Public Value of Medical Innovations

A quest for all and for all seasons

Payam Abrishami

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The research presented in this book was conducted at CAPHRI Care and Public Health Research Institute, Department of Health, Ethics, and Society of Maastricht University. CAPHRI participates in the Netherlands School of Primary Care Research, CaRe.

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To Maryam and Sam

And

For the public

CONTENTS

FOREWORD

In this dissertation, Payam Abrishami argues that health technology assessment (HTA) needs often to broaden its perspectives from "targeting technology in a stand-alone setting" to a consideration of real-life circumstances, including the opinions and perspectives of a variety of stakeholders such as developers, payers, patients, and policy makers.

This perspective has theoretically been a part of HTA from its beginnings, although stakeholder involvement was not emphasised. HTA developed in the context of general technology assessment, which emerged in the US Congress in the late 1960 in response to such technological challenges as supersonic transport and environment concerns (Committee on Science and Astronautics, 1967). Technology assessment was described from its beginnings as more socially oriented than technical. "Technology assessment is a comprehensive form of policy research that examines the short- and long-term consequences (e.g. societal, economic, ethical, legal) of the applications or use of technology … It is especially concerned with unintended, indirect, or delayed social impacts" (Committee on Science and Astronautics, 1967).

HTA began to develop in the early 1970s and examples of its use were first developed by the National Institutes of Health and the National Academy of Sciences (NAS, 1975; National Heart and Lung Institute, 1973). In 1972 the US Congress inaugurated the Congressional Office of Technology Assessment (OTA) and the OTA decided to develop a health program in 1974. I was hired in that program and was put in charge of defining the essence and method of HTA.

In the first report (OTA, 1976), OTA drew on the advice of a distinguished panel of experts, including Nobel Laureates. Advisory committee members including medical scientists, engineers, economists, sociologists, and lawyers, as well as experienced health policy experts. The committee helped us to formulate the position that HTA was a part of technology assessment and should be primarily social in its orientation. We formulated a set of questions intended to elicit the implications of the technology for the patients and the patient's family, society as a whole, the medical care system, the legal and political systems, and the economy.

This perspective has, to date, been supported as a principle of HTA studies since the 1970s, as indicated by projects funded by the European Commission. The EUnetHTA project has presented a "Core Model" for HTA, which includes consideration of social effects of health technology (EUnetHTA, 2017). The Integrate-HTA project, also funded by the European Commission, recognises the limitations of HTA as usually practiced: "… current HTA usually focusses on the technology, not on the system within which it is used" (Lysdahl et al., 2016). The report recognises that technologies are complex, depend on context, perform differently depending on how they are implemented, and have different effects on different individuals and proposes that these aspects be covered in HTA reports. However, the report goes on to say that HTA reports seldom give serious attention to ethical, social and organisational aspects (but emphasise clinical and economic evaluations) (*ibid.*). The US government's Medicare program made value-based health care a central part of its program (Centers for Medicare & Medicaid Services, 2011). However, the present popular 'value-based' movement also largely ignores considerations aside from clinical outcomes and costs (Hillary et al., 2016; Porter, 2009).

Abrishami proposes that stakeholder participation can effectively meet the challenges facing HTA to go beyond "what works" into "what matters" and "what is right". He points to the extensive literature on debating the societal desirability and ethical acceptability of technical innovations. In some areas, much has already been done, for example in genetic and screening tests. However, in the future pressures of public demands and unsustainable costs, in connection with the "nano-bio-info-cogno convergence", promise to make the sorts of questions raised in this dissertation increasingly difficult to deal with. One implication of this mentioned by Abrishami is that the challenges may threaten public entitlement systems such as that of the Netherlands.

I believe that Abrishami is right. HTA has a great potential to contribute to these ongoing and coming debates, but it has failed to live up to its potential. Abrishami has written an eloquent and intelligent analysis indicating how HTA could rise to the challenges our societies face. May he be heard!

David Banta
Professor Emeritus, University of Maastricht
November 2017

REFERENCES

Centers for Medicare & Medicaid Services (2011). Medicare program; hospital inpatient value-based purchasing program. Final rule. *Federal Register*, 76(88), 26490-26547.

