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Valuing Diagnostic Innovations: Towards Responsible Health Technology Assessment

Ellen Moors and Alexander Peine

This chapter deals with valuing diagnostic innovations. Until now, this valuing has been dominated by traditional Health Technology Assessment (HTA) practices, measuring efficacy, safety, quality, and cost parameters of a new health innovation. As we are living today in an increasingly 'individualized society of consumers' (Bauman 2001), who are undertaking action to self-actualization and co-creating their own lives, a more comprehensive view on valuing is needed. Also, users and citizens want more proactive involvement in co-developing innovation. User communities are collectively engaging and creating innovation platforms for cooperation, for co-creation of shared values (Prahalad and Ramaswamy 2004), or for convergence of ideas and expertise, such as in online patient platforms. Further, innovation and institutional practices, such as regulation, norms, and informal values, are becoming increasingly

E. Moors (✉) • A. Peine
Innovation Studies Group, Copernicus Institute of Sustainable Development, Utrecht University, Utrecht, The Netherlands

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intertwined nowadays (Lounsbury and Crumley 2007). These current trends demonstrate the increasing role of users and institutional practices in valuing innovation processes.

Nowadays, diagnostic innovation is not bound anymore to specialists and laboratories, where traditional HTA takes place. It is increasingly perceived as an institutional interplay with many heterogeneous stakeholders, in which users are more proactively involved in diagnosis. The current 'e-revolution', for example, is causing a shift in information distribution between medical professional and patient, in which digital self-management of diseases and prevention is becoming more important. Furthermore, diagnostic innovation increasingly moves from professional medical practices, in which the patient is often regarded as passive receiver of healthcare, into domestic, informal care spaces, in which patients are actively involved in self-diagnosing and managing their disease or health by monitoring a diverse range of health parameters, and by maintaining contact and sharing health data with medical specialists and caregivers (see also Peine et al. 2014).

These novel diagnostic innovations, however, also lead to problematic issues, such as privacy-related threats, more awareness raising, user acceptance, and treatment compliance problems. So, besides the traditional HTA parameters of efficacy, safety, quality, and costs, other values which take into account the social and ethical norms and expectations, positions, and distributed roles of various stakeholders, become more important in diagnostic technology assessment as well.

This constitutes a challenge for traditional HTA approaches, which need to take these other values into account. In other words, it requires us to reconsider the current logic of HTA that does not fit the practices of designing, evaluating, and using contemporary diagnostic innovations. To capture, characterize, and analyse the processes of valuing, we focus in this chapter on the 'logic of valuing', which we define as the set of implicit or explicit justifications and practices that render a value valid and relevant. We assume that different practices may have different logics of valuing. We also assume that while the logics of valuing have some durability, they may also change in due course. Accordingly, this chapter critically reflects on the question *which set of values, which logic of valuing, could be leading in new practices of HTA for diagnostic innovations?*

We carry out this reflection in three steps. As a first step, the next part zooms in on how the 'logic of valuing' is currently organized in HTA. Then, as a second step, illustrative empirical cases on diagnostic innovations are presented that report on the 'logic of valuing' in actual diagnostic innovations. Third, the last part discusses how these steps are related and what this implies for HTA strategies, policies, practitioners, and the role of users in diagnostic innovations, in order to become more flexible and responsible.

The 'Logic of Valuing' in Current HTA Practices

For decades, healthcare systems in the Western world have been adjusting to different kinds of new health technologies (Lehoux 2006; Faulkner 2009). Like pharmaceutical innovation, diagnostic innovations take place in highly regulated markets and sectors, and for health policy, it is thus important to assess the value of diagnostic technologies. The increasing importance of health innovation, therefore, has been accompanied by various ideas about how to assess more rationally its value. By and large, these ideas have resulted in what is known as Health Technology Assessment (HTA)—the conviction that health policy decisions should be based on 'the "best available evidence" on the costs, efficacy, and safety of health technology' (Lehoux and Blume 2000, p. 1083). Focusing on the logic of valuing in current HTA practices, we are interested in two particular aspects that seem to be characteristic of ongoing HTA discussions:

