is on the question of what we mean by the term 'informed consent'.

According to Manson and O'Neill the standards and scope of informed consent have shifted over the years. They argue that the application of the term informed consent has drifted away from the initial purpose of the Nuremberg Code, which related to the *volenti* maxim. Both the application and the underlying justification of informed consent have changed, they claim. If they are correct to say that the role and justification of informed consent have shifted, this may mean that we have to reconsider the concept; which is exactly what Manson and O'Neill propose. They hold that the shifts in the standards and scope of informed consent are symptomatic of a faulty understanding of the concept of informed consent. I do not wish to elaborate too much on this argument here. Much of this discussion will play a role in chapter 3 – where I discuss the justification of informed consent –

79 US Council for War Crimes (1949).

80 Throughout this thesis, I will refer to Manson and O'Neill (2007) and O'Neill (2002). Although they are certainly not the only ones who have published on the topics I am concerned with, they do offer a currently very influential systematic account of informed consent (amongst others in the field of public health), explicating many of the arguments often left implicit in other accounts. Furthermore, on some points their account starkly contrasts with the account that I prefer. Although I will at some points be critical of their work, my criticism should not be taken as an outright rejection of their theory. Particularly on the point of the role of informed consent as a 'second-order right' (see section 3.3), I am much indebted to their work.

81 Manson & O'Neill (2007), pp. 3-4. Being harmed differs in this respect from being merely disadvantaged. See Aristotle (Ethica V:11) for an interesting parallel to this point. See also Feinberg (1986).

82 US Council on War Crimes (1949), p. 181. Exactly how (or if) informed consent can establish this is the topic of chapter 4.

and chapter 4, where I examine the standards of informed consent. For now, I wish to focus on the suggestion in this argument that the shift in the application and use of informed consent is indicative of a more fundamental change in the conception of informed consent.

The general thrust of their argument is that accounts of informed consent have become increasingly individualistic and demanding. They argue that the way of conceptualizing informed consent has drifted away from its initial purpose towards a misguided ideal of rugged individualism, leading in turn to changed standards and scope. Roughly their argument is that informed consent has become more and more an ideal which emphasizes the blessings of free choice. The focus on individual autonomy leads to a conception of informed consent where informed choice is valued as worthwhile in itself. From this it would follow that providing more information and offering more choice in an expanding number of areas is to be considered a ”good thing”.[83] According to Manson and O'Neill, this shift necessitates a rethinking of the concept of informed consent. Since I will attempt in this chapter to give an indication of the proper conceptualization of informed consent, this shift is of interest here. What exactly do Manson and O'Neill think has changed?

Manson and O’Neill argue that since the Nuremberg Code there have been three notable changes in the use and application of the concept of informed consent.[84] First, the scope of informed consent has expanded. The Code focused only on medical research, whereas nowadays informed consent is considered relevant to *all* medical interventions. Second, the standards have been raised. For example, the very influential Helsinki Declaration not only requires consent, but adds that this consent should be obtained ”preferably in writing”.[85] Also it is no longer deemed sufficient to merely *enable* the subject to make a decision, it is required that subjects *actually* make a free and informed decision. According to Manson and O'Neill, this raises the standards beyond the requirement that subjects are protected from grave harm to much more exacting and even over-demanding standards.[86] More generally, recent treaties have emphasized explicitness and specificity of information, more so than the Nuremberg Code did. Third, Manson and O'Neill hold that whereas the intention of the Nuremberg Code was to prevent coercion, manipulation and the like, the more recent documents rely on 'individual autonomy' – meaning the ideal of individual independence – as a justification for informed consent. Later statements emphasize notions of

[83] Ibid. pp. 32-4. Of course, this argument hinges on the conception of 'individual autonomy' that one adheres to, an issue to which I will return in chapter 3.
[84] Manson & O'Neill (2007), chapter I.
[85] Helsinki Declaration (2004). The Helsinki Declaration, first drafted in 1964, is generally considered to be one of the landmark documents in the recent history of informed consent.
[86] Manson & O'Neill (2007), p.7. I will return to this point in chapter 4.

independence, self-determination and choice, which are absent in the Nuremberg Code.

Although Manson and O'Neill are certainly correct to point out that there have been changes in the use and application of the concept of informed consent, I want to emphasize that the implications of this must not be exaggerated. I will show in the remainder of this section that despite the shifts noted by Manson and O'Neill, it is possible to identify a core conception of informed consent throughout the years.

Certainly, Manson and O'Neill point towards a change of emphasis on the importance and interpretation of informed consent. But does this reflect a *substantial* difference in approach between modern day thinking on informed consent and its more 'modest' roots? Manson and O'Neill certainly seem to think so and are very keen to point out the differences, but I am not so sure. I am not convinced that at this point it is necessary to conclude that these differences are large enough to warrant the claim that the current use and application of the term informed consent differs substantially from the way it was originally intended. There is more consistency between the different understandings of informed consent than Manson and O'Neill suggest. To illustrate this, I now return to the third change they identified, which was that the focus in the later reports is on 'choice' rather than 'consent'. Whereas the Nuremberg Code seemed to focus on the protection of subjects, later treaties and judicial verdicts seemed to place more emphasis on the notions of 'choice', 'self-determination', 'individuality' and so on. I want to briefly linger on this point. I hope to show that it is at least possible to construct continuity in the use of the concept. The way to do so is by focusing on the notion of 'authorization' implicit in the concept.

As mentioned, Manson and O'Neill believe that the shift reflects a different attitude towards the role of 'individual autonomy', interpreted as individual independence:

> "Conceptions of *individual autonomy* have risen to prominence with the revival of liberal political and economic thought during the last forty years, and have also now become central themes in medical ethics and research ethics. It is easy to see why those who see autonomy as a matter of individual independence link it so closely to informed consent: informed consent procedures protect individual choice, and with it individual independence."[87]

[87] Ibid. pp. 16-22.

Indeed, since the 1970s judicial documents on informed consent have had a strong 'liberal' and individualistic ring to them. Take for example the following statement: "The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his *own determination on treatment*".[88] From the Nuremberg Code to later statements, the emphasis has shifted from protecting subjects against harmful interventions to the exercise of autonomous agency in choosing the preferred treatment. In the Nuremberg Code the challenge seemed to be 'merely' to prevent the occurring of force, fraud, deceit and so on, that is, practices that are considered morally wrong by any reasonable standard. The focus was thus apparently not on enabling choice or on enhancing an ideal of individual autonomy.

How should we understand the shift towards an apparently more 'choice orientated' understanding of informed consent? My claim is that the justification in the different formulations is not fundamentally different, or at least it need not be interpreted as such. I will propose an interpretation which is consistent with both the Nuremberg approach to informed consent and more modern applications. For this, we need to consider more closely the shift in the application of informed consent requirements. According to Manson and O'Neill, the preoccupation with choice caused a larger domain of application to develop. It is, however, equally possible to see matters in the reverse way: perhaps the shift from consent to choice can be explained with a reference to the application of the requirements: a broadened scope could lead to a stronger emphasis on individual preferences. As mentioned, over the years, particularly since the 1970s, there has been a growing tendency to apply informed consent requirements not only to the non-therapeutic research context but to any intervention in the medical domain. While the Nuremberg Code refers only to research subjects (without distinguishing between therapeutic and non-therapeutic research), it seemed a natural step to transfer this demand to other fields, specifically the clinical context, which is what increasingly happened.[89] Of course, 'natural' does not mean 'unproblematic'. Precisely what is being disputed by Manson and O'Neill is the broadening of the scope of informed consent. If, however, as we have assumed, the goal of informed consent is to prevent abuse, coercion, fraud and so on, there seems no *a priori* reason to presume that these are not at issue in the clinical context.[90]

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88 Canterbury v. Spence 1972, quoted by Faden and Beauchamp (1986), p. 96 (my emphasis). Compare also the phrasing in the Belmont Report: "the opportunity to choose what shall or shall not happen to them". See also Faden and Beauchamp (1986), p. 133.

89 Manson & O'Neill (2007), p. 4.

90 This is the 'double standard' argument: if informed consent is important to protect research subjects, why is it

Over time, informed consent has come to be seen as a general restriction on health care workers' discretion.[91] The purpose of clinical care is, however, entirely different from that of research; in the latter the primary goal is to enhance medical knowledge and thereby to improve the health of people other than the research subject, or perhaps society as a whole, whereas in the former the focus is (or at least should be) on curing the patient. Note that this is the reason why the concept of 'paternalism' has come to play a large role in the informed consent literature.[92] Contrary to its goal in the research context, the goal of informed consent in clinical medicine is often to protect patients from interferences for their own good. What is often considered to be problematic in relation to the absence of consent in the clinical situation is that the choice of what is good for a person is taken out of that person's hands. In other words, paternalism – not abuse – is often the issue in clinical medical ethics. If, for example, a doctor proceeds with surgery without proper informed consent, what is problematic is often not that the patient is being used to the advantage of others, but that the doctor takes away the possibility for a patient to make his own decision on whether to proceed or not.

I submit that the reason why the choice of different options is stressed in clinical ethics, rather than merely the 'choice' of whether or not to participate in research ethics, might be indirect: proper disclosure requires that alternatives are given. For example, in the Belmont Report this is precisely what we find when the requirement is stated that the health care professional should not "withhold information necessary to make a considered judgment".[93] This is strikingly reminiscent of the Nuremberg Code formulation. Recall that the Code speaks of "sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision". Here we find the central elements of the notion of informed consent in a nutshell: a voluntary consent, which requires the understanding of sufficient and adequate information. The question is – and this is where the Code and later documents differ – what counts as "sufficient knowledge and comprehension"? This is different for the different fields of application (not to mention the topic of constant legal and philosophical controversy).[94] Whether

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not equally important to protect patients? See Levine (1995), p. 1282 and Cassell & Young (2002), p. 315.

91 This is evident from the Canterbury v. Spence verdict, see note 88, which is concerned with 'patients' rather than 'research subjects'. See also O'Neill (2002), pp. 37-42.

92 See chapter 5 for discussion on the concept of paternalism.

93 Belmont (1979). It should be mentioned here that the Belmont Report focuses on research. However, research ethics too has become more sensitive to the different decision-making contexts, for example in discussion of therapeutic research. Determining what counts as 'necessary information' will thus be dependent on the type of research concerned.

94 In contrast, see Manson & O'Neill (2007), pp. 16-17, where they claim that recent discussions on informed consent differ in a fundamental way in their justification from the initial intentions of the drafters of the Nuremberg

a patient's permission can be seen as valid is partly dependent on the type of intervention. For some interventions it suffices to offer a very limited set of options ('yes' or 'no'), while for others a more elaborate offer is required. If this is correct, the choice emphasized in later documents is not something different from 'mere' consent, but rather a specific way to implement the requirement of consent in this context. If we take into account the changing scope of informed consent requirements, the shift from consent to choice should not surprise us too much. Central to the different formulations is the notion of *authorization;* the idea that what matters in consent is not primarily the content of the choice that is made, but rather that the choice is made by the consent giver: the *author of the choice*. The subject's permission is necessary for the moral justifiability of a certain intervention. The shift primarily concerns *what* is being authorized. Whereas the Nuremberg Code focused solely on the possibility of research, later statements included *all* medical interventions. This implies that in some contexts, specifically the clinical context, choice becomes an integral part of the informed consent procedure: a subject of a treatment can clearly not be deemed 'properly informed' if he is not aware of the alternatives available, simply because often there *is* more than one option for treatment. In non-therapeutic research, it generally seems inappropriate to use the notion of choice, other than whether the subject wants to participate or not. By contrast, in the clinical context it appears that respect for patients implies offering different options, given that often different courses of treatment are available. If this is correct, 'authorization' has been the central concept of interest over the years, and the concepts of 'consent' and 'choice' are of importance in as far as they are needed to specify how this authorization comes about.[95]

To summarize, I have shown that whereas the Nuremberg Code referred only to research and had a narrow emphasis on the individual decision-making process of research subjects, later documents had a greater emphasis on individual choice. Yet at this point there is no reason to assume that this signifies a substantial shift in the way that the concept of informed consent has been understood, if interpreted as a requirement that aims to ensure valid authorization by the subject or patient. I have argued that, viewed in this way, there is more continuity in the usage than there seems at first glance. I have yet to show, however, the viability of the analysis of informed consent in terms of authorization. I will proceed by taking the notion of authorization as a point of departure for the analysis of the concept of informed consent and to further specify the content of the concept of informed consent and the role of authority in it.

Code.

[95] This is not so much a historical point on the intention of the drafters, but rather a suggestion for how to read the informed consent doctrine in current legislation, that is, as one that centres on the idea of authorization, rather than on decision making. See Beyleveld and Brownsword (2007) and Brock (1987), pp. 99-100.

2.2 Authority and exclusionary reasons

After this brief introduction, I will now dig deeper into the concept of informed consent. I have suggested that the core of informed consent – authorization – has remained more or less the same over the years. I shall elaborate in this section on the concept of practical authority and discuss its role in conceptualizing informed consent in section 2.3. In the documents mentioned in the previous section, informed consent was brought to the stage as a necessary condition for the justifiability of at least some medical interventions. The essence of it is this: if, for example, a doctor wants to perform surgery, he should first ask permission from the patient.[96] This is the principle of informed consent in a nutshell: whenever a physician wants to perform a medical procedure, informed consent is a necessary (albeit not a sufficient) requirement for the moral acceptability of this procedure. This claim is considered to be evidently true by many ethicists. We may wonder what it entails and what its normative status is. Why is informed consent necessary to morally justify medical procedures? What happens when someone gives an informed consent? An obvious reply to these questions is that informed consent *authorizes* certain acts; the patient has the discretion to decide whether or not a certain medical intervention is allowed. 'Authority' is ascribed to agents; the exercise of this authority is an authorization. It is used both as a term for something that one *has* and something that one *is*. The specific authority that one has (or is) determines what one is authorized to decide.

To illustrate how (practical) authority functions, consider the following example. Suppose I am training for a sports event and I have found a coach whom I meet on a regular basis in an attempt to improve my strength and stamina. This coach – let us call him Ben – does voluntary work on the municipal track and trains different athletes on a purely disinterested basis. The likely reason for me to engage in this coach–pupil relationship is my belief that a coach is more capable than I am in assessing what training would benefit me. Ben has more knowledge of physiology and – not unimportantly – less pity on me when I am exhausted. Thus, whenever we meet, Ben decides what exercises I should perform and my role is simply to perform them. In other words, in the context of my conditioning training, I treat Ben as an authority. I should emphasize at this point that I do not wish to make a claim on whether, in this example, Ben actually holds legitimate authority over me.

[96] Of course, issues of informed consent do not arise in the relationship between physician and patient only; instead, informed consent is potentially relevant for many interactions between individuals. However, following much of the literature, I will speak here mainly of this specific relation, at least until I address the issue of informed consent in public health care in chapter 5.

This example merely serves as an illustration, in which I assume that he does. Now, suppose I am at the end of a training session, and consequently I am very fatigued. I might in these circumstances be of the opinion that it would be better to stop training. Perhaps I am a bit ill, or I have been training very intensely for the past few days and so I'm worried that I might 'overtrain'. Also I might take into consideration that if I stop now, I might be able to get a bus back home. All in all I might judge it best to stop training, yet Ben tells me to run another lap. And I do so. Clearly Ben has balanced the relevant reasons in a different manner, or has taken different reasons into consideration, and decides in favour of continuing. He might not even be aware of all the reasons that mill around in my head. Yet his command is decisive in determining what I will do. There is a sense in which we can say that this is a situation where I deem it best to stop running but do not act accordingly. Now, I would argue that the fact that I actually obey his command and run another lap can be understood as an example of 'second-order reasoning': Ben's directives overrule my 'first order' assessment of the situation.[97] Even if you judge it best to stop running, when your coach tells you to run one more lap, respecting his authority entails running one more lap, regardless of your own assessment. Crucial in understanding this authority relation is that Ben is the one who decides; in a way, it is not *up to me* to decide on the matter. Furthermore, this obedience towards my coach is not necessarily irrational: implicit in the notion of second-order reasoning is that it can be rational to act against one's own judgement of what is best. From the reader who does not find this explanation compelling, I ask for a little more patience, because I want to make some remarks on the type of reasons in play here.

How should my obedience towards Ben be understood? One might be tempted to construct Ben's directive as one among the reasons for or against continuing my ordeal. On this construction his command functions as a first-order reason: it *adds weight* to the sum of considerations pro-continuation. The fact that Ben tells me to run another lap adds to the relevant considerations, thus tilting the balance of reasons in favour of continuing. In this section, I will propose an alternative understanding. I will suggest that this understanding does more justice to the fact that I have *delegated* my decision making. My reason to engage in this relation in the first place was that I needed someone to make my decisions *for me*: I have entrusted Ben with the decision making. From this perspective, it seems more accurate to say that Ben's command *replaces* my own

[97] This way of framing the point might lead to some confusion with first- and second-order mental states, specifically desires and beliefs (see for example Frankfurt (1971)). Higher order mental states play a role in my obedience towards Ben, but should not be mistaken for authority relations, which, as I will argue below, derive from normative relations between agents.

judgement, rather than adding a new consideration to it.[98] The point of delegating decisional authority in this way was that it is in the long run the best way to achieve my goals of enhancing my strength and stamina. Therefore, even if in a particular instance I firmly believe Ben is wrong, I follow his judgement – up to a point, of course.

According to this interpretation, the authority of Ben offers reasons that are in a sense external to my deliberative process. This feature of Ben's authority can be captured by saying that authoritative directives function as second-order reasons. Following Joseph Raz, I will call reasons that annul certain substantive ('on the merit') reasons, *exclusionary* reasons. An exclusionary reason is defined by Raz as a "second-order reason to refrain from acting for a reason".[99] Ben's directive to keep running is *exclusionary* with respect to my first-order ('on the merit') considerations.[100] This consideration does not oppose the considerations in favour of stopping, but instead it nullifies them and renders them, as well as those reasons to the contrary, irrelevant.[101]

This description accounts for the fact that I seem to 'surrender my judgement'. The outcome of the decision plays a different role in practical deliberation to the reasons which are not backed by an authoritative agent. What this way of describing the matter offers from a theoretical perspective is that it explicitly addresses the fact that Ben's directives are themselves the result of a deliberative process on the merit of continuation. When I obey an authoritative directive, I presume that the authority has taken into account all, or at least a sufficient number of, the relevant reasons.[102] It would generally not make sense to obey Ben if I suspected that he was, for example, randomly distributing orders without giving them any thought or merely thinking of his own interests. The reasons that he should take into account need to be relevant to his role as coach. The authority that he has been given was given to him on the presumption that he exercises this authority in a way that corresponds with the reasons for giving it to him. This means that in obeying Ben, I acknowledge that he has sufficient authority to make the decision, based on the relevant reasons for and against

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98 Raz (1975), p. 39. See also McMahon (1987), p. 306. Note that this way of phrasing my relationship with Ben and my deliberation need not be representative of all or even any pupil–coach relationships. The point here is that we can imagine such a relationship based on authority within which the authority's reasons function in the way I describe.

99 Raz (1975), p.39.

100 I thus claim that every authoritative reason is an exclusionary reason. Whether there are exclusionary reasons that are not based on authority is an issue which I will not address here.

101 Compare a similar distinction in Brownsword & Beyleveld (2007), p. 61: "[...] whereas a substantive (or, 'on the merits') form of justification refers to some set of background standards characterising (in the justificatory argument) particular acts as permitted (including required), a procedural justification refers to an authorising act or decision."

102 This has been captured by saying that the second-order reasons' terminology precludes 'double counting' of reasons (Raz (1975)).

continuation. The reason for me to disregard my own first-order reasons is precisely that I must suppose that Ben has taken at least some of these reasons into account.[103] Ben is a deliberator, and in attributing authority we assume that he takes into account the relevant reasons. He may be fallible, but to the extent that he is an authority he must consider the merits of a course of action.

This brings me to the question of the conditions of Ben's authority. Even though in this explanation, in terms of exclusionary reasons, the authority of my coach renders arguments in favour of stopping void, by no means is this authority absolute or immune to counter-considerations. The authority to order me to run another lap is dependent on a variety of background assumptions and contextual factors, amongst which are other authority relations. Moreover, Ben's authority should correspond with the normative framework which underlies our relationship: it is only then rational to obey Ben's commands if I assume that he legitimately exercises his authority.[104] Conditions under which it would not be rational to follow his directives are, for example, when he asks me to do something that is against the law or when he commands me to run another lap when I have just sprained my ankle. Also there are various situations conceivable when it would be legitimate for me to discontinue our relationship, for example if I think that his methods do not work. Ben's authority is conditional upon my acquiescence: our relationship is based on the fact that I have agreed to the terms. In this respect, Ben's authority differs from the authority of, for example, a judge, which is thought to hold regardless of whether or not a person recognizes this authority. Here too, however, there are limits to the legitimate exercise of authority.

There are a number of scenarios in which it would be rational not to comply with Ben's commands. The point here, however, is that if exclusionary reasons cancel the weight of certain first-order considerations, they do so by pre-empting their content: whether or not there are such substantive reasons in favour of or against continuing to run is irrelevant *within* the context of an authoritative relationship. In this sense this relationship sets a threshold: given a certain context (in this case, the coach–pupil relationship), and up to a certain extent, it does not matter what I think, that is, what reasons I entertain 'on the merit'. This threshold can perhaps be illustrated by a variation on the example I have been considering. Suppose now that it is the end of the training session, and instead

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[103] This distinguishes the exercise of authority from, for example, the tossing of a coin. See Hartogh, den (2002), p. 141.

[104] The difference to keep in mind here is between legitimate and *de facto* authority. De facto authority is the same as legitimate authority in its claims, but differs from legitimate authority in not necessarily being justified. See Raz (1986), p. 26. This raises the questions of when and why authority is legitimate. From a moral perspective, the answer will depend on the normative presumptions of the authoritative relation. I cannot address this issue here. My purpose here is merely to illustrate the notion of practical authority. However, I will return to the question of the moral presumptions of informed consent in chapter 3.

of ordering me to run another lap, or do push-ups or any of the other exercises that Ben usually has in store for me, Ben says, "Today you can decide for yourself how you wish to finish your training; you are free to stop, but you can also run another few laps if you want to." This command is likely to confuse me. And, although I may have been cursing Ben for his previous commands, it may trigger a deliberative process, perhaps even resulting in the decision to run another few laps. What this variation of the example illustrates, I think, is that as long as Ben is the one who decides, his reasons are decisive, and my own thoughts on the merit of continuation do not have an importance, even to me. When the threshold of Ben's authority falls away or is exceeded, my own reasons become relevant in considering what needs to be done, but not before that.

Let us take stock. I have suggested that there are reasons (first-order reasons) which justify, by virtue of adding to weight to the balance of reasons pro or contra, a certain course of action. The choice of action will be substantively justified if, all things considered, the weight of the considerations tilts one way or the other. In contrast, an authoritative reason offers an exclusionary reason for action that is not based on first-order, substantive reasons, but rather on authority. This authority pre-empts first-order reasons.

Whether or not exclusionary reasons offer an appropriate description of authoritative relationships remains an open question. Not everyone is convinced that they do. One could argue that from a deliberative perspective, all we have to go on is the assessment of the strength of different considerations for or against a course of action. To return to my example, a critic could suggest that my commitment to Ben or my fear of my peers' disapproval is so great that it may *seem* that considerations of the opposite are cancelled, but the only thing that actually differs is the strength of the different considerations. This critic would hold that Ben's command simply adds one more consideration (albeit perhaps a strong one) to the set of relevant considerations, thereby rejecting my proposal to understand authority in terms of exclusionary reasons. This view relies on a powerful account of the relation between rationality and human action. It holds that it is rational to do what one has overall most reason to do, which seems to exclude the possibility of exclusionary reasons. For example, Govert den Hartogh has argued that a "surrender of judgement" is in tension with the "truism" that it is irrational not to do what on the balance of reasons one has most reason to do.[105] Therefore he doubts whether the concept of exclusionary reasons, which presupposes such a surrender of judgement, is a viable one. Can this challenge be met? I think it can, but I hasten to add

[105] Hartogh, den (2002), pp. 129-31.

that there is a sense in which the point is obviously correct: it is evidently true that there is a way in which that which we have most reason to do derives from a process of weighing the reasons involved There is a trivial sense in which the claim that it is rational to do whatever we have most reasons to do is true. Certainly, the fact that I am engaged in an authoritative relation with many different people adds to my overall judgement in determining what is best to do. They are not mysterious forces that drive me in an incomprehensible manner. However, the identification of exclusionary reasons takes place on another level. There is a normative perspective from which it makes sense to distinguish between first-order substantive and second-order authoritative reasons.