Committee on Science and Astronautics (1967). *Technology Assessment. Statement of Emilio Daddario, Chairman*. Washington DC: US Congress, 90th Congress.

EUnetHTA, (2017). HTA Core Model®. http://www.eunethta.eu/hta-core-model Accessed 27 October 2017.

Hillary, W., Justin, G., Bharat, M., Jitendra, M. (2016). Value based healthcare. *Advances in Management*, 9(1), 1.

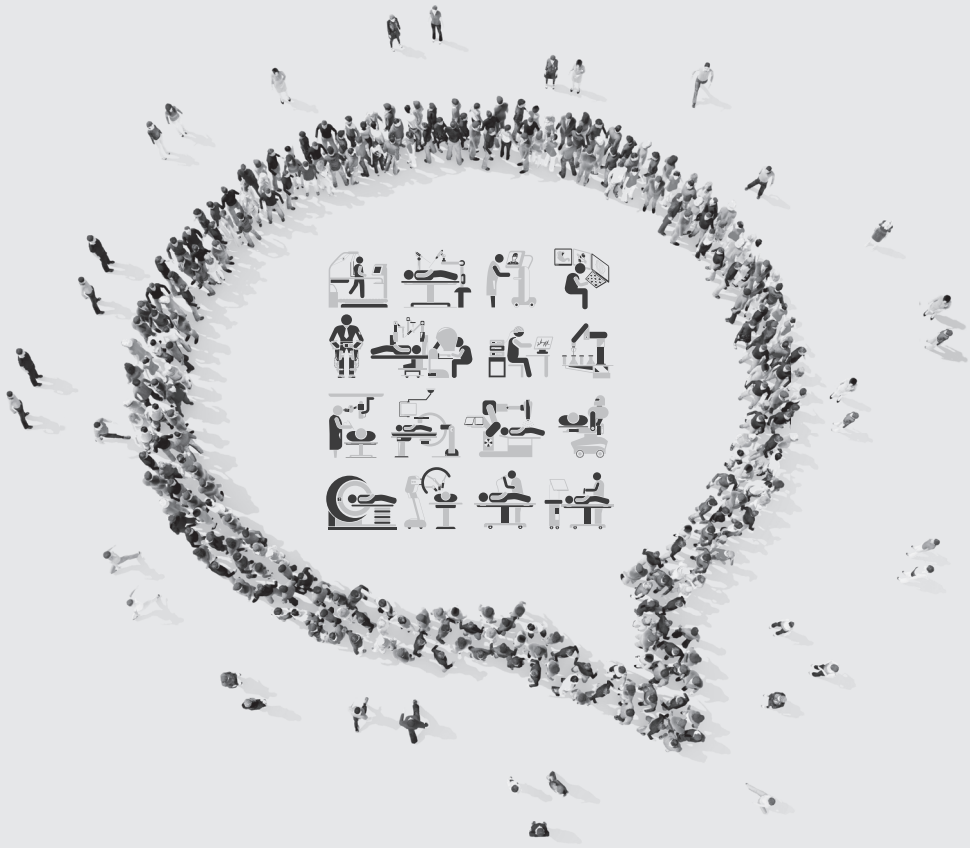
Lysdahl, K.B., Mozygemba, K., Burns, J.B.C., Brönneke, J.B., Hofmann, B., (2016). Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies. http://www.integrate-hta.eu/downloads/ Accessed 27 October 2017.

NAS (1975). *Assessing Biomedical Technologies*. Washington DC: National Academy of Science.

National Heart and Lung Institute (1973). *The Totally Implantable Artificial Heart*. Washington DC: NAS.

OTA (1976). *Development of Medical Technology*. Washington DC: US Congress, Government Printing Office.

Porter, M.E. (2009). A strategy for health care reform - Toward a value-based system. *New England Journal of Medicine*, 361(2), 109-112.