First, HTA revolves around the idea that health policy decisions should be based on 'facts' (Banta and Perry 1997) to evaluate the value of a particular health innovation. According to Lehoux, HTA is as a scientific and policy movement operating in the manner of 'regulatory science' (Jasanoff 1990) and seeking to foster the institutionalization of knowledge-based changes in healthcare systems, and the relevance of adopting and using technologies proven to be effective, safe, and economical (Lehoux 2006, p. 1). Although HTA approaches should be broad *in principle*, most *actual* approaches are grounded in epidemiology and health economics, thus focusing on the treatment value for patients and the often

substantial costs of adopting new health technologies (Lehoux 2006). Standard HTA procedures can be seen as a cost-benefit analysis that tries to assess the value of a new technology in terms of costs per health benefit. However, the wider ethical and social values, although considerably sidelined, have been part of the HTA literature since its inception as well (Banta 2003; Draborg et al. 2005). Only recently, discussions have more decidedly focused on the value of technology beyond the logic of cost-benefit analyses. Such discussions have tried to unravel how social and ethical values can be addressed in HTA procedures (Bombard et al. 2011; Lehoux and Williams-Jones 2007; Busse et al. 2002), and how they are addressed by different stakeholders (May 2006; Lehoux et al. 2010, 2011, 2012). The scope of values to be included and addressed in HTA exercises is principally infinite, and a prolific body of literature has proposed a variety of procedures to deal with this issue worldwide (see also Banta and Johnsson 2012), thus widening the knowledge base of HTA (Battista 2006). Less attention, however, has been given to the *position* of these values in relation to emerging technologies.

Second, in this latter regard, the emergence of HTA has been closely connected with the evidence-based medicine (EBM) movement in healthcare (Moreira 2007). Although EBM is much narrower in focus—it deals with assessing the clinical effectiveness of medical interventions—its basic tenet that interventions should be based on sound evidence has been central in defining the HTA field (Giacomini 1999). EBM carried a specific idea about what constitutes sound evidence in HTA procedures. Indeed, randomized controlled trials as well as systematic reviews of existing evidence are seen as the gold standard for proving the value of an intervention in EBM, whereas anecdotal evidence from case studies and practice are regarded as less reliable (Williams et al. 2003; Lambert et al. 2006). In this sense, EBM is strongly associated with an empiricist and positivist epistemological position (Goldenberg 2006; Hjørland 2011), and the art of compiling systematic reviews and meta-analyses has become the stronghold of procedural and methodological debates (Moreira 2012). This position is subject to ongoing disputes within both the medical profession itself and critical analyses from science studies (see also Drummond et al. 2013; Moreira 2007). Nevertheless, the basic ideas of EBM have quickly gained attention among health policymakers due to

their putative ability to provide an unambiguous basis for decisions about health interventions (Goldenberg 2006; Gordon 2006). HTA has been quick in borrowing from EBM the basic logic that decisions about health technology should be based on a sound understanding of the costs per quality-adjusted life years (QALYs) (Drummond et al. 2013). This has two effects that permeate established HTA practice: it describes a rigid scheme of what counts as evidence (i.e. ideally insights about a clear-cut medical effect and its costs based on the results of randomized controlled trials compiled in a systematic review), and it describes how this evidence should be included in policy decisions (i.e. as 'facts' established before the technology is adopted or rejected). It is this logic of assessing the value of health technology that interests us most in this chapter, because it implicitly ascribes certain roles to patients and users, policy makers, and technology developers in defining and assessing value.

What transpires from this discussion is not so much that the value of health or diagnostic innovation is too narrowly defined in the practices of HTA. Rather, it becomes apparent that HTA both describes a range of knowledge, in terms of values, to inform decision makers, and a relation of this knowledge to decisions about emerging health technologies. The latter narrowly frames knowledge about the value of a specific health or diagnostic technology as an *input* that can be assessed before this technology is put to use, as a one-time decision, instead of a continuous assessment as a result. In this way, traditional HTA is not so flexible with regard to changing values and creative or unexpected use of new innovations. The HTA field inherited this stance from its origins in medical practices (Perleth and Lühmann 2010), where health innovations meet their users as patients. The question is whether this basic position, this logic of valuing can fruitfully inform the assessment of current diagnostic innovations that increasingly meet their patients as consumers or citizens in their informal care and domestic environments. In domestic life, even more than in other care spaces, health technology not only meets a medical need, but also needs to address emotional values, to contribute to an evolving sense of self and place, and to function as both a functional and symbolic object in the everyday practices of people (Peine 2009). As the boundaries between medical professionals and patients and citizens are blurring, it leads to possibilities for co-creation of health and care