First of all, it is important to distinguish between different examples of 'surrendering judgement'. Often when examples are offered by either proponents or opponents of exclusionary reasons of (legitimate) authority, the examples referred to are those where a person judges it best to leave a certain decision to someone who is better equipped to deal with the practical problem at hand. For example, when an amateur sets out to climb a mountain, it is often a good idea to let a guide decide whether or not to cross a certain glacier. Or, to take another example, it can be rational to leave certain complex decisions concerning financial matters to someone else, particularly if one feels weary or upset.[106] In these cases, the fact that I have reason to follow other persons' directives depends on my own inability to appreciate the arguments for and against a certain course of action.[107]

This is, however, not practical authority in the sense I had in mind when introducing the case of Ben and me. Characteristic of these examples is that I do not surrender my judgement but rather use other people's judgement, assuming that someone else will assist me in making a better decision. One only has reason to follow the 'directives' of the mountain guide or the person taking care of one's finances in as far as one has reason to believe that they are right. If somehow I come across information that contradicts their verdict, I have no reason to follow their directive. Therefore, what these 'authorities' claim contributes to my balancing of reasons. On the contrary, the exclusionary reasons which Ben offers are, again, up to a threshold that is independent of whether Ben is right or not. This indicates that my actions can be described on different levels.

To see this, consider Den Hartogh's argument with respect to coordinating authority. By way of

[106] Raz (1975), Hartogh, den (2002), pp. 134-5.
[107] Hartogh, den (2002), p.135.

example, he discusses a football match.[108] He suggests that following the instructions of one's coach that one does not agree with can be understood without reference to exclusionary reasons:

> "Following a superior strategy on your own is not a way of improving your chance of winning. You are only required to "surrender" a judgement that, perhaps, would have been valid in the hypothetical situation in which no authoritative instructions had been given, or in the equally hypothetical situation in which you had been able to give them yourself."

Granted, if following a strategy on one's own is not a way of improving one's chances of winning, it follows that the balance of reasons would dictate that one follows the team strategy. But what if that's not necessarily the way of improving the team's chances? It is an annoying, yet fascinating, aspect of very good players that they sometimes diverge from the team strategy, often resulting in victory. We have conflicting attitudes to the way in which we approach such stubborn players. On the one hand we praise them, but on the other we reproach them for not being 'team players', even if their actions result in goals. In this example it is perhaps debatable whether the directives given to the individual player offer exclusionary reasons, that is, whether the reproach towards disobedient players should be understood in another way than in terms of which strategy proves most effective for the purpose of winning. However, if we consider one of Raz's original examples, concerning military disobedience, the conflicting attitudes come to the fore even more .[109] He discusses the problem of determining the right attitude towards disobedient subordinates: "armies have been known to solve such problems by both decorating and court martialling the individual concerned for the same action".[110] Here the authoritative structure is much more explicit and formal than in the case of a soccer team, and therefore it is all the more apparent that the action can be described from different levels, leading to different conclusions. Whether or not we believe that in the case of the football match there is exclusionary reasoning going on, we may conceive of situations in which this is the proper description. It makes sense to describe the situation of the disobedient football player as one in which he did the right thing in one sense and failed to do the right thing in another.

The fact that certain authoritative directives have been given creates a social reality in which one has reason to follow a certain course of action which one otherwise would not have. But this establishing of authoritative reasons is quite different from the examples where the issue was

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108 Hartogh, den (2002), p.142
109 Raz (1975), pp.41-2,
110 Ibid. p. 43.

whether the agent is epistemically capable of assessing specific reasons. It is not merely because the coach is more knowledgeable that he is the one giving the directives: rather the authority has force in itself. This was the case even in the example of Ben. The reason that I engaged in an authority relationship was partly that he is more knowledgeable than me (the other was that he has little pity on me). However, as long as Ben and I maintain the athlete–coach relation, I have a second-order reason to obey his commands, albeit within limits. To illustrate this, consider the fan who sees his favourite team lose match after match while he sees perfectly what should be done in order to ensure victory (this is a feeling of frustration familiar to most football enthusiasts). This fan may shout his directives for ninety minutes during the match (and additionally approach individual players outside the matches who might even agree with him), but it is still unlikely that anyone will follow his directives. The reason nobody listens to the fan's advice is not necessarily that the fan is less knowledgeable on the topic of what needs to be done (ex hypothesi he is). The reason is simply that it is merely *advice*, since he is not the coach and so is not in a position to issue directives.[111] The status of authority requires recognition. Without the attribution of authority, there is de facto no authority. This does not imply that authority is 'in the eye of the beholder'. The status of authority at least needs to be recognized by *the right* persons or institutions. In this example, what will crucially matter in determining whether someone has the authority as a coach is whether the club and the football association recognize him as such. What matters here is that it is the coach who gives the orders. If the players disobey and ignore the coach, they are disrespecting his authority, not merely not following his advice. They may have good reasons for this, but they also still have reason to obey in as far as the coach holds authority over them. Indicative of this is that they will typically feel the need to justify themselves for this disobedient behaviour or be called upon to do so. This is the normative sense in which exclusionary reasons can be distinguished from first-order reasons. It is not primarily a claim about my deliberation, but rather about relations between persons.

So far I have done no more than sketch a way to understand authoritative directives. A critic might still object and point out that there is no reason at this point to assume that there are any other reasons than substantive reasons for acting. My claim, however, is that in order to understand the normative importance of authority we need a conception such as the one I have described in this section. Specifically, as I will argue in the next section, I think that if one denies that there are authoritative reasons for actions, it is not possible to maintain a conception of informed consent that gives moral or legal discretion to individuals to decide on certain self-regarding matters. How does

[111] Thomas Hobbes makes a similar distinction between command and counsel. See Leviathan XXV.

authority function in informed consent requirements?

2.3 Informed consent as autonomous authorization

I will now apply the account of authority as described in the previous section to the notion of informed consent. In this section I introduce and describe the term 'autonomous authorization' as a description for what informed consent establishes and give an indication of what questions need to be answered in order to give more content to that term.

If informed consent should be understood as a type of authoritative directive, the authority expressed is the source of exclusionary reasons, silencing considerations 'on the merit' of a certain course of action. This means that if, for example, a patient indicates that he does not want to undergo a certain procedure, this functions as an exclusionary reason for the doctor in the sense that whatever his 'on the merit' assessment of the situation is, it is irrelevant to the justification of the intervention. The patient has authority to make decisions; he gets to decide what happens to him.[112] Informed consent is based on the idea that some decisions (such as those that interfere with a person's body) are *wrong* for anyone but that person himself to decide upon: what is relevant for the justification of a specific decision is not primarily its content, but rather who makes the decision: who the source of the directive is. The authority expressed by informed consent is of course a very different exercise of authority to that in the examples mentioned in the previous section.

An important difference between informed consent as an exercise of authority and, for example, Ben's authority as a coach is that the latter refers to the authority attached to a specific role, whereas the first apparently does not. Ben's directives (or for example the directives of a CEO or a state official) do not derive their force from the authority of an individual person, *qua* an individual person. I listen to Ben because he is the coach. By contrast, the reason that informed consent is necessary is not that certain specific individuals have authority by virtue of their role, but rather that informed consent expresses an authority that everyone possesses in virtue of being a person.[113] This implies that the authority to consent does not refer merely to a specific role that an individual fulfils (for example the role of being a patient or that of a person who is entitled to claims on the grounds of their health care insurance). If the authority related to informed consent is not connected to a

[112] See Brock (1987).

[113] Some authors have pointed out that this is an individualistic approach that does not fit well with cultures that attach great value to the role of the family in medical decision making. See for example Chan (2004), Fan (1997) and Fan & Tao (2004). I recognize that authority could be attributed to families as well, but this is not my present topic. I will return to the role of the family in decision making for children in chapter 6, however.

specific role we have to look for properties of persons in general in explaining such authority.

What properties of persons are relevant to the authority to give consent? Obviously, a person needs to have decision-making capacity. Without the ability to make intentional decisions, it makes no sense to attribute authority.[114] However, this is not a distinguishing feature. All legitimate authority requires the capacity to make decisions. In the case of informed consent, the fact that a person has the capacity to make decisions is directly relevant to the source of the authorization. Somehow we attach moral importance to people making their own decisions.[115] Informed consent is a means to respect people in their decision-making capacity. In giving or withholding consent, I am making a self-regarding decision: *I* decide whether *I* want to undergo surgery. Since this is a requirement that applies to all, respect requires that I do not make decisions for another person. This means that a theory of informed consent needs to explain what decisions count as appropriately self-regarding. For the validity of consent it is minimally necessary that the person involved comes to his decision in the absence of external constraints such as force, fraud, coercion and the like.[116] Otherwise, the consent could not properly be said to be *his.* This is what one might call, for lack of a better word, the constraint of freedom.[117] Note that this constraint does not preclude the doctor expressing his opinion on what is best. It is consistent with respecting the patient's authority to advise him on the decision to be made, as long as it is clear that the decision is the patient's to make. The authority of competent persons to make self-regarding, free decisions, I will call autonomous authority. Informed consent is the expression of this authority.[118] Autonomy is a notoriously contested concept.[119] In the next chapter I will try to explicate how a specific conception of autonomy can be understood as a source of exclusionary reasons, thus contributing to a justification of informed consent. First, I will address a possible counter to the claim that informed consent should be understood as involving an autonomous authorization.

Some authors (often called 'welfarists', although I will argue that this classification does not cover both sides of the dispute adequately), explain the purpose of informed consent in terms of what is

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114 See Beauchamp & Childress (2001), p. 58.

115 See chapter 3.

116 Recall the Nuremberg criteria for informed consent, where it was emphasized tthat here should be no “force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion”.

117 Important and necessary as this condition may be for our understanding of informed consent, it is also very hard to determine both practically and theoretically when exactly it is met. When is a subject free to decide? Where does informing end and manipulation begin? Can financial compensation impair freedom of choice? These and many more questions relate to the condition of 'freedom'.

118 See Beachamp & Childress (2001) and Faden & Beauchamp (1986).

119 See Dworkin (1988), pp.5-6.

best for the patient. Authors such as Dan Brock and – more recently– Mark Sheehan, have argued that it is possible to explain the discretion of patients to make self-regarding decisions with a reference to the principle of beneficence: the obligation "to act for the benefit or good of others".[120] If, in the justification of informed consent, welfare is the decisive criterion, the question of determining the appropriate informed consent procedure may seem a matter of weighing up which course of action improves upon the welfare criterion the most. If this is correct, the welfarist seems to resist the distinction between reasons 'on the merit' and authoritative reasons. The welfarist position therefore seems to imply not only a denial of a central role for autonomy in explaining informed consent, but also a sceptical position on the very possibility of exclusionary reasoning as applied to informed consent requirements. A closer look, however, reveals that this implication is not inevitable. In order to show this, I will consider the welfarist objection to the use of the term autonomy in explaining informed consent. I will hold that there are two ways to interpret this claim, one of which is implausible, the other being in line with my characterization of informed consent as autonomous authority.

Mark Sheehan describes what he calls 'the conflict problem', where a doctor must choose between respecting a patient's decision and doing what is (medically) best for the patient. Sheehan argues that what he calls 'autonomists' depict this conflict as 'pitting beneficence against autonomy'. According to Sheehan, there is no need for an opposition between trying to enhance or protect a patient's autonomy on the one hand and improving his well-being on the other.[121] One could understand 'autonomy' as a function of well-being, particularly if one assumes that well-being is at least partly dependent on preference fulfilment. The way to accomplish this is to point out the intertwinement of the preferences of the patient and their well-being. As Pellegrino and Thomasma state, "the best interests of the patients are intimately linked with their preferences".[122] Therefore, Sheehan argues, informed consent is misconstrued if it is understood as a matter of opposing values: autonomy on the one side and beneficence on the other. If this is true, then the importance of informed consent can indeed be wholly explained in terms of well-being and there is no need to refer to autonomy as a source of exclusionary reasons.[123]

This view has been criticized by Beauchamp and Childress, who claim that it amounts to "little

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120 Brock (1987) and Sheehan (2003). It must be noted that Sheehan is primarily concerned with paternalism, not informed consent; however, he addresses this problem in a way that is directly relevant to the issue at hand.

121 Sheehan (2003).

122 Pellegrino & Thomasma (1988), also in Beauchamp & Childress (2001), p. 176.

123 Sheehan (2003), p.129.

more than a restatement of the autonomy model".[124] Beauchamp and Childress argue that to stress the importance of patient consent amounts to an affirmation of the importance of autonomy, regardless of the justification of this principle. The welfarist can safely acknowledge this: his point is not to deny the importance of autonomy *per se*, but rather to show that the conflict problem can be described wholly in terms of well-being. It seems therefore that the question of what course of action should be followed (i.e. what reasons count as decisive) in the case of a conflict between autonomy and what is best for a patient is determined with reference solely to the weight of the reasons involved. However, we need to look at precisely what point the welfarist wants to make.

The welfarist's claim can be interpreted in both a strong and a weak sense. The strong interpretation is that he denies the possibility of attributing any specific authority to the patient. This option, a flat denial of the role of authority in informed consent requirements, is particularly unattractive. If one holds that there is no special significance of the source of a certain directive, it becomes hard to see what consent could even mean, other than a way for the patient to signal his preferences. If this is the correct interpretation, it is obscure as to when a doctor should be reproached for failing to gather informed consent. As I mentioned in section 2.1, informed consent emerged as a way to protect patients. This protective function can only be established if the practice of giving informed consent is embedded in an institutional context. The principle of informed consent presupposes that a physician can be held accountable for failing to respect a patient's power to consent. This accountability can only be taken seriously if the voice of the patient is more than the signalling of preferences: the patient should be considered to be a proper source of authority.

To this it may be replied that this authority is still one of the sources of reasons that bring a certain weight, and that physicians who disregard informed consent balance their reasons incorrectly. This, however, would be to miss the point, which is that we need to distinguish between the perspective of the individual physician and the institutional perspective from which the patient is endowed with discretionary power. If a physician bypasses the will of the patient, he fails to acknowledge that it is not up to him to decide. He did not make an incorrect assessment of the situation, but rather it was wrong for him to substitute his judgement for that of the patient. In the weak interpretation, the welfarist acknowledges that there is a sense in which we can talk about exclusionary reasons as provided by patients, but that this authority has a bearing at the institutional level. On a justificatory level, this welfarist would claim, we need to look at what procedures best promote patient well-

[124] Beauchamp & Childress (2001), p. 176.

being. In the weak interpretation, the welfarist is committed to the view that individual subjects have the authority to make certain self-regarding decisions.[125] As mentioned in the previous section, the status of decision maker needs to be recognized by the appropriate persons or institutions. This in turn raises the questions of when and where authority should be attributed to individual subjects.

Two issues need to be separated when discussing the welfarist/autonomist discussion with respect to informed consent. One is the question of whether informed consent is best conceptualized as autonomous authority; the other is the issue of the moral justification of this authority in either well-being or some other moral category (e.g. the 'right to autonomy'), to which I will turn chapter 3.[126]

I have stated that informed consent expresses autonomous authority, which is a source of exclusionary reasons. This is a point which even a ('weak') welfarist must concede. This leaves open, however, the question of how this authority is acquired. What is the rationale behind the exclusionary reasons offered by consent? What is necessary at this point is a justification for thinking that such decisions are worthy of our respect. Why is it that informed consent procedures should protect autonomous decision making, and what does this imply? This is the topic of the next chapter.

2.4 Conclusion

In this chapter I have examined the concept of informed consent, and have suggested analysing this concept in terms of authority. I have argued that authoritative directives can be understood as sources of exclusionary reasons, reasons which overrule first-order ('on the merit') reasons, by virtue of their source, the authority. I have applied this to the concept of informed consent and proposed that informed consent is a special type of authoritative directive: autonomous authorization. The source of this authority is the individual that makes certain self-regarding decisions. This raises the question of from where this authority derives its normative force. The

[125] Of course, the proponent such a position would have to make plausible the claim that informed consent serves the moral purpose of enhancing the welfare of the patient. I will argue in the next chapter that this is not unproblematic if one tries to do this directly, that is, without the use of a notion of waiver of rights. An indirect account, however, is still an option for those welfarists who accept the possibility of an indirect justification in terms of rights.

[126] I do not want to suggest that the justification of autonomy is unrelated to the content of the concept. Of course which ethical theory one defends is not immaterial to the conception of autonomy. Clearly, a notion such as 'autonomous authority' will mean something different to a consequentialist compared to a deontologist or a contractualist. The point here is merely that the conceptualization of informed consent in terms of autonomous authority is not at odds with a welfarist perspective. This does not mean that my argumentation in this chapter is neutral with respect to ethical theory. Not all theories can accommodate what I have said so far and what I will argue for in the pages to follow. Important at this point is, however, the observation that a commitment to informed consent implies a commitment to autonomous authorization, however justified.

challenge is to find a conception of autonomous authority which justifies the requirement of informed consent.[127]

[127] Note that this issue depends on the normative role that we attribute to the concept: the right conception of autonomy here is that which helps to explain the purpose and application of informed consent. There may be other concepts of autonomy that are of value in other domains, but here I will only consider the concept relevant to the issue of informed consent.

Chapter 3 Justifications of Informed Consent

In the previous chapter I have explored the concept of informed consent and argued that it should be understood as an authoritative directive. Authoritative directives provide exclusionary reasons for action, which means that they pre-empt first-order, 'on the merit', reasons. I conceptualized informed consent as the expression of a specific type of authorization: autonomous authorization. Now, in order to answer the question of when and why autonomous authorization is morally relevant, I will have to probe further and look at its normative presuppositions: in this chapter I want to spell out some normative presumptions about the role and value of autonomous authorization that I believe are implicit in the concept of informed consent. From the outset, I want to emphasize that I discuss the justification of informed consent in order to discuss the standards of informed consent, so that later on in this thesis I will be able to address the question of strengthening informed consent requirements for a specific type of intervention (in this case newborn screening). The question of the conditions under which informed consent is justified needs to be answered at this point: for a specific type of intervention, how can we determine what, if there is one at all, is the appropriate informed consent procedure? A justification will offer us a normative background against which to assess claims on the desirability of specific informed consent procedures. If we know why in general informed consent is important, it also becomes possible to say something about the standards with which it is implemented in specific instances.

The question for a specific intervention is: what is the normative background against which we measure whether an informed consent procedure is successful? Since authority implies a certain level of generality, this question is not a question about specific events, but concerns types of interventions. For a specific type of intervention (such as newborn screening, a kidney transfer or knee surgery) why should we require informed consent from an institutional level? There are two types of answers to this question: the first measures the success of informed consent directly with reference to certain values or goods. If the procedure does not enhance the specified values or goods, the procedure has to be adapted or abandoned. I argue that informed consent cannot be justified directly. It follows that the autonomous authorization relevant to informed consent should not be justified directly, but rather by a claim of the individual that is independent of promoting specified values or goods. I will spell out the presumptions of informed consent in terms of a power to the waive rights.

In chapter 2 I have mentioned that the principle of informed consent applies to competent

individuals. Contrary to the authority of a coach, a CEO or a state official, for example, the authority connected to informed consent is not derived from a particular social role. This raises the question of if it is not on the basis of a specific role, on what basis do we grant people the status of authority with respect to certain decisions? And why should informed consent procedures that secure this authority be installed? In answering these questions, there are two possible paths one can take.

The first possibility is to show that informed consent procedures promote certain values or goods. This is what I will call 'direct justifications' of informed consent: such justifications explain the value of informed consent as being directly in the interest of the subject. The domain of informed consent is in that case delineated with respect to these goods or values; whether for a specific type of intervention informed consent is required depends on the question of whether this would enhance these values or goods or not. Note that this position differs from the strong interpretation of the welfarist position in that it is not denied that the subject's decisions function as exclusionary reasons. Contrary to the strong interpretation of welfarism, this justification of informed consent aims at genuine authority. The point is not that valuing a subject's preferences will lead to a better outcome, but rather that giving a subject authority is in his interest. The second possibility is to add another layer to the justification: to hold that the subject of consent has the disposal over a set of rights, which may either be waived or claimed. These rights, which in turn require justification, determine whether an individual has the power to consent with respect to a specific intervention. I will discuss the second view, which I will call rights-based justifications of informed consent, in section 3.3. First I will examine the possibility of explaining the normative importance of autonomous authority in a direct manner.

There are roughly two possibilities for a proponent of a direct justification. It could be argued that informed consent is necessary because this procedure will produce decisions that are in the patient's interest. Patients are granted authority because this generates the best decisions. This is what I call an instrumental justification. The other possibility is to say that making one's own decisions is in a person's interest or valuable in itself. This is an intrinsic value justification.[128]

The alternative to direct justifications are rights-based justifications of informed consent. There are two possibilities for a rights-based justification. If one adheres to an 'interest theory' of rights, the

[128] See for example Schermer (2001) for “instrumental” and “intrinsic value” notions of autonomy.

justification of informed consent is in the end rooted in the interests of individuals, but this is done indirectly, in the sense that the informed consent procedure need not aim at these interests. Rather, the procedure aims to make sure that the individual is free to decide within the space offered to him by the rights that he possesses. Will theories base the importance of rights on autonomy or agency. The will theory of rights would justify informed consent not so much indirectly, but rather on rights which are not rooted in the interests of the subject involved.

The structure of this chapter is as follows. First, I look at two possible direct justifications of the doctrine of informed consent: an interest based justification (3.1) and a justification which refers to the value of autonomy (3.2). I reject these possibilities because neither can offer a satisfying independent standard. I proceed with the rights-based account (3.3). I argue that rights-based justifications are best suited to explain the importance of the requirement of informed consent.

3.1 The instrumental justification of informed consent

In this section, I discuss the instrumental justification of informed consent. A proponent of the instrumental justification would explain the Nuremberg Code's emphasis on the prevention of harm as crucial to the importance of informed consent. I will show that, although I agree that the prevention of harm is central to the concept of informed consent, the instrumental justification is in itself insufficient to ground the requirement of informed consent. The proponent of the instrumental justification holds that informed consent is important because it serves the best interest of individual persons. What reason do we have to think that individuals will choose to their benefit in specific types of decisions?

A possible answer is the self-interest argument, which is based on the assumption that persons are inherently motivated to decide in their interest. According to this argument, even if it is clear whether or not a specific intervention will benefit a patient, an informed consent procedure may still be required in order to benefit the patient, because it provides an extra safeguard. This argument focuses on the protection of subjects against abuse: if one desires to protect a certain individual's interests, one could give this individual an authoritative voice so that his interests are in fact served. Recall the atrocities which gave rise to the first Nuremberg Code. It is clear that if the research subjects had been offered a choice they would not have consented to these violations of their interests. Therefore it seems reasonable to suppose that informed consent could contribute to the prevention of abusive practices. Yet it is uncommon for the self-interest argument to be stated or

defended explicitly. The reason for this, I presume, is that it does not straightforwardly point to *informed consent* as the way to protect these interests. Clinical cases of a failure to obtain informed consent are usually dissimilar to the concentration camp example in that the physician is trying to help the patient. Therefore it seems that the motivation is not always the crucial issue here. And even in cases of research subject abuse, it is not always obvious that the absence of informed consent is objectionable *because* it would have prevented harm to the subjects. It is not clear that it would in fact prevent this harm, and furthermore it seems like an unnecessarily complex way to prevent it from occurring. In many cases it would suffice simply to forbid those practices that oppose the interests of the patients; that is unless we suppose that the patient somehow has a privileged position in determining what is good for him. The instrumental justification becomes more interesting when we ask ourselves the question of how to determine what is in fact in the best interest of a patient. Proponents of the instrumental justification often supplement the self-interest argument with the presumption that there exist a multitude of evaluative frameworks and that what benefits one need not necessarily benefit another. From this presumption it is a small step to assume that an individual may know better than others what is in his interest.[129] The reason could be that the individual has a privileged epistemological position, because he has better access to the relevant facts (i.e. his own experience, value pattern, etc.). According to this argument, the exercise of informed consent is of importance in order to live one's life according to one's *own* values. In this view, paradigmatic cases where informed consent requirements have not been met should be interpreted as problematic because there are different perspectives on the best course of action. A doctor who proceeds with surgery without permission of the patient in this view hazards imposing his conception of the good on that of the patient. There is the possibility that the person involved does not share the values of the intervening party, and that what is good from the perspective of the doctor need not be good for the patient. Take for example the case of a sportsman about to undergo surgery. Here, a doctor plans to perform low risk surgery, which is likely to result in a slight limitation of movement. The patient, however, prefers surgery with a higher risk of an adverse outcome, which could result in complete recovery. It could – rightly – be argued that the patient and physician differ in their assessment of the preferred course of action because their evaluative framework differs. Whereas the surgeon considers the slight limitation of movement to be an unfortunate side effect, to the sportsman it matters a great deal, since it prevents him from doing what he values most (or at least he values it substantially more than the surgeon does). Therefore, according to the instrumental justification, it is morally required for the doctor to inquire what

[129] Recall the remark I made in chapter 1. There I mentioned that the necessity of informed consent is often linked to the impermissibility of *specific conception of the good* by the government.

exactly the patient desires or expects before starting surgery.