1 On the public significance of medical technology

The Economist Magazine's Front Cover 12.01.2013

"With the pace of technological change making heads spin, we tend to think of our age as the most innovative ever. We have smartphones and supercomputers, big data and nanotechnologies, gene therapy and stem-cell transplants … Yet nobody recently has come up with an invention half as useful as that depicted on our cover. With its clean lines and intuitive user interface, the humble loo transformed the lives of billions of people. And it wasn't just modern sanitation that sprang from late-19th and early-20th-century brains: they produced cars, planes, the telephone, radio and antibiotics."

The Great Innovation Debate

The Economist

Advances in medical science and medical technology have allowed us to live healthier and longer lives in the era of modern medicine. Many medical innovations have offered significant benefits for patients and enormous opportunities for health care professionals to improve the quality and efficiency of care. The influx of innovative medical technologies into clinical practice continues in contemporary health care systems. Horizons are continuously being pushed in ways that would have been inconceivable to society just a few generations ago. Developments in pharmaceutical, biological, cognitive, genetic, diagnostic, surgical, and digital technologies are indispensable to present-day health care. More substantial developments are on the horizon including potential combination of those developments, e.g., the so-called nano-bio-info-cogno convergence. In their journey from inception to emergence and to establishment, new medical treatments and procedures face a turbulent swing in the midst of diverse ambitions, expectations, contestations, and use conditions, whilst taking different trajectories of success and failure. Some end up helping no one and do not find their way to widespread use; some are initially embraced – and sometimes widely used – but later rejected because they are harmful (e.g., Refecoxib [Vioxx] and Thalidomide) or ineffective compared with what they replaced (e.g., Atenolol for preventing cardiac risks of hypertension or surgical/arthroscopic repair of degenerative meniscal injury) (Prasad & Cifu, 2015); and some become so ingrained in the fabric of medical care that we

can hardly imagine life without them (the advent of immunisation programmes, anaesthesia, or antiseptic hand-washing before surgery). As for the 'humble loo' (above), it is the journey from emerging as the extraordinary to eventually becoming the ordinary that manifests the merits of innovation. It is this journey of new therapeutic technologies that is the focus of this dissertation.

The introduction of innovative medical technologies after market authorisation[1] has taken place within a highly interactive and continuously evolving context, and has been referred to as 'medical innovation ecologies' (Consoli et al., 2016). Innovation ecosystems accommodate endeavours that are inherently of *social* nature. Technology 'introduction' implies acquisition, use, dissemination, and routinisation in clinical practice, while making the therapy accessible to patients by means of financial arrangements such as insurance coverage. These efforts involve diverse interpersonal human relationships. What an innovation actually *does* during introduction, i.e. its impact, is also influenced by these interrelationships. A large body of scholarship on innovations in health care and beyond has highlighted the dynamics of innovations as a crucial element of innovation systems (Consoli et al., 2016; Etzkowitz & Leydesdorff, 2000; Faulkner, 2009; Gelijns & Rosenberg, 1994; Rye & Kimberly, 2007; van Est & Brom, 2012; Webster, 2007).

Innovation ecosystems also involve – and reflect on – societal issues: the complexity of contemporary health care systems, well-informed and demanding consumers (patients) with a growing need for medical services, not least due to population ageing, progressive specialisation of medical care[2], market-oriented and personalised care provision arrangements, and the increasing scrutiny of public authorities by concerned citizens with divergent opinions on innovations. Moreover, within innovation ecosystems, traditional linear models of biotechnological developments (from the industry's laboratory, to the animal model, to the bedside) have been replaced with more interactive, non-linear innovation platforms with the following characteristics: cross-disciplinary, cross-institution, and sometimes internationalised R&D processes; diverse stakeholders, most notably health care professionals, engineers, entrepreneurs, investors, asses-

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1 Once a new technology has been granted market authorisation, it can be launched onto the market and become available on a commercial scale. In Europe this is regulated subject to CE marking.

2 During the first decade of the 21st century, the number of general hospitals in the United States dropped by 11 per cent, whereas specialty hospitals escalated by 190 per cent (from 499 to 956) (Moses et al., 2013).

sors, and patients as innovation partners; the strategic positioning of innovators in an overlay of multiple collaborative networks and communications; a hybrid institutional context including academia, the industry, the organisation of care delivery (e.g., hospitals), and spin-off intermediary research institutes; and a more recent mode of production and consumption of research (evidence) required for innovation that resembles patterns of supply and demand. It is this non-linearity, i.e., the overlay of social interactions, interdependencies, and networks among diverse actors within the innovation ecologies that is the focus of this dissertation.