innovation, defining the needs and wishes, creating values and co-creating solutions in healthcare practices, in which various types of stakeholders are involved. Innovation is then not just geared towards efficacy, safety, quality, and low costs, but also implies specific social expectations, values, and norms. From an STS perspective, this question translates into the problem of agency: how current HTA practices impute roles and responsibilities on different stakeholders in emerging diagnostic innovation systems, and on patients and their formal and informal caregivers as end users in particular (Akrich 1995).

The next part illustrates, by means of some empirical examples, various practices of diagnostic innovations in order to better understand their set of values.

Empirical Findings on Valuing Diagnostic Innovations

Building on empirical examples of practices of Alzheimer's disease (AD) diagnostic innovations in Cuijpers and van Lente (2015), of various diagnostic innovations in this volume (Van der Laan, this volume; Egher and Wyatt, this volume; Miller et al., this volume) and of Point-of-Care (POC) diagnostic innovations in primary and secondary care practices (Ten Kate 2011), we extend the logic of valuing in current HTA practices to the analysis of how values evolve in the entire diagnostic innovation process.

Cuijpers and van Lente (2015) argue that in the HTA practice of the Dutch Leiden Alzheimer Research Nederland (LeARN) project, various meanings of early diagnostics exist: as value for money, as changing healthcare practices, as innovation trajectory, as changing disease definitions, as a step towards medication, and as early management. A diagnostic test for AD, or combination of tests, would change the AD practice a lot and would have far-reaching consequences for AD care. Early AD diagnostics could be part of disease management in early phases, providing better information at an earlier stage of the condition, when patients can still understand the diagnosis. In this way, it provides possibilities for patients, and for professional and informal caregivers to better

manage the AD condition, that is, timely making plans, arranging care and support. So, values might shift from the need for an accurate AD diagnosis towards also delivering value in terms of patients better dealing with the diagnosis when they are better informed. Traditional HTA fails in this as it focuses only on costs and limited type of evidence as treatment outcome, but not on new values, such as recognizing the roles and responsibilities of the various stakeholders involved in AD diagnostic innovation (Cuijpers and van Lente 2015).

Van der Laan (this volume) highlights the heterogeneity of Dutch AD diagnostic practices and the distributional mechanisms underlying these different practices, based on observations in different AD diagnostic settings: a nursing home, a memory clinic in a general hospital, and a memory clinic in an academic hospital. She discerns five diagnostic values, including the epistemic values *causal explanation* and *describing functionality*, about what is the matter. The value of *prognosis* is a predictive one, about knowing what the future will look like, what to expect. The values of *control* and *living with*, concern the 'directives' of diagnoses (see also Pols 2012), about 'what to do?' These two latter values concern ways in which diagnoses lead to certain actions, for example, fighting or eliminating AD, or diagnoses that direct to improving life with AD, for example, enabling 'patients and informal caregivers for care services, and empowering them to make particular individual choices, such as quitting their jobs, writing a will or helping them to give meaning to the symptoms' (Van der Laan, this volume). She argues that these five diagnostic values are connected, while enacted in different modes of diagnosing. She discerns two modes of diagnosing AD: pulling out all the stops, and holding back way of working, in which various diagnostic values are enacted and aligned. These modes are not only based on traditional HTA approaches of scientists and AD specialists, but also on preferences, concerns, and practices of patients, caregivers, on healthcare professionals, policymakers, and stakeholders contributing to the public discourse on AD.