According to the proponent of the instrumental justification, informed consent is required because we (members of a modern liberal society) have differing conceptions of the good and therefore a physician cannot suppose that what he considers to be important in life is also held to be important by his patient. In this view, what determines whether informed consent is required is dependent on whether the opinions differ, or at least whether they might be thought to differ. In practice this boils down to a default of value congruence: in many situations it will probably be clear what values are at stake – as well as their relative ordering – and therefore it will be clear what course of action to take, but there are also cases where one is confronted with a difference in underlying values, which requires a sensitiveness to this differing perspective.

In the instrumental justification, the scope of informed consent is determined by the answer to the question of whether the patient is likely to reach better decisions than the doctor. Similarly, the standards depend on the answer to the question of what standards will produce the best results for the patient. The implication of this justification for the idea of strengthening informed consent is that the standards need to be adapted to best serve the subject's interests. As a consequence, making sure that a patient has, for example, freely agreed to an intervention is important to the extent that this improves his chances of reaching a decision which is to his benefit. Whether or not patients are influenced by their family or doctor is important to the degree that this produces better or worse decisions: the criteria are secondary to the content of the decision.

The instrumental justification fails as an explanation of the importance of informed consent. It has a hard time taking into account that people might be *mistaken* about what is in their interest. Not all of us are masters in self-knowledge, and furthermore for complex medical decisions it is more than likely that physicians have a better notion of what actions will produce the best results than lay people will. Yet, the instrumental justification rests upon the idea that authority with regard to certain types of interventions should be granted to the extent that this produces the best decisions. It seems that this should best be interpreted as 'generally the best decisions': there is no reason to assume that in fact subjects are always better capable than others in determining their own good, unless one supposes that what is in the subject's interest is determined by what he claims to be in his interest. Only a very extreme view, which allows for no possibility for making the wrong decision, would be able to support this claim. This would imply that by definition one cannot make a choice that makes one worse off. I set this view aside as implausible. More plausible variants of the

instrumental justification would say that the individual in general knows what is best for him, thus allowing for the possibility that a person could be mistaken about whether a specific decision promotes his good.

A less radical form of the instrumental justification will say that the patient is perhaps not always right, but that granting him authority will *in general* produce the best outcomes. The question of whether informed consent is required for a specific type of intervention is then answered by an assessment of whether it is likely to produce better choices. Reasonable as this might sound, this claim is problematic. If the value of informed consent is based on its tendency to produce the best outcome, the problem arises what to do in the face of possible disagreement. Take, for example, a case where medical evidence clearly points towards the desirability of surgery: should one offer the option to consent? Since in this case the best outcome of the decision-making process is to proceed, it seems that the instrumental justification is committed to the claim that informed consent is not necessary.

But what if a proportion of the population rejects that specific intervention, for example on religious grounds? It seems that the answer depends on whether we believe that the possibility of refusal is reasonable. But whether or not a decision is reasonable depends at least in part on one's conception of the good. The question is how to do justice to the fact that the instrumental justification sees the value of informed consent in terms of its goal, while at the same time basing this authority on the fact that there are differing conceptions of the good. The instrumental justification offers no ground from where to determine what choice counts as 'better' and seems unable to avoid a large extent of arbitrariness in posing informed consent requirements. Compare the example discussed in chapter 2, where a trainer makes the decisions for me because I believe that this delivers the best training result. In this case it is relatively clear what the criteria for 'the best training result' are and when they are met. By contrast, if we attempt to justify informed consent by reference to the instrumental value of the subject's decision-making authority, and accept that there are differing conceptions of the good, a standard is lacking by which to determine whether the good of a person is in fact achieved. In the former there lacks a procedure for determining whether informed consent requirements are justified; in the latter the 'right decision' itself is indeterminate, because it is unclear whose standards should be adopted in assessing the question of which decision is the right one.[130] The argument up until this point has been on the scope, but a similar point also applies when

[130] An additional problem is that the instrumental view offers us no way to understand other areas where consent is morally required. For example, think of consensual sex. It would be very strange to conceptualize the moral

we consider the standards: if informed consent is in the service of producing the best decision, the standards should also be determined with a reference to the outcome. This implies that strengthening the informed consent procedure should be in the service of producing that decision that is most likely to be in the person's interest. But what decision is this? Suppose that there are two ways of offering an informed consent: a weak and a more thorough one. Suppose also that this leads to a different outcome in the proportion of subjects who dissent; let's say that the more thorough variant leads to a larger number of dissenters. By what standards do we determine which of the two options is better? Should we say that a person who consents in the weak variant, but would dissent in the thorough variant was initially wrong? What if the thorough variant feeds on fears that the health care professional considers irrational? Again, a standard is lacking from which to determine which option is best. This is not merely a practical problem which might be solved by using a rule of thumb in applying the requirements of informed consent. It is a more fundamental problem in explaining the importance of informed consent. If the good of the patient is what justifies the importance of informed consent, and this good is itself the object of dispute, there is no ground from where to decide when and how the criterion of informed consent applies.

At this point the proponent of the instrumental justification could object that my characterization of informed consent as the exercise of authority is based on faulty assumptions on the concept of informed consent: perhaps the interaction between physician and patient should be seen more in the context of shared decision making, not in terms of individual *claims*. The suggestion would then be that rather than pitting the physician and patient against each other, we should conceive of informed consent as a method to achieve *better decisions together*.[131] I agree that an instrumental argument can be used to support the importance of shared decision making. I think it would be a mistake, however, to conflate this argument with an argument for informed consent. The reason is that once informed consent is reduced to shared decision making, it is stripped of its normative force. When would the requirements of informed consent be met if it is interpreted as shared decision making? Strictly speaking, shared decision making implies no more than that some communication takes places and some decision is reached. But this is too meagre a basis for a requirement of informed consent as autonomous authority. At best it offers an ideal of person to person interaction, not of exclusionary reasons.

Summarizing, the instrumental justification as I have described it here depends on the observation

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requirement of consent to sexual activities in an instrumental way.

[131] Berg et al. (2001).

that there exist differing conceptions of the good. This observation is, however, in tension with the idea that informed consent can be justified with a reference to the goal of promoting a patient's good. There is no ground from where to determine success and thus whether informed consent is morally required. The instrumental justification cannot give a solution to the question of which conception of the good should be followed. It might offer reasons for an emphasis on shared decision making, but not a basis for informed consent requirements.

3.2 The intrinsic value justification of informed consent

It seems that the instrumental justification is unable to give an account of the moral importance of informed consent. There is, however, another option available to those that want to defend informed consent in a direct manner. One could opt for an 'intrinsic value justification' of informed consent.[132] It can be argued that informed consent is important not because it leads to the best decisions, but because choosing autonomously itself is a worthy goal:

> "[...] the value of autonomy […] derives from the capacity it protects: the capacity to express one's own character – values, commitments, convictions, and critical as well as experiential interests – in the life one leads."[133]

An adherent of this view could justify informed consent by pointing out that the possibility of being able to choose contributes to the ideal of an independent life. Although this view does not base the importance of informed consent in its function to promote people's interests in the sense of enabling them to make the 'right' decision, it does refer to an idea of what is good for the patient; the answer to the question of whether for a particular intervention informed consent should be sought depends on whether the informed consent promotes the ideal of autonomy. The scope of informed consent then depends on whether granting a person the possibility to consent better enables him to give direction to his life. According to the intrinsic value justification, strengthening informed consent would be necessary to the extent that more thorough procedures lead to overall more autonomous patients. Informed consent is a means to improve upon the exercise of independence of individual patients. Therefore informed consent procedures need to emphasize the role of autonomous decision making. The intrinsic value justification of informed consent avoids the central pitfall of the instrumental view: it offers an independent standard – autonomy – to determine when the 'best'

[132] Some authors, such as Brock (1987) and Dworkin (1988) seem to shift between the instrumental view explicated above and an intrinsic value account.

[133] Dworkin (1994), p. 224. Also quoted by Schermer (2001), p. 28.

outcome is attained. Yet I believe it, too, fails as a defence of informed consent. We can see this once we ask ourselves what, in the intrinsic value framework, the scope of informed consent requirements should be.

The problem is that often health care decisions only marginally contribute to 'an independent life', and therefore for many decisions it is indifferent to the independence of the subject, whether or not he gets to decide on the topic. Of course, some health care decisions are important to 'defining one's life', but the decision to consent to, say, a mouth swab, or the extraction of a tooth are but small footnotes in the creation of one's life story. According to Sigurdur Kristinsson, accounts which expressly link the value of autonomy to the notion of informed consent in the way intrinsic value justification does, fail in the end because they cannot explain why a small infringement is morally problematic:

> "[the] moral concern behind the call for consent cannot simply be concern for having control over one's life. In that case, the omission of consent in such limited areas of life as research participation would be viewed as a mere nuisance".[134]

Kristinsson's point here is that it is hard to see how a commitment to the value of autonomy can pose obligations with apparently great weight: the intrinsic value justification seems unable to explain that, for example, the unauthorized sampling of data by means of a mouth swab appears to be morally objectionable.[135] This problem could perhaps be solved by being indiscriminate as to which decisions are the objects of informed consent, in which case affirming the value of autonomy not only covers life-changing decisions, but also the small, seemingly trivial ones. This move would lead to an expansion of the scope of the informed consent requirements so that mouth swabs also require consent. If autonomy is to be promoted, and informed consent is a way to do this, the conclusion seems warranted that informed consent is a good thing for a large number of decisions.[136] This move saves the intrinsic value justification from allowing interference in many

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134 Kristinsson (2007).

135 Kristinsson's solution is akin to mine in section 3.3, namely that respect for persons and not "the promotion of autonomy" is what matters in informed consent. Similarly, Manson & O'Neill have argued that 'autonomy' cannot be used to demarcate the area within which people should be allowed to make decisions for themselves. The dilemma they sketch is between protecting 'mere, sheer choice' and a more demanding notion of rational autonomy, which they claim cannot justify informed consent procedures because "informed consent procedures protect actual choices, which are often not rational ones". See Manson & O'Neill (2007), pp. 20-2. Manson and O'Neill consider this to be a problem for all accounts of informed consent that refer to autonomy, but it is my contention that it is only a problem for perfectionist accounts such as are described here.

136 See Manson & O'Neill (2007), p. 33.

medical decisions, but only at the cost of losing its position as a neutral, independent standard. By requiring informed consent in a great many domains, the intrinsic value justification would impose a specific conception of the good life. This non-neutrality is problematic, if what we are looking for is an *independent* standard by which to measure the importance of consent.[137] The desirability of independence is itself an object of reasonable disagreement, particularly in the context of decisions which do not greatly influence the course of one's life. While many would agree that it is in general good for a person to make his autonomous decisions on, for example, whom he marries and where he lives, this is much less obvious for many other decisions. Many people attach value to living a life where not all that one does is the object of constant scrutiny. The value of the spontaneous life is in conflict with the idea that all choices, even the insignificant ones, need to be promoted. If it is not necessarily true that a larger scope of informed consent is always better than a smaller one, we need somehow to determine when the possibility of consent is called for and when not. The intrinsic value justification is torn between neutrality on the one hand and expanding the scope of informed consent on the other.

Summarizing my argument thus far, attempts for a direct justification of informed consent fall short of giving a plausible interpretation of the role of autonomy in the doctrine of informed consent. As argued in the previous section, instrumental views cannot provide an independent standard, whereas in this section I demonstrated that intrinsic value justification can only derive an independent standard at the cost of losing its neutrality.

3.3 Rights-based justifications of informed consent[138]

In the previous sections I have argued that direct attempts to justify informed consent do not suffice to explain its supposed normative relevance. The problem with both direct justifications is that they have difficulty in achieving an independent standard by which to measure the value of consent. My claim here is that the underlying reason for this is that direct justifications attempt to locate the moral importance of informed consent in the promotion of a good or value. In this section, I explore alternative justifications of informed consent which do not base the moral importance of informed consent in the promotion of a good or value: rights-based justifications.[139] Rights are claims which

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137 Dworkin (1988), see also chapter 8 for the notion of 'burdens of choice' .

138 There is a reason for the plural here, which is that there are two rights-based justifications described in this section: one based on the will theory of rights and the other on the interest theory of rights.

139 There are in fact two other possibilities. The first is to argue that there is no further argument available for the fact that we believe informed consent is important and there is no further explanation possible of the doctrine of informed consent. The reason for rejecting this view is not so much that I believe it to be mistaken (which I do), but

define the boundaries of morally acceptable conduct.[140] What is the normative role of rights? In answer to this question, I find the characterization of Hillel Steiner useful:

> "The job of rights […] is to demarcate domains - spheres of practical choice within which the choices made by the designated individuals (and groups) must not be subjected to interference - and to specify those demarcations without reference to the content of the choices to be made within those spheres."[141]

This characterization is in line with the idea of authorization, as described in the previous chapter. In this section I will explain how it helps to justify consent and examine the implications of a rights-based justification for the informed consent requirement.

First, a brief recapitulation of the argument thus far. In chapter 2, I suggested that an analysis of informed consent should focus on authorization rather than consent or choice *per se*. Informed consent procedures protect competent individuals by granting them authority to decide upon certain self-regarding matters. I characterized authority as a provider of exclusionary reasons, attributed in the case of informed consent to all competent individuals. In the present chapter I have argued that the moral reasons to attribute this discretion cannot be explained with a reference to promoting his interests or the value of promoting his autonomy. This points towards a different approach, where the requirement of informed consent is not explained in terms of moral reasons that refer directly to a substantial conception of the good. I suggest that informed consent should be understood as a waiver of rights.

A rights-based justification defines the moral limits of one person's actions with respect to another person in terms of rights. In ordinary, daily interaction, the role of rights is limited to that of

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rather that it would keep any attempt to argue on the topic of the desirability of informed consent suspended in mid-air. I am engaged in an ethical study, which implies that I am interested in reasons, not merely unexplained normative assumptions. The second possibility is to claim that the reasons for informed consent are mixed. In this view the different justifications can exist alongside each other: informed consent serves the interest of the individual as well as protecting his rights. In practice, I think such an amalgam is often in the background when establishing informed consent procedures. I have no problems as such with this view, but two points should be made. It must be noted that this view minimally requires a rights-based justification, and is thus not in contradiction with my account in this section. Further, when employing such an amalgam, it is important to be specific about which reasons do the justificatory work. See section 5.3.

140 As I will show shortly, these so-called claim-rights are not the only category of rights relevant to consent.

141 Kramer, Simmonds & Steiner (1998), p. 238. See also Darwall (2006), p.262, who, referring to Fichte, speaks of "'spheres of freedom" within which individuals have enforceable rights to do as they will and with respect to which others are required to forbear interference." See also Manson (2007) and Brownsword & Beyleveld (2007). I focus here on individual rights and make no claim about whether or not group rights exist too.

background conditions. They normally come to the foreground only in cases of 'adversarial circumstances'.[142] Rights can function to decide on the course of action in cases of conflicting views. The role of consent herein is to lift the normative force of a particular right: consent turns what would otherwise be an unjustified breach of rights into a justifiable act.[143] A waiver of rights annuls the moral import of these rights. Take, for example, the role of consent in sexual intercourse. If one engages in sexual activity with another person without consent, this infringes upon that individual's rights. But of course this does not imply that any sexual activity would be an infringement of rights. Rather, the relevant right (or rights) in play – in this case presumably physical integrity – becomes void at the moment the subject decides to waive them.[144] There is thus a prima facie right not to be interfered with in this manner, a right that can be waived by consent. This is a moral explanation of consent that does not refer directly to interests or values, but rather relies on 'powers' that an individual possesses to annul rights.[145] In this justification, consent is the activity of authorizing acts that would otherwise be an infringement of rights. The implication is that 'harm', interpreted as a disadvantage to the subject, is not directly relevant to the requirement of informed consent. Rather, the relevant question is whether a person is 'wronged', in the sense that his rights are infringed upon.[146] Examples of rights that most rights theorists subscribe to are physical integrity, the right to ownership and the right to privacy. As I will show in chapter 7, particularly the last item is of importance in this thesis. Let us look at rights-based justifications in more detail.

When we speak of 'rights' we can mean a variety of different things: claim-rights, powers, liberties (privileges) and immunities:

> "A right is one's affirmative claim against another, and a privilege is one's freedom from the right or claim of another. Similarly, a power is one's affirmative 'control' over a given legal relation as against another; whereas an immunity is one's freedom from the legal

142 Kramer, Simmonds & Steiner (1998), p. 238.

143 Here I consider primarily *moral* rights, not legal ones. The question of the role of moral reasoning in a legal context is a complex one. The mere possibility of giving a moral backing to legal principles is, however, presupposed in the debate on informed consent for newborn screening, discussed in the introduction of this thesis (recall for example Austoker's (1999) quote). I will thus put these issues to one side. See also chapter 4.

144 George Fletcher has put the point like this: "When individuals consent to undergo medical operations, to engage in sexual intercourse, to open their homes to police searches, or to testify against themselves in court, they convert what otherwise would be an invasion of their person or their rights into a harmless or justified activity", quoted in Beyleveld & Brownsword (2007). See also Vorstenbosch (1990), p. 127.

145 For this reason, the power to give informed consent has also been called a 'second-order right', a term which I will avoid in order to prevent confusion with the notion of second-order reasons and because the term 'power' is more accurate. See Brownsword (2004).

146 See Levine (1995), p. 1283 and Feinberg (1986), p. 173.

power or 'control' of another as regards some legal relation."[147]

Claim-rights, or 'rights' in a narrow sense, necessarily correspond to a duty of another person; a 'liberty' refers to the absence of a duty; a power is the ability to change existing rights-duties relations; and an immunity consists in not being exposed to a power. All four types of rights can potentially be the object of waiver. I will, however, focus in this thesis mainly on claim-rights. The justification of informed consent is primarily concerned with interferences, which involve rights-duties relationships. It follows from this characterization that the informed consent, which changes the rights-duties relationship, is to be understood as a 'power'. From here on when I speak of 'rights' I refer to claim-rights, unless specified otherwise.

One can distinguish between negative and positive claim-rights. For example, in the case of cutting someone with a knife, I have a negative right that some person, in this example, a surgeon whose name is Randy, does not cut me. In turn, Randy has a duty not to do so. If, on the other hand, I am drowning in a duck pond and a passer-by, whose name is Chuck, can save me by offering me his cane, I have a positive right that he prevents me from drowning. However, if I choose to waive my right not to be cut by Randy or not to be saved by Chuck, I relieve Randy or Chuck from their duties. Informed consent does precisely this: it releases another person (or persons) from a moral duty towards us. Rights and duties have a certain level of abstraction: rather than 'the right of Niels Nijsingh not to be cut in the stomach by Dr Randy at 4 pm on Wednesday, etc.' I have a right to "physical integrity".[148]

It is not necessarily true that all rights can be waived. Perhaps Chuck is not released from his duty to save me when I tell him I would prefer to drown. Depending on which theory one holds on the moral role of rights, one can imagine, for example, a right to life as a right that the subject may not forfeit. This is a central topic of dispute between 'will theories' and 'interest theories' of rights. The former base their justification of rights on the moral import of the exercise of free will, whereas the latter hold that rights serve to protect certain basic interests of a person.[149]

An interest theory would hold that only some rights can be waived. Interest theories can thus account for 'inalienable' rights. According to interest theories, rights correspond with specific

147 Hohfeld (1923), quoted by Brownsword & Beyleveld (2007).
148 See Kramer, Simmonds & Steiner (1998), p. 43.
149 See for example Jones (1994), Kramer, Simmonds & Steiner (1998), Edmundsen (2004) and Campbell (2006).

beneficial duties: “necessary but insufficient for the actual holding of a right by a person X is that the right, when actual, preserves one or more of X's interests.” [150] If Matt's interests are a sufficient reason for a duty imposed on Dan, Matt has a right towards Dan.[151] Because the will theory does not necessarily link having a right to the power to waive that right, it is theoretically possible that one person's rights are the object of another person's powers. If, for example, I have ordered flowers for my girlfriend, the interest theorist could hold that my girlfriend thereby attains a right that these flowers are delivered, whereas I have the power the cancel the order (but, of course, I wouldn't do that).

According to the will theory (or 'choice theory'), rights derive their normative input from autonomy or the agency of the subject: “nothing counts as a right unless it has an assignable right-holder, and no one counts as a right-holder unless she holds the option of […] waiving the duty correlative to the right.”[152] According to the will theory it is necessary when holding a right that the right-holder is both “competent and authorized” to waive that right. The discretion of individuals to decide upon waiver is thus integral to the concept of rights itself: by definition, rights imply the possibility of waiver. In the will theory, having an interest is neither a sufficient nor a necessary criterion for a subject to dispose have rights. In this thesis, I will remain neutral between these theories, but will show where the different approaches might lead to different outcomes.

According to rights based justifications, if there is a case of justified informed consent, the subject has forfeited a certain right in this specific situation, which therefore no longer counts in the moral assessment of the action. Metaphorically speaking, we can say that informed consent allows access to a domain that would otherwise be off limits: individuals have a morally significant claim to decide whether or not to waive the rights within the scope of this domain. Informed consent is then appropriate only in those cases where rights would be infringed when it were absent.[153] Not to gather informed consent constitutes a *prima facie* wrong. It does not mean, however, that the intervention is wrong, all things considered, if informed consent is absent. It is possible that other considerations overrule this *prima facie* consideration. Rights-based justifications demand a justification for infringements of rights; they do not claim that infringements are always wrong, all things considered. It is conceivable that someone's rights are overruled, for example when rights of

150 Kramer, Simmonds & Steiner (1998), pp. 66-8. My claim here is not that this has to be the position of the interest theorist, but merely that rights and powers over those rights can be ascribed separately in an interest theory.
151 Jones (1994), pp. 28-9
152 Edmundson (2004), p. 122.
153 Brownsword & Beyleveld (2007).

others are at stake.[154]

Contrary to the intrinsic value justification, the rights-based justifications can attribute authority to subjects on decisions which do not determine their life story, without sacrificing their neutrality. By demonstrating that respect for autonomous authority entails respect for rights, we can illustrate what makes these minor interferences so troublesome from a moral perspective. Rights-based justifications assign a domain which delineates the boundaries of legitimate action towards an individual. Informed consent is a way to give that individual control over these boundaries. Regardless of which specific rights an individual has based on different justifications, the individual has the power to make changes to the normative framework that limits the interaction. Instead of the ideal of autonomy, rights-based justifications see autonomy as a necessary condition for exercising the power to waive rights. The attribution of autonomy then marks out those individuals that have a right to waiver.[155] A will theorist of rights would hold that the set of persons who are autonomous is identical with that of rights holders, whereas an interest theorist would claim that there are some rights holders who are autonomous and whose rights include a specific type of rights that allow for waiver. The upshot is the same: all individuals who are sufficiently autonomous have the authority to make certain self-regarding decisions. The question is how can autonomous authority be established in an institutional context?

In summary, the requirement of informed consent presupposes that there is a certain class of acts which constitute a *prima facie* wrong by infringing upon rights. This justification of informed consent entails that it is possible for the individual person to waive the relevant rights, thus acting as an authority.

3.4 Conclusion

In this chapter, I have examined three possible justifications for the requirements of informed consent. I have argued that direct justifications – referring to the good of the subject of consent or to the intrinsic value of developing autonomy – do not suffice and that therefore we need an rights-based justification for informed consent. Such justifications are based on the idea of the waiver of rights. In health care, informed consent protects the private sphere of individuals by imposing

154 I return to this issue in chapter 5.

155 Christman (2004): "[...] to say that [a person] is not autonomous implies that she does not enjoy the status marker of an independent citizen whose perspective and value orientation get a hearing in the democratic processes that constitute legitimate social policy". See also Darwall (2006), p. 80n34.

constraints on the patient–professional interaction. The fulfilment of the requirement of informed consent releases a person from the obligation not to engage in certain specified activities. Thus, the effectuation of informed consent constitutes the forfeit of a specified claim-right. Given this justification, it is now time to examine in what way informed consent requirements can establish the protection of people's rights. In the next chapter, I elaborate on the criteria of informed consent.