Miller et al. (this volume) highlight the challenges of informally regulated diagnostic innovations in the care of patients with advanced, end-stage cancer, in which clinical and research aims are blurred by various translational imperatives. They argue (Miller et al., this volume): 'Team

members were not trying to assess whether intervention had the potential to work as in a typical clinical trial, they were not asking whether the intervention improved diagnostic accuracy, reduced clinical symptoms, or resulted in few adverse effects. Instead, the study assesses endpoints like completion rate: could tissue in sufficient quantity and quality be collected to enable genomic analysis, across testing platforms? As well, it assessed timeliness, could patient recruitment, tissue retrieval, laboratory testing, result adjudication and report to physician be completed within three weeks?' In their case, the researchers were not just testing diagnostics or clinical pathways, but designing a socio-technical system for translation of genomics in clinical care in the context of end-stage cancer care, in which 'hype and hope' and the expected needs of the patients are often justifying risky care patterns. In other words, physicians as users of these informally regulated genomic innovations actively tried to serve the needs of patients as end users. They sought to improve patient care and to assess feasibility. The case of Miller et al. (this volume) showed that limited accountability implied limited responsiveness to regulatory institutions, which embody traditional HTA expectations related to safety, effectiveness, and quality. This limited accountability is extended in their case to cognitive and normative values, representing expectations related to the meaning of benefit, the significance of hope or harm, and the role of professionalism and patient autonomy.

Egher and Wyatt (this volume) assume that innovative Internet-based (self-)diagnostic technology could change the way how risks and benefits of disease categories and treatments are interpreted and how diagnostic expertise is constructed and demarcated. They explored how the Internet transformed responsibility with regard to diagnostic (self-)tests for AD, and identified three main roles of the Internet regarding online (self-)tests—namely, as medium of distribution, as medium of education (anticipating and preparing for the face-to-face encounters between medical professionals and lay people), and as medium of data collection. The role of the Internet as a *medium of distribution* by making tests available worldwide is especially interesting when studying the logic of valuing in distributed practices of diagnostic innovations. Democratizing values might be considered, as the Internet provides everyone who wants (including (pre-)patients, families, people in particular countries, or

healthcare systems) with access to diagnostic tools, formerly available only to medical professionals. Egher and Wyatt (this volume) indicate that the validity of test results might be affected by worldwide distribution, due to the fact that the content of diagnostic tests may be culturally biased and 'bear traces of power relations from their place of origin'. So, cultural habits and personal interests may play a role in valuing diagnostics. Online diagnostic tests call upon the participant himself or herself to become responsible for the accuracy of the data provided, of the quality of the data. This shows that user compliance is needed to bring about these diagnostic processes. 'How they take or administer such tests, and how they react to the results depends on their intentions, on their attitude towards the Internet, and their digital skills' (Egher and Wyatt, this volume). It is the question whether they consider the Internet as a reliable diagnostic tool. 'People might even attempt to displace such tests from a medical context, by completing them in order to train their memory or simply out of curiosity'. Then, playfulness and entertaining elements comes into play. Egher and Wyatt clearly showed that the Internet as distributed practice leads to confusing categories, enabling users to experiment with various roles in valuing diagnostics.

We also revisit a case study conducted on the set of values medical professionals in primary and secondary care discuss in relation with Point-of-Care (POC) diagnostics (Ten Kate 2011). POC diagnostics are those analytical testing activities that take place near or at the site of patient care, outside clinical laboratories. These new diagnostic devices are often based on biosensors and deliver fast results, are small, handheld, enabling data management and communication with a larger ICT infrastructure, also sometimes referred to as 'labs-on-a-chip', because they make the laboratory step in the diagnostic process unnecessary. We found that values such as analytical accuracy (validity and reliability proven by means of medical scientific results), diagnostic accuracy (value of diagnostic test is the difference in health outcome resulting from the test), clinical utility (health-related outcome of test-plus-treatment strategy), cost effectiveness (total costs test-plus-treatment -strategy), and indirect utility, such as non-health-related (efficiency) impact on procedures, routines, social behavioural impacts, and lifestyle are important for POC technology. The key POC implementation path would initiate in secondary care,

where important evidence could be collected in a relatively confined organizational setting. The more distributed primary care setting, with its comparably high distribution of actors and activities, was perceived to be too messy to collect the necessary evidence in a clinically meaningful way. This focus on secondary care indicates the importance of collecting best available evidence from valid and practically relevant scientific research before a decision is made by clinical guideline developers to take up a new diagnostic tool and thus make it accessible to larger patient groups. This logic fits well the models of traditional HTA procedures, as it highlights costs and effects as the most relevant values of POC diagnostics. What emerges from this focus on the secondary care setting is a logic of addressing value that revolves around compiling high-quality evidence according to the established hierarchy of EBM. The values to be addressed, therefore, are regarded to be more or less pre-given, while the collection of evidence is delegated to experts and specialists. Although some of these specialists, most importantly general practitioners (GPs), are also users of the technology, their role is largely confined to probing into the value of the POC device along pre-figured dimensions. Other, less specialized users such as nurses or patients are not perceived to be central actors in this process. This POC diagnostics case demonstrates how in professional medical settings the performance of a new diagnostic technology has to prove its effects on established values, before its wider impact can be explored and become manifest.