Chapter 4 The Standards of Informed Consent

In the previous chapter I claimed that a rights-based justification is best suited to explain the normative role of informed consent. I have argued that the justification of informed consent should be that it protects rights by giving the opportunity to waiver. This should give us the tools to determine what the conditions of informed consent are. I now proceed to discuss the standards of informed consent. The observation that informed consent is an expression of autonomous authority does not yet answer the question of what the criteria for a successful informed consent are. Merely "consent as a mental state" does not suffice as an exercise of authority.[156] Consent is essentially also an expression of acquiescence. The question now is how to determine the conditions under which this expression corresponds with the normative presumptions of the informed consent doctrine. As I claimed in the previous chapter, rights make up the background against which to address this question. The criteria of informed consent are established to properly enable the waiver of these rights. How and when does an informed consent requirement help to protect individuals' rights in an institutional context? We can answer this question if we can find an account in which informed consent is effective with respect to the goal of protecting rights.

There are roughly two approaches within the realm of health care: the first emphasizes the importance of the doctor–patient interaction. According to this view, informed consent should be understood primarily in the context of communicative acts within which the agent is enabled to exercise his authority. The norms governing this practice are complex and cannot be captured in a set of sufficient and necessary criteria. These are the 'broad accounts'. The competing – narrow – accounts focus on a set of formal requirements which link directly to the goal of autonomous authorization. I will first present the narrow accounts in 4.1, then discuss some objections to these accounts (4.2) and present the competing broad accounts in 4.3. I will then state some of my objections to broad accounts in 4.4 and conclude by countering the initial objections to narrow accounts in 4.5.

4.1 Narrow accounts of informed consent

I have discussed in the previous chapter the moral justification of informed consent. Now, what are the criteria for a successful informed consent? Given the supposition of the power to exercise autonomous authority, what requirements does the doctrine of informed consent pose? The purpose

[156] See Feinberg (1986) p. 173.

of informed consent requirements is to protect the subject's rights by posing requirements on the interaction between doctor and patient. But this does not yet give us the answer to the question of when these requirements are fulfilled. This is a question about the institutional application of the principle of informed consent.

There are two groups of answers to this question. According to the first – the 'narrow' accounts – the relation between individual discretion and informed consent is simple: informed consent is an expression of an individual field of discretion, and the criteria of successful informed consent are defined in terms of this individual discretion. The contrasting view (the 'broad' accounts) holds that a morally satisfiable exercise of autonomous authority should be assessed with a reference to more complex communicative norms. I will first discuss the narrow accounts.

According to narrow accounts of informed consent, the protective function of informed consent is established by setting demands of various stringency (the *standards*) on the disclosure and comprehension of the person (the *informational component*) on the one hand and his voluntary, competent consent (the *consent component*) on the other.[157] Narrow accounts thus characterize informed consent as a transaction between the person making an offer on the one hand and the person consenting to this offer on the other. Whether the informed consent is successful depends on whether it is sufficiently autonomous. If a patient understands what intervention is at stake and freely and competently waives his rights regarding this intervention, this means that the informed consent was successful, according to narrow accounts. The way this is thought to protect patients should be clear: the requirements are aimed at enabling them to decide on those matters that fall within their field of discretion. The notion of accountability is central here: physicians can be held accountable for at least attempting to ensure that the requirements of informed consent are met. In this way the authority of the individual patient is enforced by a set of rules which function as a 'checklist': if all conditions are met, informed consent is given. The other side of this coin is that informed consent procedures also protect doctors: if the doctor can demonstrate that proper informed consent was given, this releases him from some responsibilities. A doctor cannot in general be sued for an adverse outcome of a procedure if he has sufficiently explained the risk of this procedure (and of course if he has also conscientiously performed his task).

Narrow accounts presume certain competences and circumstances in order for the consent to count

[157] We have already encountered these aspects of informed consent in the GR report, which I discussed in chapter 1. Representatives are Wear (1992), Faden & Beauchamp (1986), Berg et al. (2001) and Brock (1987).

as sufficiently autonomous. If, and only if, a set of requirements relating to autonomous consent is fulfilled does the informed consent count as fulfilled. Specifically, this requirement poses *informational* obligations on the part of the person offering an intervention to ensure that the consent is sufficiently autonomous. The person making the offer should ensure that the subject is properly informed on what he is consenting to.[158] This aspect is emphasized with a view to the vulnerability of patients: if we want to make sure that they do in fact know what they are consenting to, we must pose a positive obligation to ensure that they are properly informed.[159] Whether or not the information transfer is successful depends on whether the patient grasps the content, so that he knows what he decides upon.[160]

An account of informed consent that specifies the requirements of informed consent in this way is the analysis by Ruth Faden and Tom Beauchamp. Their analysis of informed consent distinguishes five elements. In their analysis, proper informed consent consists of a disclosure of information, which the patient must comprehend and then be in a position to freely and competently choose whether or not to consent to the proposed procedure, or, more formally:

"Action X is an informed consent by person P to intervention I if and only if:
P receives a thorough *disclosure* regarding I,
P *comprehends* the disclosure,
P acts *voluntarily* in performing X,
P is *competent* to perform X, and
P *consents* to I."[161]

This is a formal specification of the criteria of informed consent. It is a finite list of necessary and sufficient criteria,[162] which may or may not be met. Failure to meet any one of these criteria means that X is not an informed consent, or rather, as most would put it, not a proper informed consent.[163]

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158 Although informational requirements play a role in all sorts of transactions, they play a particularly significant role in informed consent transactions. The reason is that in many informed consent transactions the authority (i.e. the patient) is in a vulnerable and dependent position.

159 For other forms of consent (e.g. in contract law) the existence of these positive obligations is more controversial: to what extent is someone who sells property obliged to inform the other party on the drawbacks? See Brownsword & Beyleveld (2007), (page?).

160 See Manson & O'Neill (2007), p. 33 and pp. 48-9.

161 Faden & Beauchamp (1986).

162 That is, necessary and sufficient with regard to the question of whether an event is an informed consent, not whether the intervention is morally justified or even whether the rights of the subject are respected. See section 4.4.

163 Note that this notion of 'proper informed consent' implies graduality in applying the criteria: informed consent can be achieved to a larger or lesser degree.

In attaining a proper informed consent, the health care professional has to take care that these criteria are fulfilled. Also, when we think about 'strengthening' an informed consent procedure, it seems natural to think along two lines of improvement: information (disclosure and comprehension) and consent (voluntariness, competence and actual consent). Improvement along the line of information could include the amount of information, the comprehensiveness of the information and the comprehension of the subjects, which could be affirmed by, for example, posing questions. Improvement along the lines of consent may be that subjects have more options, are better aware of making a choice or feel less pressure in making a certain choice. An indirect way of improving consent could be to promote competent decision making, for example by means of education.

According to the narrow conception, informed consent poses a set of requirements on the interaction in which the patient autonomously authorizes an intervention: consent is given by an individual on the basis of the disclosure of information by the intervening party. The purpose of consent requirements is that the decision to proceed with an intervention is within the discretion of the individual authorized to decide for himself. Only when consent is given voluntarily and on the basis of sufficient and correct information can informed consent be considered legitimate.

These criteria are established with the purpose of protecting the rights of the individual patients.[164] The criteria are designed so that the intervening party may be held accountable for his role in establishing that the subject is placed in a position to make up his own mind in a voluntary manner. The criteria function as a way to ensure that the subject knows what he is consenting to (the informational obligations) and that this consent is authoritative in the right way (the consent obligations). The criteria of informed consent thereby enforce the responsibility of the physician to verify that the subject understands what the implications of waiver are and that he is free to abstain from consenting. This is a very influential view of informed consent, but narrow accounts are not uncontroversial. According to proponents of broad accounts of informed consent, it is not possible to come to such a definitive list of criteria and they accuse the narrow accounts of being too 'legalistic' and giving too little thought to the complexities of communication. The remainder of this chapter will be devoted to elaborating on this skeletal frame the narrow accounts have offered thus far and to defending it against criticisms.

[164] According to Faden & Beauchamp (1986), the *sole* purpose (p. 137).

4.2 Criticism of narrow accounts

In this section I discuss some criticisms of narrow accounts of informed consent. It has been argued that narrow conceptions of informed consent tend to be too legalistic.[165] Proponents of broad accounts of informed consent often argue that the rigid character of narrow accounts leads their opponents to assert excessive demands: the standards of informed consent are set too high.[166] As we have seen, narrow accounts hold that requirements of informed consent can be described with the five criteria mentioned earlier. According to broad accounts, however, this leaves out many morally relevant features of the informed consent transaction. Before turning to the broad accounts, I will now give two types of reasons why it is thought that narrow accounts set standards which cannot be met.

A first set of criticisms centres on the perceived relation between the formal character of the criteria of consent and its goal, which is to enable an autonomous authorization. Some authors object that it is a mistake to view consent as a contract or a transaction:

> "[...] A procedure, informed consent, has been substituted for what is, in fact, an extremely complex moral action."[167]

Specifically, these authors object to reducing the complexities of the doctor–patient interaction to the explicit signalling of consent, preferably in writing:

> "Explicit consent typically relies on documents, signatures and formal statements; it may require witnesses who confirm that proper procedures for consenting have been followed. The formal procedures are typically designed to create enduring records, thereby reducing later uncertainty about the consent given and perhaps forestalling dissatisfaction, complaint and litigation."[168]

The focus on explicit and documented consent, so it is argued, obstructs a trusting doctor–patient relationship and creates a false sense of controllability. This, it is claimed, is in tension with the

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165 Manson & O'Neill (2007), p.13.

166 Some of the arguments that emphasize the excessive standards of certain approaches to informed consent aim not so much at narrow accounts, but rather at what I have called 'intrinsic value justifications' of informed consent (see section 3.2). I will focus here on the arguments directed at narrow accounts.

167 Tauber (2005), p. 151.

168 O'Neill (2004), p. 274.

goals of consent: a formalistic approach apparently serves well to protect doctors against litigation, but does not necessarily help to protect patients, which of course is the primary purpose of informed consent.[169]

In line with the criticism of explicitness, narrow accounts are also criticized in relation to the specificity of the consent.[170] The specificity relates to the detail of the information that the subject consents to. The description of the intervention for which consent is sought needs to be sufficiently detailed in order to give explicit consent. The question is, however, what counts as 'sufficient'? According to Manson and O'Neill, accounts of informed consent in 'standard literature' cannot escape being overly exacting in this respect. If it is true that informed consent needs to be explicit, it does not suffice to present the patient with a short, technical description describing the proposed intervention. Rather, specificity seems also to require that the physician makes sure that the patient receives all relevant information and grasps the implications of that consent. This emphasis on specificity is, however, problematic because, as Manson and O'Neill argue, "full or complete specificity is unobtainable, and unnecessary for valid consent".[171] Since descriptions are never fully specific and more detail can always be added to them, O'Neill compares the quest for a *general* standard of specificity to the question "How long is a piece of string?"[172] There can be no general standards specifying what information counts as sufficiently specific. It is thought by critics that narrow accounts, due to their rigidity and focus on accountability, cannot escape being highly demanding in this respect.

Both criticisms attack the 'formalistic' character of narrow accounts: proponents of broad accounts object more generally to an ethics of 'ticking boxes'; the seeking of explicit consent to "a great many propositions".[173] The underlying motivation for rejecting narrow accounts is that their inflexibility does not do justice to the complexities of practical reality:

> "[D]emands for explicit and specific consent insist on formalistic, uniform and, strictly speaking, impossible procedures and standards, rather than looking for feasible, proportionate and normatively justified requirements."[174]

169 Manson & O'Neill (2007), p.16.
170 Ibid. pp. 11-16.
171 Ibid. p.15.
172 Ibid. and also O'Neill (2004), p. 1134.
173 O'Neill (2003), p. 6.
174 Manson & O'Neill (2007), p. 11.

The general thrust of these objections is that this formalistic character of the narrow account gives no thought to the relational and interpersonal aspects of informed consent. According to this objection, legalistic theories of informed consent have paid too little attention to the interpersonal aspects of the doctor–patient relationship. The remedy to this is to describe informed consent as a much more 'rich' concept, including other communicative norms than merely disclosure and consent. Therefore, before addressing the challenge that they pose for narrow accounts, I focus on the suggested alternative.

4.3 Broad accounts of informed consent

Proponents of broad accounts argue that informed consent requires a much richer story than narrow accounts offer. The aim to offer sufficient and necessary criteria for autonomous consent is insufficient to capture all that is at stake in the patient/doctor interaction.[175] The view of proponents of broad accounts is that we should use a more sophisticated and complex moral vocabulary in explaining the importance of informed consent. Instead of a focus on disclosure and subsequent consent, this alternative view tries to do justice to the complexities and context-dependency of communication. According to Manson and O'Neill, paying attention to broader communicative norms has substantial consequences for the concept of informed consent, which in turn reflects on its standards.[176] I argue in the next section that to the extent that these 'broader' communicative norms are relevant to informed consent, narrow accounts can incorporate them without losing their legalistic character. First, however, I will expound more on the argument made by proponents of broad accounts.

I want to take a closer look at the ideas on the doctor–patient interaction that motivate some of these discussions. One of the central arguments in broad accounts is that the concept of informed consent itself has (recently) been mistakenly centred on the idea of disclosure, thus highlighting only one of the many morally relevant aspects of doctor–patient communication. This in turn is claimed to obscure many aspects of what is in fact a normatively complex interaction.

As mentioned, narrow accounts of informed consent focus on the importance of information disclosure. Neil Manson and Onora O'Neill have suggested that the "*metaphor of disclosure"*

[175] The most influential and most elaborate account of what I call 'broad accounts' is that by Onora O'Neill and Neil Manson (Manson & O'Neill (2007), O'Neill (2002), O'Neill (2003), O'Neill (2004)). In this section, I will mostly focus on the theory of Manson & O'Neill. See also Hallowell (2008), Stirrat & Gill (2004) and Tauber (2005).

[176] Manson & O'Neill (2007), p. 64.

downplays certain essential features of what matters in informed consent procedures.[177] At first sight metaphors of disclosure (information is being 'stored', 'transferred' or 'received') seem innocent enough, yet Manson and O'Neill suggest that it might have distorted our way of thinking about informed consent. It seems clear that the physician has 'access' to certain information, and that this information needs to be 'shared' in order to enable free choice. By this we do not literally mean that the physician 'owns' a 'pile of information'. However, as Manson and O'Neill try to show, this manner of speaking might not be as innocent as it seems. According to them, this terminology tends to downplay important aspects of what constitutes successful communication.

Communication can fail in many ways, and Manson and O'Neill suggest that we risk neglecting this if we limit ourselves to the disclosure terminology. Instead of regarding a doctor–patient encounter as the exchange of information and consent, proponents of broad accounts emphasize the context-dependent aspects of communication. They argue that communication is a shared activity, which requires a broader context than the narrow accounts presuppose. The aspects of communication that are highlighted by these accounts give us only a very limited picture of what is relevant about informed consent from a moral perspective. Broader communicative norms such as intelligibility, relevance, accuracy, and sensitivity to audience should be considered. For example, if the disclosed information is not relevant, or if the information does not relate in a proper way to the epistemic context of the receiver, something has gone awry in the effort to successfully communicate, even if the formal criteria of informed consent have been met. Broad accounts emphasize that communication is not solely about exchanging propositional content, but is also a way of doing things, of establishing certain things in the world. Therefore communication cannot be reduced to the exchange of propositional content:

> "Agents with the appropriate socially sanctioned authority may use speech acts to do complex acts of many sorts: they may marry a couple; condemn someone to death; pardon a traitor; agree to a legally binding contract, and so on. What all of these speech acts have in common is that they take place against a background of a shared acceptance of complex sets of cognitive and practical commitments, entitlements, expectations and social roles, and shared understanding of ways in which others' commitments can be modified."[178]

Narrow accounts of informed consent systematically miss important aspects of communication, so

177 Ibid., chapter 2.
178 Manson & O'Neill (2007), p. 57.

proponents of broad accounts argue, because, due to their legalistic fixation on accountability, they are prone to focus on disclosure. Contrary to some other communicative norms, disclosure lends itself to explicit determination. Therefore, neglecting other norms leads to excessive standards and a situation of lack of trust.[179]

Manson and O'Neill propose an alternative account of informed consent; they suggest a way to 'rethink' informed consent: the 'agency model' of informed consent. In their model, the focus is not so much on a set of criteria, but rather on the context within which informed consent takes place. The appropriate policy rules are those that create an environment in which there is room for trusting relationships between persons. I interpret this as a call to not attempt to always 'enforce' the exercise of autonomous authority by way of informed consent requirements, but to create circumstances where the rights of individuals are respected. In this model there are no uniform standards of consent, but rather a general responsibility to create a context in which agents can establish relationships of mutual respect. In some cases, this purpose could be served by *removing* informed consent requirements that hinder such a trusting relationship. In this relationship, the focus should be on supporting agents in their choice rather than burdening them with a decision.

Informed consent interaction is to be assessed in this model with a reference to a broader scope of norms than those mentioned in narrow accounts. Not all these norms can and should be made explicit. Yet, they are important for determining whether or not an informed consent was successful, so Manson and O'Neill argue. This move, the introduction of norms that need not be explicitly invoked in an informed consent procedure, enables Manson and O'Neill to come to less exacting standards than the narrow accounts seem to allow for: these communicative norms can be respected without requiring their explicit recognition.

Summarizing so far, broad accounts, such as that of Manson and O'Neill, emphasize the importance of context for understanding informed consent, and reject narrow accounts, which tend to focus on disclosure. Manson and O'Neill claim that communication (and thus informed consent) is necessarily a much more complex practice than formal rules could capture. Since broad accounts are generally suspicious of the way the formal requirements of informed consent are supposed to establish a morally satisfying communicative interaction, the focus is rather on creating a setting in which the patient's rights can be respected. I will argue that broad accounts of informed consent are

[179] See chapter 7.

mistaken, or at least not helpful in the context of the practice of informed consent.

4.4 Refuting broad accounts

In this section, I defend narrow accounts against the criticisms levelled against them in section 4.2. Before commencing to do so, I must emphasize that I agree with some of the objections to formalistic approaches to informed consent. Particularly in some countries, for example the United Kingdom and the Netherlands, the so-called audit-culture has had a destructive impact on the efficiency of medical practice. It is important to warn against excessive requirements that emphasize explicitness and accountability. However, I think it is a mistake to attribute the emergence of the audit-culture to narrow accounts of informed consent. Any acceptable account of informed consent should set *reasonable* limits to the specificity of information required and the explicitness of the consent. But this is possible within the framework of narrow accounts.

Recapitulating thus far, narrow accounts of informed consent have been criticized for being over-demanding: supposedly they lead to excessive standards. Critics argue that instead of focusing on disclosure and individual consent, we should consider the communicative norms underlying the doctor–patient interaction. There are, however, problems with this alternative.

Proponents of broad accounts seem to expect too much normative work from informed consent. They focus not only on the transaction of disclosure and subsequent consent, but instead have an eye for the normative complexities of communication in general and of the patient–doctor relationship in particular. It is laudable that these authors insist that informed consent is not a panacea for moral problems in the medical context. This, however, gets broad accounts into paradoxical positions:

> "[…] Disclosure alone is not sufficient for successful communicative transactions, so in particular not enough for successful informed consent transactions."[180]

Here, Manson and O'Neill argue that disclosure is not sufficient to capture all that is morally relevant to a doctor–patient interaction. Oddly, they derive from this that disclosure is not sufficient for the moral acceptability of an informed consent. This seems to imply that they believe that the acceptability of such an informed consent depends on the success of the communicative transaction,

[180] See Manson & O'Neill (2007), p. 88.

period. But it seems entirely conceivable to have an unsuccessful communicative transaction, while the informed consent has satisfactorily been dealt with. Informed consent is but one element in this transaction. The argument quoted above seems to work only if the success of a communicative interaction fully depends on the success of informed consent. But why would we think that? We can acknowledge completely that there are communicative norms beyond disclosure and still hold on to the requirement of informed consent as one important element in this communication.

To be clear, Manson and O'Neill do not mean to argue that informed consent should be sufficient for moral permissibility (in fact they vehemently oppose this), but rather to give a fuller account of the role of communicative norms in informed consent, so that the relationship between doctor and patient is not reduced to the formal aspects of the transaction. Compare the following remark by O'Neill:

> "[Informed consent] is generally important because it provides an important measure of protection against coercion and deception, and *also because it can make a distinctive contribution to the restoration of trust.*"[181]

Instead of being merely a tool to safeguard individuals' discretion, the role that O'Neill envisions for the concept of informed consent is to capture more features that are relevant in the doctor–patient interaction. The importance of informed consent is explained in terms of the relevance of good communication.[182] However, this move jeopardizes the clarity of the concept of informed consent. If the main purpose of informed consent is to protect individuals from coercion, manipulation and the like, one should not let go of the formal character of the informed consent procedure. The gain of emphasizing the complexities of communication is made at the price of losing its protective function.

What proponents of broad accounts tend to disregard is the fact that enforceability depends at least to a certain extent on standardized procedures. As we have seen in 2.1, informed consent did not in the first instance arise as an ideal of health care workers' conduct, but as a way to protect people from unwanted interferences. Accountability and control have been ingrained in the concept of

[181] O'Neill (2002), p. 145, my emphasis. See O'Neill (2002) 151/152 for an argument with similar conclusions. See also Hallowell (2008).

[182] To an extent, this move entails a rejection of the conception of informed consent as an authorization. There is a tension in Manson and O'Neill's approach, since at other places they do subscribe to the idea that informed consent is an authorization.

informed consent from the very start and cannot be removed from it without the cost of losing sight of the initial purpose of informed consent.[183] Especially when fundamental rights such as privacy and physical integrity are involved it is important to back up the patient's claim with considerable force. Taking autonomous authority seriously means that responsible institutions take up their responsibility in ensuring that the subject's rights are respected. Therefore the need for a set of clear criteria cannot be brushed aside. By attempting to accommodate a category such as trust in the assessment of informed consent, the concept loses much of its force in practical discourse. Therefore I am of the opinion that it is a mistake to attempt to incorporate communicative norms other than those of disclosure and comprehension in the informed consent conception. I think that a narrow conception of informed consent is important because it works the best for what it was devised to do: to protect research subjects and patients.

Proponents of broad accounts are generally suspicious of standardized procedures and tend to reserve them for routine interventions.[184] But in doing so, they seem to conflate 'formal' with 'bureaucratic'. To be accountable is not identical with the 'ticking of boxes'. Precision, care and detail *can* be part of a standardized requirement of informed consent (as well as the ticking of boxes). Broad accounts are thus in danger of creating a false contrast between being accountable and attending to the specific needs of a patient in a particular case. Proponents of broad accounts seem to underestimate the possibility of the previously mentioned criteria of narrow accounts being flexible, yet demanding. Observe the following quote, where Manson and O'Neill suggest that there are no uniform standards for informed consent:

> "Similarly a doctor who offers a diagnosis and proposal for treatment in simplified language that omits much detail does not seek, and will not receive, highly specific consent to the proposed treatment: but this may be acceptable provided that the treatment does not deceive or manipulate the patient, and the subsequent treatment does not force or coerce.*"*[185]

This quote is ambiguous in a problematic way. What is the status of the 'provided' clause here? Manson and O'Neill seem to suggest that if all is well there is no need for formal accountability.

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183 Arnold (2002), p. 31.

184 Manson and O'Neill (2007), pp. 80-1.

185 Manson & O'Neill (2007), p. 81. See also O'Neill (2002), p. 37, "What is grandly called patient autonomy amounts simply to a right to choose or refuse treatments on offer" and Manson and O'Neill (2007), p.21: "Informed consent protects actual choices, which are often not rational choices".

This presupposes that the physician means well and has no intention to ‘deceive’, ‘manipulate’, ‘force’ or ‘coerce’. But this is precisely what, from an institutional level, cannot be presupposed. Returning to the beginning of chapter 2, we can see why this quote is problematic. The reason that we have informed consent requirements is precisely because we cannot always assume that doctors aim for the best. The protective function of informed consent procedures derives precisely from the fact that a physician can be held accountable for meeting its requirements; in fact the enforcement of informed consent was crucial to introducing the concept in the first place.

Summarizing, I have argued that the broad account of informed consent fails to guarantee its protective function and that there is no reason to think that adherence to a narrow account leads to a ‘bureaucratic’ model of informed consent. Narrow accounts can deal with the criticism levelled against them by adopting a pragmatic stance in the application of the criteria. Bringing aboard other communicative norms besides those of disclosure and comprehension, as broad accounts do, threatens the practical applicability of the concept of informed consent.