Discussion

The illustrative empirical examples in the previous section demonstrated the process of valuing in various diagnostic innovation practices. This section discusses how these practices are related to current HTA practices and what this means for (improvement of) HTA strategies and policies of practitioners and users of diagnostic innovation.

The empirical cases revealed that emerging diagnostic technologies impact a broad range of values, such as epistemic, predictive, and directive values (Van der Laan, this volume) that are complex and interrelated. Egher and Wyatt (this volume) demonstrated that the Internet as

distributed self-testing diagnostic has contributed to changing the ways people value and relate to their medical state and interact with medical professionals. The cases also showed that these values are difficult to predict and to anticipate, as diagnostic innovation becomes more distributed between formal, specialist care practices and more informal, home care practices, and clinical diagnosis becomes more socialized (see also Webster 2002). In other words, the examples showed that there is a need for flexibility and experimenting to cover the broad range of often emergent values in the early development of novel diagnostic innovations.

As argued in the previous section (e.g. in POC-diagnostics case), standard procedures of HTA are likely to carry the image of passive diagnostic technology users. This is potentially problematic, as these HTA interventions impute only limited agency on both the emerging diagnostic device and most of its technology users. Against this background, we argue that current HTA practices are not suitable to guide health policy decisions about more spread diagnostic innovations and that an alternative approach is needed, incorporating another logic of valuing diagnostic technology in order to fully take into account the potential of novel diagnostic innovation processes. To rethink current HTA practices and to indicate in which direction current HTA could be transformed, we connect the discussion of our cases to Callon's recent distinction between *prosthetic* and *habilitating* social policies (Callon 2008). In this distinction, Callon highlights that a key task for social policy making is to compensate 'for maladjustments encountered by individuals in their professional and private lives "to" the mold of the Western neo-liberal subject' (Callon 2008, p. 46). He defines *prosthetic* social policies as measures that produce disciplined agency where individuals are empowered to follow preconfigured scripts for individual action. *Habilitating* social policies, by contrast, are those measures that include individuals in the creation and exploration of scripts for individual action, and thus, empower them to contribute to the evolving mould of the neo-liberal subject itself. It deals with *interactive individual agency,* where individuals are empowered to explore and develop their needs and preferences.

There are striking similarities between Callon's discussion of social policy and the policy debates about the value of and meaning of diagnostic innovations in healthcare (see also Peine and Moors 2015). In other

words, traditional HTA works as a *prosthetic device* that evaluates diagnostic practice according to values defined in the traditional medical, institutional domain. At the same time, it downplays values associated with experimentation, learning, playfulness, and everyday care practices. Established HTA procedures highlight costs and effects as the most relevant values of diagnostics. What emerges from such a focus on the professionalized specialist care setting is a logic of addressing value that revolves around compiling high-quality evidence according to the established hierarchy of Evidence-Based Medicine (EBM). The values to be addressed, therefore, are regarded to be more or less pre-given, while the collection of evidence is delegated to experts and specialists. Although some of these specialists, most importantly doctors, are also users of the technology, their role is largely confined to probing into the value of the device along preconfigured dimensions. Other, less specialized users such as nurses or patients are not perceived to be central actors in this process. The valuing practice that emerges from these analyses resembles a prosthetic logic: novel diagnostic devices should be optimized in such a way as to deliver the best value within the pre-defined mould of existing clinical standards. The exploration of new values is considered to be ancillary to cost effectiveness and clinical impact. This demonstrates how in professional clinical settings the performance of a new technology has to prove its effects on established values, before its wider impact can be explored. As a side effect, this logic imputes only limited agency on both the emerging devices and most of its users in defining new values that might be more suitable to assess new, emergent networks in distributed care settings. It shows the practices and pitfalls of mainstream HTA practices and the underlying logic of evidence-based medicine.