4.5 Conclusion

In this chapter, I have examined the standards of informed consent. I argue for a formal, 'narrow' account of informed consent, which focuses on accountability. This view contrasts with 'broad' accounts, which focus on the contextual, environmental aspects of communication. This analysis provides me with the conceptual tools to determine, in the remaining chapters of this thesis, under what conditions there is a case for strengthening the current demands on informed consent procedures. In this chapter I have argued that the institutional realization of informed consent can be specified with reference to the ‘traditional’ five elements of disclosure, comprehension, voluntariness, competence and consent. This presupposes an account which may be described as ‘narrow' in the sense that it explains informed consent in terms of an exchange of information and consent.

Conclusion Part II

In this part I have presented a framework for the requirements of informed consent. In chapter 2 I focused on the concept of informed consent, and have given an explanation of this concept in terms of autonomous authority. I have argued that authoritative directives can be understood as sources of exclusionary reasons, as opposed to first-order ('on the merit') reasons. Authoritative reasons derive their force from their source: the authority. In chapter 3, I have discussed three possible justifications for the requirements of informed consent. My argument was that direct justifications do not suffice; we need an indirect justification for informed consent: the waiver of rights. Informed consent protects moral rights of individuals by imposing constraints on the doctor–patient interaction. The fulfilment of the requirement of informed consent releases a person from the obligation not to engage in certain specified activities. Thus, an informed consent constitutes the forfeit of a specified claim-right. In chapter 4, I have specified my account of informed consent further by analysing the criteria in the five elements of disclosure, comprehension, voluntariness, competence and consent. I have argued for a narrow account which explains informed consent as an exchange of information and consent. This is opposed to the broad accounts which focus on the contextual elements of communication.

Part III Three Complications

In part II, I have argued for a conception of informed consent as an autonomous authorization. I have argued that this authorization derives its normative importance from the protection of rights. The implementation of informed consent requirements should, furthermore, be specified according to a limited set of criteria focused on autonomous decision making. Given this conceptual frame, I will in the remainder of this thesis address the question of how this applies to newborn screening. I need to take some further steps, however, before I can proceed to address the issue of informed consent for newborn screening. There are some ways in which newborn screening differs from prototypical informed consent scenarios. I will examine some of the relevant features of newborn screening in isolation. In part III I will look at three features of newborn screening that complicate the application of the principle of informed consent to newborn screening procedures.

Two of these problems refer to the types of rights (chapter 6: parental authority, chapter 7 epistemic rights), the other to the relation between individual rights and collective interests.

Chapter 5: Informed consent and Public Health Interventions

As I mentioned in chapter 1, nowadays nearly every child in the western world will be screened for a number of diseases in the first week after birth. Moreover, not only are they all confronted with newborn screening, they are all individually confronted with more or less the same procedure. In order to grasp what is at stake in the issues that surround newborn screening, I want to take a step back and point out a structural similarity between the practice of newborn screening and some public health interventions. In this chapter it will become apparent that this raises specific questions that centre around the distinction between the collective and the individual level of decision making.

In this chapter I will suggest that newborn screening should be understood as a *discretely instantiated public health intervention ('diphi')*. It shares this feature with interventions such as some forms of counselling, vaccination, quarantine and other types of screening. These are collective interventions which aim for the health of the public, yet they are implemented on an individual level. I then demonstrate that this feature has implications for the ethical issues surrounding these interventions. The question that I raise is whether the normative role of informed consent is different in the context of public health. Does the collective character have implications for the way in which informed consent procedures protect individual rights? This will prompt me to give an account of the relation between the individual and the collective in public health interventions of this kind. I argue that since diphis are offered to large groups at the same time, it will be necessary to make collective decisions on which interventions are preferable. I will examine the consequences of this argument for the requirement of informed consent.

As we have seen, the question of when informed consent is required is best answered by a reference to individual rights; interference with these rights calls for informed consent. A complication, however, arises when we apply this principle to the case of public health interventions. This complication is often described in terms of the tension that is perceived between the collective character of public health interventions and the individualistic nature of informed consent.[186] In order to address this issue, I must first specify what is meant by the term 'public health intervention'. What does it mean to say that an intervention is a public health intervention? Marcel Verweij and Angus Dawson analyse the concept of public health as "collective interventions that aim to promote

[186] See for example Grill (2007), pp. 104-105, Bayer & Fairchild (2004), O'Neill (2003) and Holland (2007), pp. ix/x.

the health of the public".[187] I will return later to this definition and give it more substance. For now, note the contrast with the prototypical doctor/patient relationship. Public health interventions contrast with clinical care in their scale and aim. Whereas the prototypical informed consent scene involves a single doctor and a single patient with the former proposing an isolated intervention or a course of treatment (or a selection of isolated interventions/interventions to choose from), public health interventions concern many individuals and many actions performed by different people. It is fair to wonder whether the principle of informed consent has any bearing on such complex and multi-layered interventions. There are two ways in which it may be argued that it does not. The first line of argument could be that for such collective interventions informed consent is simply not possible. Given that public health applies to many different people, informed consent, so the argument goes, cannot be the object of individual choice. This is not an attractive path, but it will be instructive to see why not. The other – initially more promising – line of reasoning accepts that informed consent may be possible for public health interventions, but argues that it is often not desirable because it runs counter to its aim, which is promoting the health of the public. An argument of this type needs to make plausible that there are moral considerations which play a role in the context of public health that are largely absent in a clinical context. I will argue that such an argument is possible, but only in a specific interpretation.

I start in 5.1 by giving a characterization of public health interventions. In 5.2 I proceed with addressing the question of whether informed consent is possible in the context of public health. I argue that for a specific category (discretely instantiated public health interventions ('diphis')) it is. I examine a tension between the collective and the individual level of decision making that arises in public health practices. This sets the stage for a further analysis of the conditions under which informed consent is appropriate for this category of interventions in 5.3, where I discuss the justification of diphis in terms of third parties' interests and the individual's own good and the implications of this for the informed consent requirements. This raises the issue of paternalism. I argue that the 'normative core' underlying anti-paternalism is that for certain interventions reasons that refer to the inability of the person to reach the 'right' decision are not allowed. I examine the implications of this claim for the justification of diphis. I will conclude that, although the application of informed consent in public health practices is different from that in the clinical context, the need for informed consent procedures cannot be brushed aside when infringements of

[187] Verweij & Dawson (2007), p.21. They do not consider the "description" to be a definition, but seem to suggest that it offers only an outline, which requires further specification. Note that their analysis (in contrast with some popular views) is value neutral: there is no claim contained in this description on whether public health interventions are good or bad. See also Nuffield Council on Bioethics (2007).

rights are at stake. However, there is one possible argument, which refers to the necessity of making non-neutral decisions on the collective level. This argument implies collective choices on the 'good life' but does not rely on a paternalistic argument.

5.1 Public Health

In order to assess the role of informed consent in the context of newborn screening, I will now focus on the concept of public health. The category of public health interventions is a diverse assembly of different collective actions aimed at "preventing disease, prolonging life and promoting health".[188] The history of public health dates back to antiquity, but the practice received a boost with the emergence of epidemiology in the 1900s. Although the precise categorization differs from author to author, the category of public health interventions is generally thought to encompass such preventive interventions as vaccination, smoking bans, hygiene law, food safety regulation, interventions in public space (for example the construction of stairs rather than escalators), screening and alcohol taxation. Whether or not an intervention is classified as a public health intervention is partly dependent on its justification. Alcohol taxation, for example, could be described as a public health policy or, alternatively, as an economic or public safety policy, dependent on what we consider to be the main aim of the policy.

The aim of public health interventions is improving the health of the public.[189] Applying in this way the concept of health to the collective, instead of individual persons raises the question of whether there is anything more to the health of the public other than the sum of its constituents. My suggestion would be that there is not. The health of the public is nothing more, and nothing less, than the "[Aggregate] of the health status of all members of the population".[190] Compare, for example, Pellegrino and Thomasma:

> "Public health physicians act for the good of all to the extent that medical knowledge can serve that good. They are the de facto advocates for the common good. Their "patient" is

[188] Acheson (1988) and also see Verweij & Dawson (2007), p.15.

[189] Some policies do not become public health interventions until after they are implemented. For example, it appears that the construction of sewers was initially intended as a measure against the stench.

[190] Verweij & Dawson (2007), p. 21. That the health of the public should be understood as an aggregate does not mean that public health programmes cannot focus on specific subgroups, such as children, men older than 50 or homosexuals. The point here is that the aim of such programmes is improving the health of the public as the sum of its individual members. This sum is also increased when one focuses on a particular subgroup. For example, it has been mentioned that the purpose of public health interventions can also be to adjust inequalities in society. They would do so, however, by improving the health of the public, albeit of a specific subgroup. Here too, the aim is thus the health of the public.

> society and its ills. They serve the good of society's individual members secondarily by assuring a healthy community in which the individual can flourish."[191]

I am unsure exactly what Pellegrino and Thomasma mean here. In one interpretation, which corresponds to the view to which I subscribe, they mean that the goal of public health interventions is to promote the aggregate health of individuals by means of collective interventions. In another reading, they reject the aggregative view, which is the interpretation suggested by the last line of this quote. I do not think that this interpretation can be sustained.

If Pellegrino and Thomasma mean to reject the aggregative view, this implies that not only is the intervention aimed at the collective, but also that the health of the community is something qualitatively different from the sum of its members. This seems to be the suggestion in the phrase that the health of individuals is served *secondarily* by public health measures, which seems to indicate that the former somehow supervenes upon the latter. If this is the correct reading of this quote, we have to conclude that the health of the public is at least to some extent independent of the health of its constituting members. This is a puzzling proposition.

Agreed, one could talk metaphorically about healthy societies, as one can talk about healthy relationships, healthy companies, healthy ecosystems and so on. But it is unclear what public health professionals have to do with them, apart from trying to improve the health of persons. Naturally, in their attempt to realize this goal, they have to stay aware that there are other important goods that may be affected by their actions. But it can hardly be argued that the primary purpose of a screening programme, for example, is to improve the good of society *in general*. Of course, public health interventions aim for the good of society. But this is not specific to public health interventions. Indeed, it seems like a basic requirement for any proper policy. If the category of public health policy is to be meaningfully distinguished from another policy category, we need to limit the scope to the health of persons and thus adopt an aggregative view.

But surely, it may be insisted, there are certain (health) goods that cannot be reduced to the health of individual persons? Herd immunity seems to be an example of a *common good* that transcends the

[191] In Boylan (2004), p. 21. Like many authors on public health, Thomasma and Pellegrino do not make an explicit distinction between the collective character of the intervention and the collective character of the object of that intervention.

individual.[192] This observation opens the possibility of another interpretation of the quote above. Herd immunity, like infrastructure or clean air, is a good that can only be conceived of – and established – on a collective level. For example, in the case of vaccination, herd immunity entails more than the fact that the vaccinated individuals do not become ill. What is being realized is a *common good*. However, the existence of common health goods does not imply that the aim of the health of the public is therefore – partly – independent from its constituents. The good that is being established is valued because it prevents the occurrence of the illness of individual citizens. The effectiveness of a vaccination programme is assessed by considering this aggregative result: the sum of people whose illness is thought to have been prevented because there is herd immunity.[193] Therefore, a focus on public goods is not contrary to the aggregative view.

The notion that public health interventions should be seen as focusing on the health of the public, rather than on that of assignable individuals should thus not be understood as the rejection of the aggregative view, but rather as a claim on the indeterminacy of its beneficiaries. The aim of the health of the public is predicated to the public as a whole, rather than to a set of assignable individuals. This relates to the preventive character of public health interventions: because the subjects are not yet ill, it is unclear who will benefit from a public health interference, although it is sometimes possible to identify *retrospectively* who has benefited.

We have thus an initial characterization of public health interventions: they aim for the protection and/or the promotion of the health of the public, which is understood as an aggregate and the beneficiaries are indefinite. This is, however, not a sufficient characterization. As noted above, public health measures are *collective* enterprises: for their realization they require the cooperation of many. Typically, although not exclusively, public health interventions are instigated by the government. The organizational aspect of public health interventions sets it apart from individual actions that aim for a better health of individual persons. A collective enterprise opens up possibilities that are not available on an individual level. There are different reasons to pursue the goals of public health collectively. I mention two. First, promoting the health of the public is an activity that is often hard to do on one's own. And even if we acknowledge that a lot of the aims of public health programmes could also be achieved by individual actions (people can take preventive health measures on their own initiative), this is often practically difficult. Collective action may

192 See Dawson (2007).

193 In order to accommodate the realization of common goods such as herd immunity, it seems sensible to add the *risk* of becoming ill to the conception of the health of the public. In this view risk factors are simply part of the overall health of the public. How these risks should be weighed is of course a different matter.

relieve the burden of taking the initiative for an action; it is often easier for people to have certain worries taken out of their hands. Take, for example, vaccination: a collective vaccination policy releases citizens from the need to investigate which vaccinations are advisable and the attempt to purchase those themselves. Second, a common good such as herd immunity can only be achieved by compliance from a large number of people, which gives an additional reason to organize public health interventions such as vaccination on a collective scale.

Public health interventions will typically affect and involve actions of many people. This marks an important difference between public health and clinical health care, because in the latter, treatment decisions usually only involve and affect one or a few persons. Decisions on a macro scale concern populations instead of individuals. This observation presents a different interpretation of Pellegrino and Thomasma's claim that public health has as its 'patient' the whole community.[194] Although the aim is the health of individuals, the object of the intervention is the collective: public health interventions concern many, instead of a few, individuals. They are collective enterprises, undertaken to realize public health goals that cannot or can only with great difficultly be established by individuals.

5.2 Discretely instantiated public health interventions

What are the implications of the analysis of public health in the previous section for the application of informed consent procedures? In the introduction to this chapter, I have briefly described two challenges to the application of the principle of informed consent in the context of public health. The first is rather straightforward. According to this argument, public health interventions, due to their collective character, cannot be the object of individual choice. Therefore, given the fact that these interventions serve important (health) goals, the requirement of informed consent needs to give way. I believe this argument is easily refuted by counter-examples, but it will be instructive to see how these counter-examples can be characterized. This section is devoted to delineating those public health interventions to which the above argument does not apply.

It has been argued that public health interventions and informed consent do not combine. For example, Onora O'Neill wonders whether an intervention can be organized on a large scale and still fall within the scope of individual consent. She argues that it cannot. She starts to reason from the collective character of public health interventions, and notes that "public policies, including public

[194] See Beauchamp & Steinbock (1999), p. 25 and Gostin (2001), pp. 7-11.

health policies, have to be uniform for populations."[195] From this observation, she continues to argue that this collective character is at odds with the notion of individual choice: "The public provision of health care can reflect democratic process, and thereby certain forms of collective choice; but its basic structures cannot be geared to individual choice."[196] She concludes the argument by stating that, "because there are no obligations to do the impossible ('ought implies can'), informed consent cannot be ethically required for the provision of public goods."[197] It follows, according to O'Neill, that individual self-determination is irrelevant for public health care. In realizing the common good, public health care has no room for individual consent. She concludes: "*Salus populi suprema lex* is not an obsolete thought."[198] In other words, the important public goals that are served by public health justify disregarding the importance of informed consent. If it is true that public health interventions and informed consent procedures are mutually exclusive, and the importance of these interventions outweighs the lack of informed consent, abandoning informed consent can be justified for public health interventions.

As I will explain in the next section, I think that O'Neill is right when she emphasizes that it is not necessarily true that the requirement of informed consent always trumps the common good.[199] Her conclusions, however, are too strong. She seems to suppose that because public health care aims at collective goods, the implementation of this intervention necessarily takes place on a public level. But for some public health interventions this is false. O'Neill fails to draw a distinction between different types of public health interventions, some of which *do* allow for informed consent procedures. For example, it is perfectly possible to ask a person whether he wants to be vaccinated or not, yet this clearly seems an example of a public health intervention.

In the remainder of this chapter I will focus on the category of public health interventions that are possible candidates for informed consent procedures, and discuss the desirability of informed consent. I now proceed to say more on those public health interventions for which informed consent is a possibility. As I mentioned, the sort of interventions I have in mind in this and ensuing chapters are a specific type of public health interventions, 'discretely instantiated public health interventions' ('diphis'). By this I mean interventions where it is *indeterminate* who will benefit – they are measures that aim for the health of the public rather than the health of specified individual persons –

195 O'Neill (2003), p.4.

196 O'Neill (2004), p. 1135. Although O'Neill speaks here of public *goods*, she later on applies this line of reasoning to public health care, specifically to vaccination.

197 Ibid.

198 Ibid., p.1136.

199 This is, however, dependent on how that common good is specified. See section 5.3.

but in principle *determinate* who is intervened with at a specific time. Examples are vaccination, screening, health check-ups, doping control and some forms of counselling. Note that these are still collective interventions in the sense that they involve populations, rather than individuals, and therefore meet the characterization of public health interventions as given in section 5.1. These interventions contrast on the one with hand with individual clinical encounters where the patient has a specific problem, and on the other with non-discretely instantiated public health interventions, such as television campaigns, sewer construction and interventions in the public space.

Diphis are realized on an individual level. A diphi intervenes with individual persons, one at a time. Although the aim may be a collective good, and although it is possible that a certain specified individual that undergoes the intervention will never benefit from it, it is still that individual that is being intervened with, at a specific time. The moment of instantiation of a diphi resembles the classical clinical encounter. Therefore, as long as this individual is competent to consent, these interventions can be accompanied by an informed consent procedure. This contrasts with, for example, sewer construction, where the notion of individual consent is generally irrelevant.[200]

There are thus public health interventions, diphis, for which informed consent is possible. These public health interventions have as their object a determinate set of individuals, at a specific time. An interesting feature of diphis is that the initiative for the intervention is taken by the government or an institution. On a public level decisions have to be made about what to offer and what not. This points towards a contrast with clinical care. Typically, in clinical care the initiative for treatment is taken by the patient. Although clinical encounters also have elements that involve collective decision making (think of infrastructure, education or legal requirements), this property of diphis sets them apart from those interventions since the very offer of a diphi is preceded by a collective, institutional decision. This poses particular challenges for ethical reflection. Since the space for decision making of the individual is to a large extent determined by the decision made on the collective level, the question arises of what should be decided on a collective level and what on an individual level. In this sense, it is true that public health interventions cannot be 'tailored to individual choice': the individual is dependent for his options on the decisions made at an earlier stage.[201]

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[200] The justification of such policies is rather established through processes of public decision making and therefore dependent on questions of the legitimacy of institutions.

[201] Any encounter between an individual citizen and a health care professional is structured to a large extent by a variety of background constraints. The observation that the individual is dependent for his options on such pre-existing structures is not specific for diphis or public policy. Some of these constraints that shape the set of alternatives,

In order to justify the offer of a specific diphi, we need an account of the relationship between the collective and the individual level of decision making. There are specific questions that come to the fore here. What offer of diphis can be justified? How much choice should be left to individuals when implementing these interventions? My focus in the remainder of this chapter will revolve around these issues, and will more specifically be on the question of whether the authority of the individual may justifiably be limited with an appeal to the aim of public health interventions – the health of the public.

To summarize, in this section I have argued against the claim that informed consent is not possible for public health interventions. I have held that for a specific type of intervention –diphis – it clearly *is* possible. I have also emphasized that there are nonetheless two levels of decision making concerning diphis: collective and individual. Since the initiative for diphis is taken on a collective level, decisions have to be made on what to offer, and in what way. This raises the question of whether there can be reasons to limit the possibilities of decision making on the individual level: can the observation that a certain intervention can be classified as a *public health* intervention give us reason to limit the authority of the individual involved? Answering this question will enable us to identify the institutional element of a diphi which further distinguishes it from clinical encounters.

5.3 Private and public decisions in public health

The individualistic characterization of informed consent has been said to be in tension with the idea of public health.[202] After all, so it is claimed, in public health it is not the individual that is the primary focus, but rather the collective good, that is, the health of the public. The question now is whether standards of informed consent for diphis can justifiably be limited, because diphis aim for the health of the public rather than the health of the individual. I argue that the collective nature of diphis can indeed give an argument to limit the informed consent standards, but only under specific circumstances.

In addressing this issue, I will first briefly refresh some points made in part II. I have argued that informed consent should be justified with a reference to claim-rights. An interference ceases to be an interference once the person involved waives the relevant rights. This presumes a certain domain over which the individual has a moral discretion. Decisions made by that individual which fall

however, are the outcome of explicit decisions. Those are the ones that I am interested in here.

[202] See footnote 187.

within the scope of this domain require no further justification. Justification is needed only at the point when my decisions or actions affect the rights of others. This view has a strong focus on the individual, since rights are attributed in this view to individual persons. The notion of justification at work also has an 'individualistic' focus: the justification of interferences is always done towards individual rights bearers.

A strong case for restricting individual rights and limiting the scope of informed consent is what one could call the 'third parties argument'. It could be argued that the goal of diphis is not necessarily to promote the good of the individual intervened with, but also the good of third parties or society as a whole. A clear example is quarantine, arguably a diphi: a public health intervention aimed at discretely identifiable individuals. This intervention is not likely to be in the interest of the individual at whom the diphi is directed (i.e. the person who is being held in quarantine); in fact it is possible that it is *against* this person's interest. In these types of cases, it may be argued, informed consent procedures are not required, since informed consent is only called for when someone's rights are being infringed *without* justification in terms of others' relevant rights. Since, arguably, the interests of others are at stake too, individuals need to submit to the general policy, and informed consent is therefore not a necessary requirement.[203] The third parties argument remains neatly within a rights-based framework: it pits the rights of the individual against those of others. Although I believe it to be sound, it only rarely offers a sufficient justification of diphis. The third parties argument does not usually apply when we think about implementing diphis. In modern society there are very few cases where we accept a justification of an interfering diphi entirely in terms of the rights of others. Only in cases where there is very clear and significant danger to others are we willing to accept that the interest of third parties overrules the right to, for example, physical integrity of the person interfered with. A reference to the third parties will not alone fully justify most diphis: the justification for diphis will, under normal circumstances, at least be partly in terms of the potential benefits of the person intervened with. It is in these cases where the issue of informed consent arises. The question at this point is how this justification in terms of benefit to the individual intervened with relates to the collective nature of public health interventions.

Reasoning from a rights-based framework, the story seems simple: if an intervention cannot be justified with a reference to the rights of third parties, this seems to imply that there is a need for

[203] This is the sort of argument also hinted at by the phrase 'salus populi suprema lex' in the previous section. In fact, the argument on the impossibility of informed consent often seems to be a somewhat disguised version of this argument.

informed consent.[204] A consequence of giving persons authority on a certain matter is that we cannot interfere with them, even for their own benefit. This is what is usually called paternalism. 'Paternalism' is often conceived as involving interference with the liberty or autonomy of persons for their own benefit.[205] Unjustified paternalism occurs in those instances where acting for a person's good conflicts with his rights.[206] From my discussion in part II, it follows that paternalistic interference is wrong. Here I will look at paternalism in the context of collective decisions.

There is a complication, which is that diphis aim for the health of the public rather than that of a specified individual. One possibility when arguing for a limitation on informed consent for diphis is to propose that they involve 'mixed paternalism'. Thomas Nys has argued that "public health care measures only take me into account as part of the public. Hence, it could well be that I never reap the benefits although I do share in the cost. From the perspective of the individual this is mixed paternalism at best: they want to protect my best interests as well as those of others".[207] Nys argues that here "we reach issues of *solidarity* and *justice*, and we move away from the problem of paternalism".[208] This argument emphasizes the public character of public health intervention as opposed to an 'individualistic' approach. Nys's observation that diphis have a mixed rationale seems to be correct and relevant, but it would be wrong to conclude that mixed paternalism is more easily justified than 'pure' paternalism.

I have sketchily characterized paternalism as involving interference with the liberty or autonomy of persons for their own benefit. I want to point out an ambiguity in the phrase 'for their own benefit'. Depending on what role we ascribe to the reason for the interference, different actions will count as paternalistic. Is it necessary that 'for their own benefit' is the *sole* reason for the action, or is the action still paternalistic if there is a mixed rationale? This points towards the importance of a

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204 There is also the possibility of the justification of an infringement in terms of other rights of the same individual whose rights are infringed. An example could be coercive measures against suicide: such measures are often justified with a reference to the non-waivable right to life. I will disregard this possibility since it is of no importance to my current topic.

205 See for example Dworkin (1988): ""X *acts paternalistically towards* Y *by doing (omitting)* Z: 1) Z (or its omission) interferes with the liberty or autonomy of Y; 2) X does so without the consent of Y and 3) X does so just because Z will improve the welfare of Y (where this includes preventing his welfare from diminishing), or in some way promote the interests, values, or good of Y." As Dworkin mentions both 'liberty' and 'autonomy', he is in need of the second clause, since only the latter implies the absence of consent. The way in which I have characterized autonomous authority in part II renders this clause superfluous: in my account an interference with autonomous authority is never accompanied by a – proper – informed consent.

206 Here I leave aside whether there are also instances of justified paternalism.

207 Nys (2008).

208 Ibid. (italics in text). Additionally, Nys and other authors argue that 'consent' can be understood in a collective sense: democratic procedures might ensure that 'the people' as a whole get to decide whether or not a procedure is acceptable. It should be clear at this point that this is not a conception of consent that I consider helpful.

specific type of *reasons* for interventions in understanding what is at stake in discussions on paternalism in public health.

I propose to focus on what Kalle Grill calls the 'normative core' of paternalism.[209] This will put us on the trail of an approach to paternalism that is more helpful than a sketchy characterisation. What is the point of discussing paternalism in the context of informed consent? Objections against paternalism can often be understood as the claim that for a certain class of reasons and a certain class of actions, "the reason in question is invalid for the action in question".[210] If we can isolate those reasons for good-promoting interventions that are normatively acceptable, we capture what is at stake in discussions of paternalism. Of course, such a move raises the problem of determining which reasons are considered invalid for such interventions. I will look for the answer by returning to the notion of authority.

Seana Valentine Shiffrin has suggested that the motive to which the anti-paternalist objects is that "the (putative) paternalist knows better than the agent, or may better implement, what the agent has authority for doing herself".[211] Paternalistic interference is, then, a special type of disrespecting the boundaries of legitimate authority: paternalism occurs when the reason for an interference expresses the judgement that the acted-upon person will not exercise his authority properly, that is, reach the right decision. Shiffrin concludes: "A's behaviour is paternalist because she takes over B's domain of action on the grounds that she treats her judgment about matters under B's purview as superior."[212] Paternalism then – by definition – refers to the sort of reason that cannot justify interference, given that, as we have seen in chapter 2, the exercise of authority offers exclusionary reasons. Second-guessing the ability of a person to exercise this authority entails disrespecting the source of their authority, because the point of being an authority is precisely that you are the one who has the discretion to decide what is best.

Rather than asking whether a specific diphi is paternalistic or not, the question should be when in the justification of a diphi 'paternalistic reasons' are invoked. This – admittedly rather subtle – difference in the conceptualization of paternalism helps to make sense of mixed motivations for diphis.

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209 Grill (2007).
210 Ibid.
211 Shiffrin (2000).
212 Compare the example of the coach and the football players in section 2.2.

Paternalism can be characterized as involving the invocation of reasons that express a person's judgement about whether a person will exercise his authority properly. This characterization has the consequence that paternalism need not necessarily occur when the reasons involved aim for the good of the person involved. At first glance this may seem odd, but it is in fact an advantage of this approach: it shows that the underlying mechanism at work is broader than often assumed. The reason that paternalism is unacceptable is not that there is something intrinsically problematic about the invocation of a person's good, but rather that such a reason crosses the boundaries of a person's discretion.

If we accept that individuals hold authority over certain decisions (say, whether or not to have a flu shot), paternalistic reasons cannot offer a justification for surpassing informed consent requirements: they are invalid for the intervention in question. This implies that there can be no justifiable 'mixed motivation', if that is taken to be a mix of (hard) paternalistic and non-paternalistic reasons, because these paternalist reasons were not allowed in the first place. From the rejection of paternalistic reasons it follows that for any infringement which cannot be completely justified by non-paternalistic reasons, *some sort* of informed consent procedure is morally required.[213] However, interfering diphis may require different standards on the grounds that they are collectively implemented.

By way of example, consider the case of water fluoridation, as described by Gerald Dworkin: "It is both effective and cheaper to put fluoride in the community water supply than it is to distribute fluoride pills to those who want them or to supply non-fluoridated water to those who do not want fluoride."[214] According to Dworkin, in these cases it can be good policy to add fluoride to the water even if this restricts the options of a part of the population. The restriction on the minority is not motivated by paternalistic considerations, but by the interests of a majority who wish to promote their own welfare. In the case of fluoridation, individuals have the possibility of opting out, but it is made more difficult for them.

If complete neutrality of the outcome is not attainable and the rights involved are relatively weak, we can make a non-paternalistic argument for limiting the possibilities of part of the population. It may be in the interest of most citizens that certain public health interventions are established, even

[213] To the extent, however, that the corresponding action is an infringement of the autonomy of that agent. A large infringement calls for a more thorough informed consent procedure.
[214] Dworkin (1988).

if this makes it difficult for citizens to opt out. This trade-off of different options arises because the initiative for diphis is on a collective level.[215] As a consequence, the standards of informed consent can in some cases be downplayed for public health interventions.

In chapter 8, I will return to the argument that the offer of diphis – in this case newborn screening – can become *more* interfering as the informed consent procedures are strengthened. There may thus be reasons to adjust the stringency of the requirement of informed consent if there is reason to believe that this makes the offer less interfering. This is essentially a 'perfectionist' argument (in the sense that it depends on a specific conception of the good) and it relies on the assumption that state neutrality is not completely attainable.[216] Informed consent procedures are themselves part of the way of offering diphis, and therefore we have to consider which offer is least interfering on the whole. This argument is not paternalistic since it does not involve overruling an individual's authority. Although I have rejected paternalist or mixed paternalist justifications of diphis, I have kept the door open for an argument for limiting informed consent. I will return to this argument in chapter 8.

To summarize, paternalism occurs when an actor invokes as a reason for interference the presumed inability of the acted-upon person to exercise their authority. Assuming the moral legitimacy of the authority, this is by definition morally problematic. This characterization emphasizes the 'normative core' of paternalism. This core is broader than just the invocation of the individual's good, since it refers not only to those reasons that invoke a person's good but to all decisions that fall within the individual's domain of discretion.

5.4 Conclusion

In this chapter, I argued that for a specific group of public health interventions – diphis – informed consent is possible. I have subsequently addressed the question of whether there may be reasons to limit the requirements of informed consent for diphis. One possible reason for this could be that these interventions aim for the interests of third parties. This reason is, however, rarely sufficient to justify diphis. Often they are justified, at least in part, with a reference to the interest of the person interfered with. The relation between the interests of individuals and those of the public raised the

[215] This issue is not entirely absent in other – clinical – informed consent situations, but plays a significantly smaller role there, because the fact that a patient indicates that he wants to be helped indicates a consensus on the aim of the intervention, even when good-promoting reasons can play a role in the continuation of the treatment relation.

[216] See section 3.3.

question of paternalism. I have argued that anti-paternalism should be conceived as the thesis that reasons that refer to the inability of a person to exercise his legitimate authority are not allowed within a liberal framework. This means that paternalistic reasons cannot contribute to the justification of a limitation of informed consent for a diphi. However, as I have suggested, there may be a different argument possible for certain diphis to weaken the requirement of informed consent. This argument referring to the burdens of informed consent is central to my discussion of newborn screening in chapter 8.

Chapter 6 Parental Authority

In the previous chapter I have discussed the first complication of three when applying the principle of informed consent to newborn screening practices: the public health dimension of newborn screening. In this chapter, I address a second complication, which is that newborns are almost entirely incompetent to make any decision. Even if we attribute to them the capacity of volition, it is hard to frame this by any standard as a decision-making capacity. The consent which is given for newborn screening is therefore not the consent of the person who is screened: parents give their consent for their children.[217] Therefore it is necessary to address the question of parental authority. I argue that parents have this authority, but that it is necessarily more limited than purely self-regarding authority.

The practice of parenting presents a problem for theories of informed consent.[218] A central tenet of the doctrine of informed consent is that one should see every person as an individual in his own right. This implies that individual citizens are restricted in their control over others. However, the notion of 'parental authority' indicates that parents have the discretion to decide for their children; more specifically, they have the discretion to give a valid informed consent for interventions which primarily concern the health of their children. The problem one faces when applying the doctrine of informed consent to the choice of parents for their children is evident: given the notion of informed consent as autonomous authority, the question concerns how we can say that parents are entitled to consent for their children and what limits there are to this authority. These are the questions which I will try to address in this chapter.

If what I have argued for in chapter 3 is correct, the attribution of the authority of parents to consent to screening presupposes that certain rights would be infringed in a case where that consent were absent. This means that the parental authority which I will discuss in this chapter should somehow correlate to rights, in this case the authority of parents to make decisions concerning their children. I examine three possible justifications of parental authority. I will first discuss the justification in terms of the child's right in 6.1. In 6.2, I discuss an account based on the rights of parents. In 6.3, I discuss an alternative view, an adaptation of the 'relational account' by Ferdinand Schoeman. I will suggest that parents have discretion to decide for their children on the grounds of both the rights of

[217] When I speak of 'parents', I do not necessarily mean the biological mother and father, see section 6.3.

[218] See Brighouse & Swift (2006). They present the mentioned problem as a problem of liberal theory, not informed consent, but the presentation of their problem is similar to mine.

children and their parents.

6.1 The child's rights

Newborns have no way to look after their interests. They do not have a developed set of preferences or a way to communicate the preferences that they do have, other than the indication of discomfort (e.g. crying, the uttering of unarticulated sounds, twitching and so on – in any case, nothing that could provide the basis of a proper informed consent). This means that those other than the child itself have to decide upon a wide variety of choices such as housing, type of food, clothing and medical issues. It has been upheld that the child's rights should be decisive in the attribution of the discretion with regard to children. A justification of parental authority based on the child's rights would assign to parents a proxy consent: the parents function as a representative for the child. What would it mean to base parental authority on the rights of children? I will show that although a child's rights cannot be ignored in assigning parental authority, they are insufficiently distinctive to justify parental authority.

The problem mentioned would evaporate if we assume that children are merely the property of their parents.[219] That this is not the case and that children have at least some rights or another morally significant stake is, I believe, relatively uncontroversial.[220] However, before continuing, I must briefly address the issue of the role of children's rights in the different theories of rights. It is often claimed that an advantage of interest theory over will theory is that the latter cannot account for children's rights. Since children lack the competences required for exercising rights, it is claimed that the will theory – which states that there an intrinsic connection between such competences and being a rights holder – cannot accommodate children's rights. It is certainly true that interest theorists can more easily integrate children's rights into their theory, but this does not mean that the will theorist must acknowledge that children have no rights. Will theorists could, for example, refer to developing agency[221] or an argument from potentiality. Also some theorists will distinguish between 'moral claims' and 'moral rights', where only the latter involves the possibility of waiver. This last solution is not very elegant, but could justify a similar range of requirements to the interest theory.[222]

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219 A view attributed to Aristotle (Nichomachean Ethics 8:12), see Schoeman (1980), p.12.

220 See Dwyer (1998) and the Declaration of the Rights of the Child (1959).

221 The argument as I present it in section 6.3 is attractive to different types of will theorists. The notion that parents' rights and the child's rights are intertwined does justice to the claim that children have rights in so far as they are developing their autonomy.

222 See Kramer, Simmonds & Steiner (1998), p. 70.

When should parents be considered appropriate proxies for their children? Consider the situations in which we *do not* think that parents should be able decide and that intervention by, for example, the government is justified. It is widely agreed that in some cases where a child will be harmed or is at risk of being harmed, the government has the right, and even the duty, to interfere, even if this goes against strongly held beliefs by its parents. Well known, although controversial, examples are female genital mutilation and the refusal of blood transfusion. In these cases, the intervention will then be justified by reference to significant harm or the high probability of such harm. This harm principle may overrule considerations of parental authority based on the interest of the child: "The relevant underlying principle is that children should be protected from significant harm, or even the risk of significant harm where there is a high risk of it occurring." [223] The harm principle sets a threshold for parental authority.

Can the child's rights justify parental authority below the threshold of the harm principle? To an extent, of course, parents are often good representatives for their children. Parents are in general concerned about their child's welfare and will likely stand up for their children. Therefore it may seem to make sense to leave the decision about whether or not to, say, have a child vaccinated up to the parents. However, if it is true that such decisions are up to the parents, this cannot be based upon the child's rights. Since newborns have neither developed autonomy nor a conception of the good or complex interests, their rights are limited to some very elementary rights, which do not differ from infant to infant. Think of a right to food, a right against mutilation and so on. Every newborn has more or less exactly the same set of rights. A waiver of these rights by the parents presupposes that somehow the parents' perspective is relevant to the decision. But for most medical decisions this is far from obvious. Therefore it is difficult to determine which decisions would respect the child's rights.

But perhaps, it could be argued, parents are better equipped to decide what their child would decide? Parents are probably (particularly in the early years of childhood) the most important persons in the formation of the identity of children. Therefore, since children do not yet have a conception of the good life, their parents' conception could be considered the 'next best thing'. There is no reason to assume, though, that parents have decisive knowledge on what their children would want in those decisions that require a lot of medical knowledge. Furthermore, we cannot simply

[223] Dawson (2007).

assume that a child's putative conception of the good life is identical with that of its parents. The argument depends on the mere contingent fact that many children adopt the point of view of their parents**.** But this does little to justify the latter making decisions for the former.[224] In any case, the argument is insufficient to demonstrate what it set out to do: to establish parental authority, in the sense that it offers exclusionary reasons. Therefore an appeal to the child's rights offers insufficient basis for making different decisions, at least for very young children.

The threshold principle tells us that if there is a clear chance of significant harm, parental authority may be disregarded. Below this threshold the child's rights are insufficiently distinctive to justify parental consent. We are still in need of a justification of parental authority. I continue to look now at the rights of parents as a possible justification of parental authority.

6.2 The parents' rights

I now return to my initial question of this chapter: is there a possible justification for parental authority? The harm principle sets a threshold for parental discretion, but it does not explain why, below this threshold, parents would have authority to decide for their children. Why is it morally objectionable to deprive people of the possibility of exercising parental authority? From our discussion in the previous section, it became apparent that the child's rights are insufficiently distinctive to justify such a right. As an alternative it may be suggested that parental authority can be derived from the rights *of the parents*. If considerations concerning the child are insufficient to justify parental discretion, perhaps the parents' perspective provides an explanation of granting parents authority with respect to their children.

One such account is that of Harry Brighouse and Adam Swift. Brighouse and Swift show that the relationship between a child and its parents is in several respects unlike other relationships between persons.[225] These characteristics, so Brighouse and Swift claim, are unique to the parent–child relationship, and of major interest to many people; the parental capacities developed in this relationship are of vital importance to achieving a full and satisfying life. The relation between a parent and a child, they argue, has a "different moral quality" to other relationships.[226] The fiduciary nature of parenting and the responsibility that comes with parenting are not comparable to any other human relation and, they add, "parents have an interest in a relationship of this sort" since

224 Kasachkoff (1994).
225 Brighouse and Swift (2006).
226 Ibid. p. 94

it is "crucial to their living fully flourishing lives".[227] Therefore, they argue, this fundamental need justifies granting people the possibility of being a parent and exercising parental authority. People have parental authority because exercising this authority makes their lives complete. Although Brighouse and Swift explicitly endorse an interest theory of rights,[228] this approach does not necessarily require a rejection of will theory. A will theorist could, rather than pointing to the interests of parents, argue that the development of certain capacities or relations is necessary for fully functioning agency, in which case the parents' interest in developing these capacities can be counted.

It is certain that for many people to bear and rear children is a project that gives a lot of additional meaning and depth to their lives. Not being in a position to share with one's child the intimacy and affection that comes with the relationship between parent and child would be considered a great misfortune by many. But it is not clear why this observation gives people the discretion to make decisions concerning their children. An account such as this faces the problem that the desire to raise a child is not universally shared. Of course, to this it may be responded that while not everybody sees the value of engaging in such a relationship, at least a lot of people do, probably even a majority, and moreover, for *those* people it is often a project of great value.[229] This response, however, requires a distinction between those who want to become a parent and those who do not, making the attribution of parental authority arbitrary.

To see this, take the case of the Parent By Circumstance. This person did not wish to have a child, but through circumstance (say, failing contraceptives) becomes a parent. Previous to this, the Parent By Circumstance envisioned his future as 'on the road' and he had no desire to settle down. As soon as the child is born the Parent By Circumstance loves his child like any other parent and is as caring and nurturing as anyone. Yet, when asked, the Parent By Circumstance would still be of the opinion that the free and roaming life would have suited him better, and that if he were to choose again he would have chosen otherwise (i.e. used more reliable contraceptives), although of course he would probably not talk about this much since, by hypothesis, he does not want to hurt or offend his child. I do not know if this is a very common scenario, but it certainly does not seem irrational for the Parent By Circumstance to perceive his situation in this way. The question is, does the parent have anything less of a right to parental authority than his opposite, the Parent By Choice? Clearly, it

227 Ibid. p. 95
228 Ibid. p. 87, n. 13.
229 Ibid.

seems not. From a moral perspective there seems to be absolutely no reason to want to make a distinction between the Parent By Choice and the Parent By Circumstance in this respect.

Brighouse and Swift do not seem to distinguish between the right to have children and the right to make specific decisions for them.[230] Whereas the argument of parental interest seems to give reasons for allowing people to have children, it seems to work a lot less obviously when applied to the granting of powers over other persons. There is no reason to link the desire to become a parent to parental discretion. While the desire to become a parent may be relevant to, for example, the right against forced contraception or perhaps the right to assisted reproduction, it has no bearing on a power to consent with regard to the child. The moral to be drawn here, I think, is that the conceptual link between the authority of parents and the fact that this role is highly valued by many is not as obvious as Brighouse and Swift make.

To this it may be responded that while parents perhaps do not derive their authority from a fundamental interest in *becoming* a parent, they could derive it from an interest in *maintaining* a relationship with their children. However, if one takes this line of argument it becomes hard to see how such a unilateral interest could establish powers of one person over another. This would imply that one person has authority over another person purely on the grounds of the contingent fact that there is an existing relationship. As Hannan and Vernon note, for any other relationship such a suggestion would be "somewhat shocking".[231]

The account of Brighouse and Swift explains parental authority partly in terms of the interest of parents in being a parent. This is implausible. Brighouse and Swift do not succeed in showing that a general interest in becoming a parent can be related to the authority parents actually have. A possible escape for an account based on parental interest, focusing on existing relations, does not solve the paradox of parental authority because it cannot justify the fact that one person holds authority over another. Therefore the argument based on parental interest is flawed, although as will become apparent in the next section, it is relevant to the argument I will suggest as an alternative.

6.3 Relational accounts of parental authority

In the previous sections I have argued that neither an appeal to the interests of children, nor an

230 See also Hannan & Vernon (2008).
231 Ibid.

appeal to parents' interests to raise children suffice as grounds for granting parents discretion over their children. This raises the question of what options are left for the justification of parental authority. In this section, I present an alternative account: a 'relationship account'.[232] Relationship accounts of parental authority hold that individuals who engage in personal relationships have a claim to non-interference. I will refer to and adapt the relational account of parental authority of Ferdinand Schoeman.[233] Although I believe his approach is on the right track, some elements in his account do not seem to sit easily with liberal tenets. My adaptation focuses on the fact that children depend largely on intimate relations for developing an identity, and that this fact provides a basis for non-interference.

Like Brighouse and Swift, Schoeman emphasizes the special character of the relationship between parent and child. According to Schoeman, the relation between parent and child is one of those relationships in a person's life that make it fulfilling and worthwhile. The conditions of such relationships are not explicated in terms of formal rights, but are rather based upon the notion of intimacy. This intimacy and its importance to human flourishing is for Schoeman the basis of the authority to parent. An intimate relation such as that between a parent and a child needs to be given space in order to allow this flourishing. Within this relation there is no place for formal rights, according to Schoeman. Therefore he has proposed that the answer to the question of the justification of parental authority should be sought in persons' importance of establishing intimate relationships with other persons on their own terms. The right of the state to intervene is limited, because intervention infringes upon the personal character of these relationships: "intrusion beclouds integrity and trust."

Schoeman's view does justice to the intuition that parental rights are intimately intertwined with the rights of their children. Instead of emphasizing the contrast between parents' and children's rights as the previous accounts seemed to do, Schoeman's account focuses on the intimacy of the parent–child relationship. However, this approach also has its weaknesses.[234]

First, the notion of intimacy, which plays such an important role in Schoeman's account, depends on the idea that intimacy and – reciprocal – formal rights are mutually exclusive. On consideration, this seems implausible. As I have already mentioned in chapter 3, the fact that a person has certain

232 This argument is neutral with respect to interest theories and will theories of rights.
233 Schoeman (1980).
234 Hannan & Vernon (2008), Brennan & Noggle (1997), Brighouse & Swift (2006).

rights towards others does not imply that these rights should constantly be in the foreground. Moreover, if there is *any* relationship between citizens in which moral duties and rights can be directly assigned it is the parent–child relationship: a parent can justifiably be blamed not only for harming his child, but also for a wide range of omissions: a parent has the moral duty to feed (but not feed too much), provide shelter, educate, provide an emotionally stable environment, protect from harm and so on. It would simply be preposterous to say that parents and children have no rights and duties with respect to each other.

Second, Schoeman risks the danger of overlooking the inequality between parent and child.[235] Unlike adults, children are incompetent to freely engage in a relationship and are, to a large extent, helpless in expressing the terms of this relationship. The suggestion that the parent–child relationship should be interpreted as individual freedom to engage in relations misses what is at stake in parental authority: the discretion of one person (the parent) to make decisions concerning another (the child). This power asymmetry cannot be framed without further qualifications in the terminology of freedom of personal relations.

I will now attempt to reconstruct Schoeman's argument in a way which avoids these problems. For this I will take the second critique on Schoeman as a starting point: the incompetence of children and the power asymmetry between parent and child. Assuming that children have a right to become autonomous, they need to engage in intimate relations which support them in realizing their potential. One condition for this is that they have guardians to make decisions for them. Here the notion of intimacy returns: in order to develop into a healthy, independent individual, the most suitable environment is that in which the parents and children share and communicate about certain commitments and values in an intimate way. This point depends on the assumption that in forming one's identity a certain emotional attachment to the people who surround one is necessary; one forms one's identity in response to a particular environment to which one is attached in a fundamental way. The intimate relations between a child and its guardian are thus vital in forming one's identity. This observation in itself does not point towards parents as the decision makers. However, it does give a reason for the state to show restraint in interfering in these relationships, since the state can never provide this kind of emotional attachment. By definition the state is impersonal and thus lacks precisely those qualities required to engage in an intimate relation with a child in the way described here. Note that this argument also supports ‘tribal chief’ authority or

235 Schoeman (1980), p. 176.

'grandparental authority' as well as foster parents' authority. However, biological parents, and perhaps particularly mothers, have a 'head start' since a relationship already exists at the moment of pregnancy.

This relational argument is not to be confused with the argument discussed in section 6.1. The attachment between parent and child is directed in both ways. The intimacy presumed to be vital to this process entails a strong link between the identities of parent and child. This is why the rights of parents should not be disregarded in the attribution of parental authority. The relationship in which a child can grow up to be an autonomous actor is itself worth protecting. This relational argument thus simultaneously invokes the rights of children and their parents. The family should be understood as the environment within which both parents and children can share an emotionally meaningful bond. Because parents' and children's rights cannot be sharply separated, the rights involved in parental authority are also strongly intertwined.[236] This means that interference with this relationship not only infringes upon the rights of children, but also of the parents involved.

6.4 Conclusion

I have argued that, up to a threshold, parents can be attributed authority to decide for their children. I have considered three accounts of parental authority before presenting my own alternative. These accounts are, respectively, an argument from the perspective of the child's rights, an argument from the parents' perspective and a 'relational' argument. My own account is a variant of the relational argument but also borrows reasoning from the other two accounts, specifically on the uniqueness of the bond between parent and child. Because parental rights are intimately intertwined with the rights of their children, parental authority cannot be reduced to either the rights of parents or those of children. Rather, the authority of parents to make decisions with regard to their children, should be based upon the relationship within which children can develop their identity. In the next chapter I will address another complication of informed consent for newborn screening: the choice of information.

[236] See also Brighouse & Swift (2006), p. 107.