We are certainly not the first to highlight the problematic aspects of established HTA procedures (Faulkner 1997, 2009; Lehoux 2006 are excellent entries into the prolific body of literature in this regard), nor are we the first to show that HTA practices are often messier and more fractious than their textbook versions suggest (e.g. May 2006). Instead, our interest in HTA has been triggered by our own involvement with diagnostic innovation, where in particular the notion of evidence in the strict sense suggested by EBM seems to permeate policy debates.

In Callon's terms, health technology decisions based on the traditional HTA logic are likely to produce technology that focuses on changing sociotechnical assemblages in diagnostic care along pre-set dimensions. Individual agency in the sphere of users and use is framed to be disciplined and passive, as erratic usership would disturb the precious relationship between costs and health effects so carefully established before. Accordingly, health policy decisions based on established HTA practices will work to discipline individual agency; they are not equipped to deal with the constant experimentation and learning in the absence of evidence that is so typical for emerging diagnostic innovation processes. The case of Miller et al illustrated this experimental dynamics for new diagnostic innovations targeting the clinic. The researchers in these cases gradually learned to perceive the users of the new diagnostic technology—for example, clinicians, nurses, or patients—as agents that are essential for the process of valuing the diagnostic technology. This way of recognizing value as something open and fluid suggests implementation strategies that ascribe the ability to experiment and explore new practices on users of diagnostic innovations. Such implementation strategies understand that users are active agents in innovation processes, and give them space to experiment and to learn about the value of a technology. It demonstrates that for diagnostic innovation, it would be crucial to broaden HTA practices in such a way that they are able to deal with this experimental co-evolution of values and evidence. Otherwise, HTA runs the risk of prematurely cutting short diagnostic innovation with promising prospects but limited available evidence, missing out on important values in various healthcare practices, which take into account the various roles of involved stakeholders.

To conclude, we use these insights to outline advice for HTA practices that might better fit the conditions of emerging diagnostic practices, give rise to habilitation interventions, and contribute to configuring users of diagnostic innovations as proactive consumers or citizens able to fully participate in policy decisions about health innovation. This suggests that the range of values itself, however broadly defined, should not be the main concern of adapting HTA exercises to the realities of emerging diagnostic innovations. Rather, the logic of valuing in diagnostic innovation processes should be broadened and be more flexible,

to embrace uncertainties, elusiveness, controversies, and diversity, to include experimentation and the use and diffusion of new biomedical technologies (see also, Boenink 2012). For emerging diagnostic innovations, the health value they will ultimately be able to deliver depends on learning processes that stretch well into the diffusion and use phase of the technology. Prosthetic values explored independently of technology are not able to deliver this. What we need, instead, are values that incorporate a habilitation logic—that is niches for experimentation and joint probing into the value of diagnostic innovations. Many heterogeneous actors should have a voice in which values are important in a HTA, not defining beforehand what a good technology should do, but together, articulating what is necessary for different involved actor groups. Dealing with early diagnostics and coping strategies, patients, and formal and informal caregivers as end users of diagnostic technologies seem, to us, especially important. Taking their values on board, and allowing them a voice in HTA practices and outcomes strikes us as crucial. So, agency and specific positions and roles of actors responsible need to be taken into account, to move towards more *responsible* forms of HTA. Current discussions in HTA fall short of delivering such broader notions of logic of valuing, although some claims for constructive forms of HTA point to the right direction (see also Douma et al. 2007). Further research is needed on how habilitation plays out across different distributed diagnostics settings.

Summarizing the above, this chapter emphasized paying careful attention to the complex interrelation between practice, values, and technology and focused on how to redesign common HTA procedures under the label 'responsible innovation', to better fit actual innovation practices as well as societal concerns about innovation. As shown, innovations in the field of diagnostics are not just geared towards efficacy, safety, quality, and low costs, but also imply specific social expectations, values, and norms. It is an emerging key challenge of responsible diagnostic innovation to be simultaneously prosthetic and habilitating, that is, it should enable individuals to follow preconfigured scripts as well as empower them to explore their needs and preferences, in order to provide stakeholders with the necessary agency to negotiate health and illness.

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