Chapter 7 Informed Consent and Information

In the previous two chapters I discussed the complications of parental authority and informed consent for public health interventions. In this chapter I consider a third complication when applying informed consent requirements to newborn screening practices. I will look at the question of to what extent people have 'epistemic rights': rights that concern the production and/or transfer of information. Newborn screening is not very invasive medically. As became apparent in chapter 1, the main concern when considering informed consent for newborn screening is not the intervention of the heel prick itself, but rather that the intervention consists in the communication of the information that may be derived from the blood drop. Controversy surrounding expanded newborn screening arises from different ideas on the question of which knowledge should be pursued and which not. Epistemic interventions such as newborn screening raise issues having to do with the value of knowledge and the individual's discretion with regard to information. How should we understand informed consent in this context? In order to answer this question, I will consider the relevant epistemic rights in this context: 'the right to know' and the 'right not to know', respectively.

In the first section of this chapter, I discuss the scope of consent for epistemic interventions. I argue that the relevant rights to 'epistemic consent' are both a 'right to know' and a 'right not to know'. These rights are specifications of a right to privacy and apply to specific information. They are relatively weak rights. Next (7.2), I consider the question of what specificity of consent fits a right to privacy. I argue against the view that the validity of epistemic consent is dependent on whether a subject has control over the type of information that he receives.

7.1 Consent for Epistemic Interventions: the Scope

This section is intended as a way to clarify the notion of consent for epistemic interventions and to give an indication of the scope of this consent. What does it mean to say that a person has authority with respect to an epistemic intervention? In UNESCO's International Declaration on Human Genetic Data we find the following statement:

> "When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be

informed of the results."[237]

I take it that "the right to decide" should be understood in this quote as a power to consent to epistemic interventions. If what I have argued in chapter 3 is correct, this means that epistemic interventions require a waiver of rights. What sorts of rights are these? Much of the debate on this issue has centred on the terms 'right to know' and 'right not to know'.[238] I will also adopt this terminology. However, it often remains unclear what exactly is meant by these terms. In this section, I will give an interpretation of these rights and sketch how they affect the scope of consent for epistemic interventions.

First, it is important to distinguish between claim-rights, powers, liberties and immunities.[239] In particular, the distinction between a liberty not to know and a claim-right not to know is often missed in the debate on a right (not) to know.[240] A liberty not to know refers to the absence of a duty to know. A claim-right not to know, on the other hand, refers to the duty of others to abstain from interfering with my ignorance. Since what is at stake here is consent for interventions, the 'right (not) to know' should express a waiver of claim-rights: the role of consent here is the control over the duties of other persons. Intuitively it seems that claim-rights imply liberties,[241] but it is clear that a liberty does not imply a claim-right: the fact that I am not morally culpable for not knowing that Paris is the capital of France (a 'liberty to ignorance'), does not imply that others have a duty to refrain from informing me on this fact (a 'claim-right to ignorance').

Claim-rights are the correlates of duties, which specify normative claims that others do or abstain from doing something. A right can therefore never refer to a state of affairs, but only to a more or less specified action or the negation of an action, such as the 'right not to be assaulted' or 'the right to medical care'. Therefore the term 'right (not) to know' is, strictly speaking, a misnomer: the state of knowing is itself not the object of the claim.[242] This means that central to assessing consent for information is either the activity of or the abstaining from informing another person or the activity

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237 UNESCO (2003).

238 Andorno (2004), Bottis (2000), Chadwick (1997), Häyry & Takala (2001), Harris & Keywood (2001), Laurie (1999), Laurie (2000), Ost (1984), Rehmann-Sutter & Müller (2009), Rhodes (1998), Rhodes (2000), Takala (1999), Takala (2001), Takala & Häyry (2000), Raïkkä (1998), Wilson (2005). From here on, I will abbreviate 'the right to know and the right not to know' to 'the right (not) to know'.

239 See chapter 3.

240 See for example Andorno (2004) and Takala (1999).

241 See, however Matthew Kramer in Kramer, Simmonds & Steiner (1998).

242 Nor can there be a 'right to life' or a 'right to health', at least not if we take this literally. See also O'Neill (2002), p. 10.

of or the abstaining from seeking information. How should we conceive of these rights?

Some have displayed scepticism on the issue of whether one can genuinely make decisions concerning epistemic interventions:

> "[T]here is no way […] to exercise the choice of not knowing, because in the very process of asking 'Do you want to know whether you are at risk..?' the geneticist has already made the essence of the information known."[243]

Indeed there are many situations in which it is impossible to ask whether a person would like to know something without already giving away some of the content of the information. However, not all situations are like this. When one can anticipate knowledge that could be attained in the future, it is possible to consider the desirability of knowing something and to make decisions accordingly. This is a specific type of deciding, which depends on hypothetical reasoning.

Consent for information is generally only an issue when it is presumed that there *is* something to know, which in this case is that the result of the test is positive. People generally do not mind knowing that they do *not* have a disease or a susceptibility to one. In other words, when I consider the question "would I like to know whether I have the BRCA1 gene?", I am considering the hypothesis that this is in fact so. Therefore, the problems of disclosing or withholding information do not arise unless there is a positive test result to disclose or withhold. There is thus an asymmetry between the situation in which there is a positive test result and that in which the result comes back negative. One cannot choose to know or not to know *that* a certain proposition is true, because this would imply that one already knows that this is true. The best thing we can do when we 'choose to know' is hypothetically wonder: "*if* I had this or that disease, *would* I like to know?"

In general the case of consent for information, contrasts with situations where the subject involved takes the initiative by pursuing information or stating that he does not want to know ("if you find that I am infected, please do not tell me"). Typically, the initiative is on the part of the person making the offer ('if I find that you are infected, would you like to know?'). These 'epistemic interventions' raise issues to do with privacy. In chapter 3, I have described privacy as an extension of the right to physical integrity: just as we have claims regarding interventions with our bodies, so

[243] Wertz & Fletcher (1991), quoted by Laurie (1999), p. 127.

we also have claims with regard to our 'private sphere'. As Graeme Laurie wrote, the right to privacy "acknowledges a sphere of separateness which should not be invaded without justification."[244] Information gathered by, for example, screening may have a considerable impact on people's lives. The requirement of informed consent for information can be understood as an expression of the right to (informational) privacy: the right of an individual to live their life to an extent free of external intrusion.[245] Note that this is a much broader interpretation of the right to informational privacy than merely the requirement that certain information is not disclosed to third parties. In the case of screening specifically, the right to privacy refers to a duty on the government and health care professionals to show restraint in interventions with people's lives. It is easy to see that this right is less strong and less strict than, for example, a right to physical integrity. The boundary between what is an acceptable influence and what is an infringement of the right to privacy is inevitably vague.

There appear to be two opposing ways to infringe upon a person's right to privacy in the context of screening; either by unsolicited disclosure of information or by withholding information without consent. In the first case people are confronted with information they might have preferred not to have had. In the second case, the screening authorities make a decision to discard information that some people would have preferred to receive. If this is correct, it follows that epistemic consent implies both a positive claim-right to being informed, as well as a negative claim-right not to be. To disclose or withhold certain information without prior permission constitutes an interference with informational privacy. This of course raises the question: what information?

When we speak of a 'right (not) to know', the question is always '(not) to know *what*?'.[246] Somehow we need to specify which information we are talking about. In the quote above by Wertz and Fletcher, the scope is limited to (personal) medical information. Yet, even if we limit ourselves to information on our own health, it would be implausible – to say the least – to claim that every bit of trivial or potentially relevant information is a possible candidate for claim-rights and thereby for epistemic consent.[247] The information involved should be relevant on the one hand (thus generating a possible right to know) and considered a possible interference if disclosed on the other (generating a possible right not to know).

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244 Laurie (1999).
245 Ibid.
246 See Chadwick (1997).
247 See Takala (1999), p. 292, for this point.

If the information involved has no medical, or at least practical, relevance, there is no reason not to discard the information. If, however, it is obvious that any reasonable person would like to receive certain information there is, equally, no reason not to disclose the information. The key cases are those situations where the subject is not able to influence the course of things, where the different options are not clearly defined or where there seems to be no direct reason for action. Particularly for these types of information the question of a right (not) to know may be pertinent. What would the right to informational privacy imply for the requirement of informed consent?

7.2 Consent for Epistemic Interventions: the Standards

I now focus on the standards of epistemic consent, in particular its specificity. According to the proponent of specific consent, to respect a right (not) to know entails enabling the subject to 'control the stream of information'. This can be established by requiring explicit consent to specific information. According to the proponent of generic consent, it is neither possible nor necessary for the subject to exercise such control. This is not merely a gradual difference, but reflects a more fundamental difference of opinion on the role of the content of the information involved. I will defend a notion of generic consent in this section and argue that the focus on specific epistemic consent rests upon a mistake.

According to Roberto Andorno, people should be free to make their own choices with respect to information.[248] The decision not to know should be, at least in principle, as fully respected as the decision to know. Andorno reasons that it is therefore wrong to either withhold or disclose information without prior consent. Thus far, the argument presupposes no more than what I have already claimed in the previous section. He continues, however, by claiming that the wish of not knowing should be explicit: "The right not to know cannot be presumed, but should be 'activated' by the explicit will of the person."[249] Andorno argues that individuals can only properly exercise their authority if they are enabled to *choose* the information they would like to receive. Here, Andorno makes a move from the requirement of consent to the claim that this consent should be explicit with respect to the content of the information: the subject should be able to control what information he receives. This is not a necessary step.

The idea of a choice of information depends on the idea of being able to "control the outward flow

248 Andorno (1999).
249 Ibid.

of information".[250] However, in many cases subjects are relatively helpless in determining what they would and would not like to know. In the case of screening, the possibilities are varied and numerous. The "flow of information" is a complex, intricate weave of very different types of strands. The different types of information vary in relevance, reliability, certainty, practical use and so on. Controlling this flow implies also controlling the flows of everything we do not know. Therefore, we may conclude that since the object of 'choosing information' is beyond our control, an explicit right to choose information will be hard to establish.

This presents proponents of the claim that the consent should be explicit and specific with a dilemma. Since specific consent is not possible for complex screening programmes, we have two rights (the right to know and the right not to know) pulling in opposite directions with no way to decide between them. Can this dilemma be solved? I suggest it can, but only if we let go of the requirement that the authority expressed can only be legitimate if the subject knows what information he can receive.

For these reasons, I propose to adopt a 'generic' consent, where the criterion of specificity is less stringent than in the case of consent to surgery, for example.[251] The standards of generic consent do not necessarily include the choice of specific information. Rather, what is stressed is that the subject knows the purpose of a specific test and understands what will be done with the information gathered (Will it be stored? Will others have access to it? and so on). This means that the offer of information is predetermined by a judgement made by the person or body offering the test on what information should be disclosed and what not. In turn, this implies the acknowledgement that sometimes disclosure or withholding of even potentially harmful information will not be preceded by an explicit informed consent, since the patient is not fully aware of the consequences of the information that may result from the test. In practice one cannot prevent intrusion into at least some aspects of a person's informational privacy. The least interfering option is often to offer layered disclosure: people who wish to inform themselves more on the options should be offered that possibility.

[250] The quote is derived from Brownsword (2003), p. 417. I am not implying that the position I criticize is one he would underwrite; in fact I think he would not.
[251] Elias & Annas (1994).

7.3 Conclusion

The answer to the question of whether people have a right to decide whether or not to know something turns out to be more complex than the phrasing at first suggests. I have suggested the claim that consent for information can be defended with a reference to a right to privacy. The claims that can be derived in this context are relatively weak and the consent that expresses the right to informational privacy should be generic rather than specific.

Conclusion Part III

In part III, I have discussed three complications in the application of the requirement of informed consent to newborn screening. Firstly, I have focused on the relevance of the fact that newborn screening is a public health intervention that aims for the health of the public rather than that of the individual interfered with. I have shown that the application of the principle of informed consent to public health interventions requires that one contemplates the relation between collective interests and individual rights. I have argued against (mixed) paternalistic justifications of limiting informed consent requirements, but have added that there are good-promoting justifications possible for downplaying the standards of informed consent. This is the case when there is no neutral collective decision possible and the rights that are violated are relatively weak. Secondly, in chapter 6, I have argued that, up to a threshold, parents have the authority to decide for their children. I have claimed that this authority can be defended with a reference to a relational argument. Parental rights are intimately intertwined with the rights of their children. In chapter 7, I have addressed the issue of informed consent for epistemic interventions. I have argued that a right to privacy could justify generic consent procedures for epistemic interventions.

Part IV Applying the Framework

In the final part of this thesis, I return to the SIC claim, the claim that informed consent for newborn screening needs to be strengthened to the extent that the disadvantages increase relative to the advantages. After having first discussed the role and meaning of informed consent in general in part II and the specific application of informed consent to the different particular features of informed consent (it is a public health practice where consent is given by parents on which information they would like to receive), I am now in a position to interpret and assess this claim.

Chapter 8 The SIC Claim

In chapter 1, I have described the SIC claim, which states that as the disadvantages of newborn screening increase relative to the advantages, there is a need for strengthened informed consent. It is now time to apply the conceptual framework and arguments sketched so far to the case of newborn screening. The validity of the SIC claim depends on the question of whether or not strengthening informed consent will result in a larger or a smaller infringement of the right to privacy. I will show that for an expanded programme of newborn screening, strengthened informed consent is not necessarily preferable from a moral perspective, even when one assumes – as I have done thus far – that the main commitments of the proponents of the SIC claim are justifiable.[252] In 8.1, I discuss in more detail the claim that informed consent procedures should be strengthened when the newborn screening programme expands (the SIC claim). I give an interpretation of this claim and examine some of the ways in which informed consent can be strengthened. In 8.2, I give a normative assessment of the SIC claim. I argue that strengthened informed consent can be burdensome and that these burdens can interfere with the privacy of families.

8.1 Strengthening informed consent

In this section, I will give an interpretation of the SIC claim. What is necessary in order to determine whether it holds? As described in chapter 1, there are advantages as well as disadvantages to newborn screening, and furthermore there is much uncertainty surrounding some test results: think of false positives, but also the diagnosis of extremely rare diseases. It is to be expected that as the screening programme expands, the controversy on the desirability of these expansions will increase too. There are good reasons for and against screening for extremely rare or untreatable diseases, screening for susceptibilities, screening for diseases that are less serious and screening for diseases where screening also gives additional information, such as carrier status. Quite a few considerations play a role in determining what types of diseases qualify for screening. The resulting complexity is multiplied by the fact that there are a large number of possible expansions that are very different in type. As a result, a lot of different arguments can be given for and against different programmes.

According to the SIC claim, if the screening programme expands, the informed consent procedure should be improved. The fact that expansion of newborn screening will possibly lead to a relative

[252] That is, a commitment to informed consent, parental authority and epistemic rights.

increase in disadvantages will lead a defender of the SIC claim to conclude that this procedure has to be preceded by a stronger informed consent procedure.

The first thing to notice when applying the framework developed in this thesis to the SIC claim is the role of the disadvantages and advantages of newborn screening. Given the account developed in part II, the reason that these (dis-)advantages affect the informed consent procedure is that they affect the relevant rights. These rights, so it can be claimed, are better served by a strengthened consent procedure. What sort of rights are these?

From chapter 7 it follows that the informed consent procedure involved expresses a right to informational privacy. Since newborns cannot process the information produced by screening, this raises the question of whether the child's rights play a role in the attribution of the right to informational privacy. As we have seen, however, in chapter 6, the authority of parents to make decisions is based on the intertwinement of the parents' and the child's rights. A right to privacy could, then, be incorporated in the understanding of parental authority. The proponent of the SIC claim will thus argue that relatively larger disadvantages lead to a greater infringement of the right of parents to informational privacy.

Turning to the question of how to strengthen the informed consent procedure, I note that this of course depends on the starting point. When introducing the issue of strengthening informed consent, I used the Dutch situation as an example. In the Netherlands, newborn screening is performed on a voluntary basis, but the informed consent 'procedure' is very minimal and very few parents opt out. This means that if a 'thorough' informed consent procedure is required, there has to be some form of strengthening.

Using this situation as a starting point, I will now expound on the idea of strengthening informed consent. Supposing that newborn screening calls for strengthened informed consent; how could this be achieved? Let us return to the components of disclosure, comprehension, voluntariness, competence and consent, mentioned in chapter 4. It seems natural when we think of ‘strengthening’ an informed consent procedure to think along three lines of improvement; disclosure, comprehension and voluntariness.[253] These standards should be in the service of respecting the

[253] Competence and consent can be eliminated from these options. The competence of a population is something which needs to be presumed when offering a diphi (see chapter 5), whereas the consent requirement refers only to the question of whether or not an actual consent was given.

joint rights of parents and children. In 8.2, I examine the limits to these standards, but first I want to explore in what way they can be strengthened.

Concerning the content of the information, the disclosure, there are three possibilities. First, it may be suggested that the expansion of the screening programme necessitates the provision of *more* information, simply by giving a more specific description of the diseases involved, data on the symptoms, the treatment options and the prevalence and so on, particularly for those diseases that are more controversial. This should enable parents to get information on what screening involves and to consider what drawbacks might be involved. The immediate problem that arises, particularly if screening is performed on twenty or more diseases, is that this would soon lead to an information overload. Second, instead of trying to give specific information on specific diseases, the diseases could be categorized according to several criteria. Different types of diseases (e.g. serious/not so serious, treatable/not treatable and so on) could then be described and this would make it easier for parents to decide what their preferences are. This would imply that one decides which features are relevant and then proceeds to map diseases accordingly, so, for example, DMD would then fall under the category of 'serious, untreatable, monofactorial diseases with an onset longer than two years'. The question, however, is whether each of the diseases can be classified so easily. Take, for example, CF, which develops symptoms differently in different patients and with which there appears to be a continuum between having very serious symptoms and having barely any.

Apart from the questions related to how much and what type of information is appropriate, there is a separate question concerning the actual comprehension.[254] People have to understand to some extent what newborn screening entails. It has been mentioned that the first few days after giving birth to a child is not an ideal time for parents to process information and to think about what this information may mean.[255] So the informed consent procedure may benefit from informing parents at an earlier stage, for example during pregnancy. That way parents would possibly be more thoroughly aware of the choice they are making when consenting to screening. Since this is intended as a way to strengthen the informed consent procedure, it requires a significantly greater effort of the health professional in providing information. It does not suffice to just hand out brochures or to use ways of informing parents that only reach a part of the population. If this is to be a part of the informed consent procedure, all parents should encounter this information.

254 Press & Clayton (2000).
255 Detmar et al. (2007).

The informed consent procedure could also be strengthened by focusing attention on the consent process, thereby making people more aware of the fact that they are making a choice. Two examples of ways to achieve this are by being very explicit about the possibility of refusal or by requiring the parents to mail the blood sample themselves. Such adaptions are likely to enhance the voluntariness of the consent. Parents will be less likely to comply simply because the procedure is standard, but are encouraged to make their own deliberation on the advantages and disadvantages of screening. However, one may wonder whether such an approach does not also decrease the voluntariness of the *dissent*.

Aside from these ways to enhance disclosure, comprehension and voluntariness, there may be another way to 'strengthen' informed consent, which is that the informed consent procedure itself could be split up into several different procedures. Although a 'take it or leave it' policy – where people either have their child screened for all diseases in the programme or for none at all – suffices for a small and homogeneous programme, it may be considered problematic for a more diverse, large one. The fact that somebody wants his child screened for PKU in no way implies that he wants his child screened for DMD. By splitting the programme up it becomes possible to use different criteria for the different authorizations. We can distinguish three alternatives here. An extreme variant is the possibility of parents choosing between a number of different diseases. Parents should then be able to choose what diseases they want their child to be screened for. Then parents could decide for themselves to have their child screened for PKU, but not DMD (or perhaps even the other way around) and so on. Merely for practical reasons this seems an unattractive option. When there are dozens of diseases offered it cannot be expected that people will be able to make a well-considered choice. Moreover, such a strategy might lead to administrative problems. For example, the mistakes made by laboratories are likely to increase significantly when everybody makes their own personal selection of diseases. Therefore, it would probably be more realistic to limit the choice between different categories. Parents could choose between having their child screened for treatable conditions but not for untreatable conditions, or for carrier status but not for susceptibilities. This is what one might call the 'category approach' to consent. To simplify this even more, the choice could also be limited to a standard screening programme and an additional optional category of controversial diseases. The downside of such an approach could be that the different controversial diseases are controversial for very different reasons. Therefore the same argument applies as in the 'take it or leave it' policy. When parents indicate that they want their child screened for DMD this does not imply that they want to know about susceptibilities for

allergies as well.

In this section, I have given a first indication of what strengthening informed consent for newborn screening might entail. Informed consent for newborn screening is based on informational privacy. If that is correct, the SIC claim entails that this privacy is better served in the case of expanded screening when the informed consent procedure is strengthened. There are different ways to strengthen the informed consent procedure for newborn screening: one could think of enhancing the different aspects of disclosure, comprehension and voluntariness. Also, there is the option of categorizing the offer, so that different informed consent procedures could be required for different (types of) diseases.

8.2 Assessing the SIC claim

I will now give a tentative assessment of the validity of the SIC claim. I will argue that it is not as convincing as it may seem at first glance. If the analysis of informed consent offered in part II is correct, the claim must be that such decisions should be left to parents themselves, and not be forced upon them, *independent* of the question of whether they make the 'best' choice. They act as authorities on the decision about whether or not to screen. The question now is whether the possibilities for strengthening consent as described in the previous section are morally desirable. As we have seen in chapter 4, an increased specificity and explicitness is not always a better way to respect rights.

First, one should determine that there are rights involved and that there are no overriding third party interests at stake. As mentioned in the previous section, parental authority combined with epistemic authority can give parents a right to decide upon such matters, and it seems that there are no large third parties' interests that stand in the way. As long as the children are not exposed to a substantial risk of serious harm, there seems to be a case for allowing parents the possibility of opting out. However, although we can ascribe epistemic rights to parents, the rights involved are weak rights, which carry nowhere near the same import as the right of an individual to physical integrity. Furthermore, consent for epistemic interventions is not specific to the type of information one receives.

In section 5.3, I alluded to an argument for limiting informed consent standards for public health interventions. There, the idea was that if a diphi affects weak moral rights, and the government

cannot escape making a decision, it can be justified to limit the standards of consent on the basis of the good of the population intervened with. This point can be applied to the SIC claim, by pointing out that if informed consent procedures are strengthened, the burdens increase too.[256] Whereas for some this might be an attractive trade-off, one can very well imagine that not all would prefer to be burdened by the possibility of choice. Therefore, a relatively superficial informed consent might be considered preferable from a policy perspective, given of course that the decision to be made is below the threshold of parental authority. In order for this objection against the SIC claim to work, it has to be shown that it is legitimate here to invoke the mentioned burdens against the principle of informed consent. I discuss three problems for adherents of strengthening informed consent.[257]

If it is correct that the expansion of newborn screening necessitates strengthened informed consent, we are faced with an immediate practical problem. It turns out that it is very difficult to get parents to take an active stance on these matters.[258] Newborn screening is an issue that most people never think about before they are confronted with it, and often not even then. Parents generally do not take the time to understand what risks or drawbacks are involved.[259] Related to this is the problem that it is very difficult, not to say impossible, not to directly influence people's choice when supplying information on a screening programme and its purposes; the way in which the information offered is structured has consequences for the way parents come to their choice.[260] The mere fact that a possibility to screen is offered by the screening authorities presents itself to parents as a reason to assume that this screening is worthwhile. Since screening is performed on an entire population and is conducted routinely, it is even more difficult not to influence the outcome of the deliberation of the parents. The solution to these problems, so the proponent of the SIC claim will propose, is to become more active in counselling. But this is only possible at the expense of the non-intrusiveness of screening. When the informed consent procedure is organized in such a way that these problems are surmounted, the informed consent procedure itself also becomes more burdensome. There are three reasons for this.

First, there is the *burden of information* itself. This burden may become unacceptably high. There is, after all, a substantial amount of information to be processed. If we really want parents to be informed we need at least a description of the different types of diseases, what carrier status is, what

256 See section 1.4.
257 See Nijsingh (2007)
258 Parsons et al. (2005).
259 Detmar et al. (2007).
260 Clarke (1991).

treatment would involve and so on. This cannot be done in a few words, and requires an attentive study by each individual in order to grasp the information, which may be considered excessive since only for one in a thousand or so will the outcome of the test be positive.[261] There is an even a stronger case to be made here. The presumption of the SIC claim is that there may be real advantages and disadvantages to the individual screened. A minimal requirement seems to be that these advantages and disadvantages become clear to the person who consents. It follows that information cannot stop at the point where the individual involved understands what diseases are being screened for, but also needs to grasp the different considerations favouring or disfavouring their addition to the offer. If this is granted, the SIC claim requires a perhaps overwhelming complexity of information. This imposes a large burden of information and also an active role for the professional in providing that information.

Connected to, but distinct from, the problem of the burden of information is the *burden of choice*. When the parents have processed the information, they are expected to make a choice. They will therefore have to sort out the relevant arguments and find out for themselves which argument should prevail. This requires an active involvement of parents in the decision-making process and may cause stress and anxiety in a proportion of the population. This burden of choice becomes larger as the decision to be taken becomes more controversial and as the emphasis on choice is strengthened. And, as noted, the decision about whether or not to screen *is* controversial for some diseases – uncommon as they may be.

A third possible problem for the SIC claim is *medicalization,* which is, roughly, the phenomenon that medicine and issues concerning health and disease play an increasingly important part in different domains of society. Usually medicalization is taken to refer to the process of medical terminology being applied to new fields, for example addictive or deviant behaviour. However, the concept can also refer to "the phenomenon that (healthy) persons tend to adjust their life and life-style according to medical information, advice and procedures".[262] There is a case to be made that newborn screening can influence lives in a medicalizing fashion. When health care professionals actively seek consent or dissent, people will be pressed to make up their mind. Medicalization can be a consequence of having to choose in this situation. Whilst newborn screening is aimed at detecting serious diseases, we are also dealing with extremely rare ones. So we may suppose that

261 See appendix for the prevalence of some diseases.
262 Verweij (1999), p.81.

for most people none of these diseases will be part of their perception of the world. This is likely to change, at least to an extent, when they are pressed to think about the consequences of screening. Apart from the stress and anxiety mentioned above, this might also lead to a different relation of people towards disease and a different role of preventive medicine in their lives. It is conceivable that programmes such as this enhance the felt responsibility for health and promote a more emphatic awareness of the possibility of being sick. Whether such a development should be considered a good thing or not, if it even occurs, is an open question. However, it raises the issue of what the role of medicine in society is and should be.

These three problems lead me to conclude that a strengthened informed consent procedure may be considered burdensome to parents. Therefore, an active informed consent procedure could – at least in some way – be considered an intrusion in the daily life of otherwise healthy people. Also, strengthened informed consent may cause a different – medicalized – perception of the world.

The proponent of the SIC claim could object by pointing out the trumping character of rights and argue that although there are indeed disadvantages and practical difficulties, they are on a different level to the considerations which point to strengthening informed consent. [263] As we have seen, however, in chapter 7, the relevant right in the case of information is a right to privacy, not a specific right to choose information. In that case the question becomes one of which interference with privacy is the strongest. The right to privacy is connected to the idea that it is important for a government to show restraint in interventions with people's lives, so that a 'sphere of separateness' is protected. The opponent of the SIC claim could well hold that an overly burdensome informed consent procedure is opposed to rather than in line with such a right. The point here is that if we consider a strengthened informed consent procedure to be an interference with the right to privacy, the question is, which procedure infringes upon that right the least? There seems to be no *prima facie* reason to prefer one over the other. We simply have to strive for the offer which least infringes upon the rights in play. [264]

An alternative position for the proponent of the SIC claim could be not to take the expansion for

[263] Needless to say, if one does not subscribe to the doctrine of informed consent as described in part II of this thesis, the dispute as described here does not arise. If one does not believe that individuals have rights which give them authority to consent, 'strengthening of informed consent' is necessary only in so far as it establishes other aims – for example maximizing the good. As mentioned earlier, the argument here depends on the assumption that autonomous authorization is important in its own right.

[264] I refer to the point mentioned in chapter 4, which is that the problem of determining the standards of informed consent needs to be approached from a pragmatic perspective.

granted and argue that the problems associated with a strengthened informed consent procedure lead to the conclusion that expansion itself becomes problematic. Given the fact that a policy where only a few diseases are being screened for leads to few complaints from the population, the last conclusion seems a tempting one. The SIC claim could give us an argument to restrict screening for diseases that fit the criteria of Wilson and Jungner, that is, diseases that are minimally controversial. It may appear that informed consent would then be unproblematic and some objections would be met. The SIC claim would then stay intact, but it would force us to be more modest in our screening ambitions. However, although there is something to be said for a limited offer, this conclusion is too easily reached. If we choose not to screen for DMD, this means that we have decided not to attain information on the health of a child, which could have been attained very easily and cheaply. Given that our premise was that screening for DMD is controversial, this means that a choice has been made not to know where some people would have preferred to know. This pre-emption of preferences can also be considered an interference with privacy. This means that, although the option not to expand the screening programme may be an attractive one, it does not avoid being non-neutral with respect to people's preferences. Whenever a possibility to screen exists, parents' choices are being pre-empted. The challenge is then to find a balance between these interferences.

To summarize, there are three positions one might take with regard to the SIC claim. Proponents will argue that the right to give consent should take priority over other considerations. Opponents, on the other hand, will claim that the right to privacy may also be infringed when the informed consent procedure is too burdensome. I have suggested that the advantages of strengthening are not likely to weigh up against the burdens.

8.3 Conclusion

I have elaborated upon the SIC claim in this chapter. I considered the ways in which informed consent for newborn screening may be strengthened. I discussed improving the informed consent standards of disclosure, comprehension and voluntariness, complemented by the possibility of giving a different consent for different categories of diseases. Then I returned to the SIC claim. I have claimed that the opponents and the proponents of the SIC claim both rely on the right to privacy, and that they differ on the question of which procedure infringes more upon such a right. Given the burdens created by strengthening consent, at this point it does not seem that the SIC claim is very attractive.

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Appendix: Newborn screening; some possibilities[265]

When PKU screening was introduced, the method used was the ferric chloride test, and it was performed on urine samples. In 1962, Robert Guthrie developed a more reliable test for PKU performed on blood spots called the Guthrie test. There are currently dozens of diseases which may potentially be the target of newborn screening, particularly due to the introduction of tandem mass spectrometry (MS/MS), which makes it possible to test reliably and relatively cheaply for a large amount of metabolic diseases. The list below gives a sample of some current possibilities. I will first list metabolic diseases that can be detected by means of MS/MS.

1. Metabolic diseases

Most diseases that are candidates for newborn screening concern the child's metabolism. Most of those, but not all, can be detected by means of MS/MS. All metabolic diseases mentioned below are autosomal recessive, which means that if both parents are carriers of the mutation, the child has a 25 per cent chance of being afflicted. Although the cause of these diseases is genetic, the screening test is not a 'genetic' test. MS/MS detects elevated levels of biochemical compounds present in the child's blood.

1.1 Amino acidemias

This group contains, amongst others, PKU, Homocystinuria, Tyrosinemia and MSUD.

Phenylketonuria (PKU)

Phenylketonuria is the first disease for which newborn screening was implemented and still the most commonly screened-for disease worldwide. PKU is caused by a malfunction in the enzyme responsible for metabolizing phenylalanine. The resulting accumulation of phenylalanine leads to mental retardation and, eventually, death. These effects can be prevented by means of a diet that is low in phenylalanine; this diet cuts out all high-protein foods. Opinions differ with respect to the question of how long the diet needs to be maintained. It is important, however, that affected women avoid phenylalanine during pregnancy. The test for PKU is extremely reliable. PKU is relatively common in western countries but much more rare in countries with a non-Caucasian population; the prevalence varies between 1 in 10,000 in some western countries and 1 in 100,000 in Japan.

Homocystinuria

Homocystinuria is a group of diseases which are characterized by an accumulation of homocysteine. The symptoms vary from mild to very serious and include the dislocation of the eye lens and vascular disease. Some patients respond to the intake of pyridoxine. Also the combination of a diet low in methionine with the intake of betaine is proven to have been beneficial. A complication in testing homocystinuria is that it also reveals other diseases, such as severe liver

[265] The following sources provide useful information on newborn screening and/ or the mentioned afflictions: Pass (2000), Erbe & Levy (1996), Levy (1998), Kerruish (2011), Gezondheidsraad (2005).

afflictions. The prevalence varies between 1 in 50,000 and one in 200,000.

Tyrosinemia, type I

People with this metabolism disorder have trouble processing tyrosine. Accumulation of tyrosine can cause mild retardation and problems in the functioning of the liver and the kidneys. Treatment consists of a special diet. Sometimes a liver transplant is necessary. Tyrosinemia is rare; the prevalence is about 1 in 250,000 in the Netherlands. Early diagnosis and treatment seem to offset long-term problems, although due to the rarity of the disease data are scarce. Since tyrosine accumulation can point towards more causes than tyrosinemia type I, screening may produce a high number of false positives.

Maple syrup urine disease (MSUD)

Maple syrup urine disease (MSUD) is caused by a deficiency in an enzyme complex that results in the accumulation of the branched-chain amino acids: leucine, isoleucine and valine. The build up of these amino acids causes the urine to smell like maple syrup. The symptoms of MSUD include lethargy and seizures. If left untreated, MSUD can cause mental retardation, physical disability and possibly death. There is a life-long risk of the symptoms of MSUD recurring. The treatment consists in a low protein diet. The prevalence is about 1 in 200,000 worldwide.

1.2 Organic acidemias

This group contains, amongst others, glutaric, isovaleric and propionic acidemia. I briefly describe propionic acidemia.

Propionic acidemia

This disorder, resulting in an accumulation of propanoic acid, manifests itself in the early neonatal period with progressive brain dysfunction. Coma and death can occur quickly. The treatment consists in a protein low diet and the intake of carnitine and metronidazole. The effectivness of this treatment is, however, limited.

1.3 Fatty acid oxidation disorders

This group of diseases contains, amongst others MCADD, MADD, VLCADD, LCHADD, SCADD, I discuss MCADD and MADD.

Medium chain acyl-CoA dehydrogenase deficiency (MCADD)

Children with MCADD are prone to hypoglycemia (low blood sugar), which can cause a variety of symptoms. Treatment consists in the avoidance of fasting and additional intravenous nutrition. Early detection and treatment is thought to prevent a lot of physical damage.

Multiple chain acyl-CoA dehydrogenase deficiency (MADD, also know as Glutaric Acidemia type II/ GA-II)

MADD is a very rare disease which causes hypoglycemia and high blood ammonia levels. Although patients with milder forms of MADD may respond to riboflavin and L-carnitine, and variable results have been noted with dietary restrictions, the rarity and complexity of the disease make the prognosis for more serious forms very bleak.

1.4 Lysosomal storage diseases

This category of diseases includes, amongst others, Tay-Sachs disease, Pompe disease and Gaucher disease.

2 Endocrine diseases

Endocrine diseases affect the glands. They include, amongst others, CAH, CH and CF.

Congenital adrenal hyperplasia (CAH)

CAH is a group of disorders of the steroid metabolism involving a deficiency of certain hormones produced by the adrenal gland. The disease can be treated, but treatment is life-long. The prevalence is about 1 in 10,000.

Congenital hypothyroidism (CH)

CH is the disorder of the thyroid metabolism. By newborn screening standards it is relatively common: 1 in 4,000. Affected children lack thyroid hormones, resulting in retarded growth and brain development. Treatment consists in oral doses of thyroid hormone.

Cystic fibrosis

CF, a disease affecting the secretory glands, causes the production of thick mucus by the body, which gets trapped in – among other places – the lungs and pancreas, severely disrupting ordinary functioning if left untreated. In the past it was detected by IRT levels, but this technique is more and more being supplemented with additional DNA analysis. Overall, we see a development of increasingly reliable and cheap tests. Early detection may help doctors reduce the problems associated with CF, but the real impact of newborn screening has yet to be disputed. The prevalence is about 1 in 4,000 in Caucasians.

3 Hemoglobinopathies

Hemoglobinopathies that provide a potential target for newborn screening include sickle cell disease and thalassemia.

Sickle cell disease

Sickle cell disease is a blood disease, which causes red blood cells to mutate into a ‘sickle’ shape. The symptoms include episodes of pain and damage to vital organs. Treatment is mostly focused on the symptoms and consists in measures against infection and blood transfusions. Cure is possible by means of stem cell therapy, but this is not uncomplicated. Sickle cell disease is particularly common (up to 1 in 500) in people of African, Mediterranean and South-Asian descent.

4 Duchenne muscular dystrophy (DMD)

DMD is a progressive, muscular disease, which leads to a degeneration of the muscles. There is no effective treatment, apart from physiotherapy, and patients have a life expectancy of 20 to 30 years. DMD is a recessive X-linked disease, which means that a carrier mother has a 25 per cent chance of having an affected boy (and an equally large chance of having a carrier girl). DMD is related to Becker Muscular Dystrophy (BMD), which is milder. Testing for DMD will also produce results on BMD.

5 Fragile X

Fragile X syndrome causes mental retardation and is considered to be the most common known cause of autism. Girls can be affected, but this is more rare and they display milder symptoms. The disease has a very variable progress, which makes it difficult to predict its course. Treatment generally consists in speech, cognitive and physical therapy, although experiments are being conducted with diverse forms of medication. Screening for Fragile X will identify some children who are, or appear to be, phenotypically normal and might also identify children with other conditions not originally targeted for screening.

6 Type I diabetes

Newborn screening for susceptibilities has been proposed. An example is screening for diabetes type I. Diabetes causes high blood sugar, in the case of type I because of autoimmune destruction of insulin producing cells in the pancreas. Such screening would not aim for diagnosis, but rather be probabilistic in nature. Potentially, with the rise of genetic understanding and the decrease of the costs of genetic tests, this type of screening becomes a more efficient way of preventing disease. Currently, however, it is mostly not deemed worthwhile.

7 Cancer

Apart from the possibility of screening for the susceptibility to various forms of cancer, newborn screening provides the possibility of screening for neuroblastoma, a form of cancer which usually begins in the adrenal glands. The screening, which is performed using urine samples, is, however, associated, with over-diagnosis.

9 Transmittable diseases

Human immunodeficiency virus (HIV)

Human immunodeficiency virus (HIV) is a virus that causes Acquired Immunodeficiency Syndrome (AIDS). Newborn screening for HIV has been implemented in some countries. Children could benefit from timely treatment.

Toxoplasmosis

Toxoplasmosis is a parasitic infection. The infection can invade the brain, eye and muscle, possibly resulting in blindness and mental retardation. The benefit of early detection and treatment is uncertain.

10 Exposure to toxic substances

Newborn screening can also include tests that detect the exposure to toxic substances, such as lead.

Index

Samenvatting

De hielprik, de screening van pasgeborenen op aangeboren afwijkingen, is in veel landen vanzelfsprekend onderdeel van de zorg rond zwangerschap en geboorte. Recentelijk is er in veel landen sprake van uitbreiding van het screeningspakket. Zo is in Nederland het aanbod in 2008 uitgebreid van drie naar zeventien aandoeningen. Deze uitbreiding wordt vergezeld door een nadrukkelijke roep om sterkere standaarden voor geïnformeerde toestemming. Dit proefschrift is een analyse van de claim dat de procedure voor de geïnformeerde toestemming voor de hielprik verstevigd dient te worden naarmate er meer aandoeningen aan het pakket toegevoegd worden, een claim die ik de 'SIC claim' (*strengthening informed consent claim*) heb genoemd.

1. De uitbreiding van de hielprik

In deel I, dat één hoofdstuk bevat, schets ik de context waarbinnen de vraag naar geïnformeerde toestemming voor de hielprik opkomt. Ik bespreek de criteria die bij de uitbreiding van de hielprik in Nederland een rol hebben gespeeld. Deze criteria zijn kennis over de aandoening waarop gescreend wordt, beschikbaarheid van een goede testmethode en behandelbaarheid. Analyse van deze criteria maakt duidelijk dat hun toepassing en interpretatie complexer en meer controversieel worden naarmate de mogelijkheden van screening toenemen. Binnen het debat over de uitbreiding valt er een opmerkelijke eensgezindheid waar te nemen over de noodzaak van een grondiger procedure van geïnformeerde toestemming naarmate er meer aandoeningen aan het pakket toe gevoegd worden. Een vlugge blik op de relevante literatuur geeft aan dat er niet alleen een pleidooi wordt gehouden voor meer informatie vanwege de kwantiteit van de aandoeningen, maar vooral ook dat de toegenomen controverse van mogelijke uitbreidingen het belang van geïnformeerde toestemming vergroot. De 'SIC' claim kan begrepen worden als de stelling dat procedures van geïnformeerde toestemming versterkt moeten worden naarmate de nadelen van de screening van pasgeborenen zwaarder wegen ten opzichte van de voordelen. In het vervolg van het proefschrift analyseer ik deze claim.

2. Het concept 'geïnformeerde toestemming'

In deel II verken ik het begrip en de normatieve rol van geïnformeerde toestemming nader. In het eerste van de drie hoofdstukken waaruit dit deel bestaat, hoofdstuk 2, bespreek ik het concept geïnformeerde toestemming. Dit

concept is toenemend populair geraakt in de laatste zestig jaar. Hoewel in de loop van de tijd de toepassing en standaarden van geïnformeerde toestemming zijn verschoven, kunnen we een gemeenschappelijke kern onderscheiden in de verschillende manieren waarop het begrip gebruikt wordt. Geïnformeerde toestemming geeft uiting aan de autoriteit van het individu om bepaalde beslissingen te nemen die hemzelf aangaan. Deze praktische autoriteit kan begrepen worden in termen van ´uitsluitende´ (*exclusionary*) redenen. 'Uitsluitende redenen' zijn redenen die niet geldig zijn op grond van hun inhoud, maar op grond van hun bron, de autoriteit. Dergelijke redenen sluiten andere ´eerste orde´ redenen bij voorbaat uit. Het toewijzen van autoriteit geeft een individu de macht over een bepaald domein van beslissingen. Deze autoriteit wordt op institutioneel niveau vorm gegeven in de procedure van geïnformeerde toestemming.

3. De rechtvaardiging van geïnformeerde toestemming

In hoofdstuk 3 onderzoek ik de normatieve rol van het principe van geïnformeerde toestemming. Ik bespreek verschillende mogelijke manieren om geïnformeerde toestemming te rechtvaardigen. Deze vallen uiteen in directe rechtvaardigingen en rechtvaardigingen gebaseerd op rechten. Directe rechtvaardigingen proberen geïnformeerde toestemming te baseren op waarden of goederen die hiermee bevorderd worden. Een mogelijke manier om dit te doen is door te beargumenteren dat geïnformeerde toestemming leidt tot inhoudelijk 'betere' beslissingen. Deze rechtvaardiging loopt tegen het probleem aan dat er geen onafhankelijke standaarden zijn om de onderlinge kwaliteit van beslissingen te vergelijken. Een alternatieve route voor directe rechtvaardigingen is te beargumenteren dat het intrinsiek waardevol is voor subjecten om hun eigen keuzes te maken. Dit zou een standaard bieden, namelijk die keuze is beter die door het autonome subject zelf gemaakt wordt, ongeacht de inhoud van de keuze. Binnen deze benadering is het echter moeilijk te bepalen welke beslissingen binnen het bereik van geïnformeerde toestemming vallen. Zodra een inhoudelijk criterium daarvoor gevonden wordt, wordt het idee dat een persoon zelf bepaalt wat een goede beslissing is losgelaten. Een alternatief voor directe rechtvaardigingen zijn rechtvaardigingen gebaseerd op rechten. Dergelijke benaderingen verklaren de normatieve rol van geïnformeerde toestemming in termen van de ontheffing (*waiver*) van een specifiek recht. Ik onderscheid twee varianten van rechten benaderingen van geïnformeerde toestemming, te weten een benadering gebaseerd op de wiltheorie van rechten en een benadering gebaseerd op een belangentheorie van rechten. Het belangrijkste verschil tussen deze twee benaderingen voor het concept van geïnformeerde toestemming is dat volgens de wiltheorie van rechten alle rechten de mogelijkheid van ontheffing in zich bevatten, terwijl volgens de belangentheorie de

macht om toestemming te geven afhangt van het belang van het individu en daarom per recht kan verschillen.

4. De standaarden van geïnformeerde toestemming

In hoofdstuk 4 bespreek ik de standaarden van geïnformeerde toestemming in een institutionele toepassing. De vraag staat hier centraal onder welke voorwaarden geïnformeerde toestemming het best fungeert om rechten van individuen te beschermen. Ik argumenteer voor een 'smalle' benadering, waarbij de nadruk ligt op de aansprakelijkheid van de interveniërende partij en er een lijst van noodzakelijke en voldoende voorwaarden is door middel waarvan bepaald kan worden of er sprake is van geïnformeerde toestemming. Deze opvatting is tegengesteld aan ' brede' benaderingen die de nadruk leggen op vertrouwen en de communicatieve aspecten van de interactie tussen patiënt en dokter. Ik laat zien dat dergelijke benaderingen onvoldoende de mogelijkheid van flexibele criteria van geïnformeerde toestemming erkennen.

5. **Geïnformeerde toestemming en publieke gezondheidszorg**

In deel III bespreek ik drie complicaties die opkomen bij de toepassing van geïnformeerde toestemming op de casus van de screening van pasgeborenen. In hoofdstuk 5 behandel ik geïnformeerde toestemming voor interventies in de publieke gezondheidszorg. Dergelijke interventies (denk aan screening, maar ook aan vaccinaties of de toevoeging van fluor aan het drinkwater) roepen een spanning op tussen het individuele en het collectieve niveau van beslissen. Ik beargumenteer dat de autoriteit van een individu om zijn eigen beslissingen te maken niet aan de kant geschoven kan worden op grond van paternalistische overwegingen. Er kunnen echter wel grenzen gesteld worden aan geïnformeerde toestemming op basis van het argument dat het in sommige gevallen onmogelijk is om op een collectief niveau neutraal te blijven tussen verschillende voorkeuren.

6. **Geïnformeerde toestemming en de autoriteit van ouders**

In hoofdstuk 6 zoek ik naar een rechtvaardigende grond voor de autoriteit van ouders om beslissingen te maken voor hun kinderen. Ik laat zien dat tenminste in sommige gevallen de rechten van de het kind zelf onvoldoende fundament leveren voor een dergelijke autoriteit. Een exclusieve focus op de rechten van het kind verklaart onvoldoende waarom in veel gevallen ouders de aangewezen personen zijn om de belangen van het kind te behartigen. De rechten van ouders bieden echter in isolatie ook te weinig houvast om de ouders de macht te geven over hun kinderen. Ik laat zien dat de oplossing ligt in het integreren van de twee perspectieven en verdedig een relationele opvatting van de autoriteit van ouders. Een relationele opvatting van deze autoriteit erkent dat de

rechten van ouders en kinderen niet strikt te scheiden zijn en stelt de intimiteit van hun relatie centraal.

7. Geïnformeerde toestemming en informatie

Hoofdstuk 7 behandelt epistemische rechten. Omdat het initiatief bij screening ligt bij de partij die de informatie verstrekt, kan het communiceren van gevoelige informatie in sommige gevallen beschouwd worden als een inbreuk op een algemener recht op privacy. De invulling van dit recht is onvermijdelijk vaag. Dit heeft consequenties voor de standaarden van geïnformeerde toestemming. Ik laat zien dat de procedure die uitdrukking geeft aan dit recht er niet op gericht moet zijn individuen te laten kiezen tussen verschillende specifieke soorten van informatie, maar veeleer op een 'generieke' toestemming.

8. Het versterken van geïnformeerde toestemming voor de hielprik

Deel IV bevat hoofdstuk 8. In dit hoofdstuk keer ik terug naar de SIC claim, de claim dat de uitbreiding van de hielprik vraagt om een sterkere procedure van geïnformeerde toestemming. Ik bespreek verschillende manier om het versterken van de procedure te bewerkstelligen. Ik betoog daarna dat de SIC claim niet noodzakelijk juist is en dat de verschillende manieren om geïnformeerde toestemming te versterken waarschijnlijk onwenselijk zijn. Versterken van de procedure leidt tot een toenemende belasting voor de ouders wat betreft het verwerken van informatie en de noodzaak om een weloverwogen keuze te maken. Tevens dreigt er een gevaar van medicalisatie.

Curriculum Vitae

Niels Nijsingh was born in IJhorst on November 6, 1977. He studied philosophy at the University of Utrecht, and graduated in 2003 in practical philosophy with a master's thesis on the philosophy of memory. From 2004 to 2009 he worked at the Ethics Institute in Utrecht, as PhD student and lecturer in applied ethics. His dissertation on informed consent and newborn screening was supervised by Prof. dr. Marcus Düwell and Dr. Marcel Verweij. In the winter of 2007/2008 he spent three months performing research at Keele University. In 2010 and 2011 he worked on a research project on the ethics of genome sequencing at the Department for Health, Ethics and Society at Maastricht University.

He has published various papers in the field of public health ethics, in particular on the topic of informed consent in public health.

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Quaestiones Infinitae

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