ARRIVING AT THE CONFLICT ZONE: PUBLIC VALUE OF MEDICAL INNOVATION

'Innovation' is a seductive word. It sounds modern. Originating from Late Latin *innovationem*, it means 'renewal, experimental variation, new thing introduced in an established arrangement' (Online Etymology Dictionary). Innovation carries a strong connotation of 'novelty' (Janssen, 2016; Lehoux, 2006). In his dissertation, Janssen beautifully demonstrates that this conceptualisation has dominated present-day thinking about innovation in health care policy and practice to the extent that innovation – and apparently specific kinds of innovations, the technological ones – are often regarded as being inherently good. Although continuous emergence of new ideas, projects, and products has apparently become the norm, it would be naive to maintain that changing to whatever is new is 'good in itself'. Innovation is also related to supremacy, or a change for the *better*, because it simply does not make sense to innovate for absolutely no improvement or for the worse. In this dissertation, I focus on new technologies with a possible betterment, leaving aside those proved harmful to patients.

If only the betterment of medical innovations were straightforward. Allow me to illustrate this with two comparisons. A new dish added to the menu of your favourite restaurant might change your preference or, if its costs were not what you expected, it might change how you spend the money left in your wallet after eating. It might also change the restaurant's niche in food supply should you continue to order the new dish again and again. After all, over the course of time, it might alter your *taste* whether you realise this or not. Taking such changes into account makes it more difficult to know whether the new dish is actually better. Now, consider another comparison. You may want to purchase a new cell

phone, so you examine whether you can afford it considering your wants and the features it offers. Though it may not always turn out to be a very easy choice, you do not need to bother asking yourself whether your purchase will influence others' access to, say, a landline telephone or public transport. These questions are simply irrelevant. The advent of a new medical technology, by contrast, does have impact on access to other health care services or other public services (e.g., education). Just as medical innovations may generate benefit (somewhere), they may also have – sometimes far-reaching – consequences (elsewhere) (Lucivero, 2016; Webster, 2007). Compared with a new dish or a cell phone, a new medical technology must fulfil a greater *public* duty in demonstrating its betterment.[3]

The introduction of a given innovation represents an array of key decisions made by diverse stakeholders involved in the regulation, adoption, spread, and use of new technology. These decisions represent certain views on an innovation's gains and losses shaped by one's preferences, beliefs and lived experiential expertise. These value perspectives motivate stakeholders to embrace or reject a new technology. There may be benefits for the individual adopters or their profession (when adopters are professionals), for patients, or for the provider's organisation. The betterment of a medical innovation also relates to its contribution to the societal goal of improving the population's health – and the foregone opportunity of providing society with other services. In as far as medical technologies operate within publicly-funded health care systems, they need to contribute to achieving societal objectives.

The betterment or *value* of a medical innovation lies, then, at the intersection of various claimed/expected values, relative to one another and compared to an alternative technology/therapy (see figure 1).[4] It is precisely at this junction that value of new medical technology gains *public* significance. The word 'public' here implies society-wide and not only state-related or as opposed to private. First, diverse perspectives and rationales exist and where different value perspectives meet, value almost invariably becomes a point of contest. Second, an innovation's value is also contingent because the paths on which new innovations must fulfil their claimed benefits are fairly convoluted and sophisticated (see chapters

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3 Of course, along with this greater societal duty comes a high privilege. It is hardly an issue that a new cell phone remains unaffordable to some for a while. However, a medical innovation can become accessible to everybody thanks to a publicly-funded health care system.

4 Note that value in this sense is relative and comparative. It is almost invariably 'added' value.

four and six). In addition, it is difficult to grasp which sets of values are endorsed/enforced by the actual impact of a given technology and which are inhibited. Accordingly, the entry of technological innovations in clinical care may generate the following societal challenges, particularly within a publicly-funded health care system: financial *sustainability*, social *solidarity*, and ethical *suitability*.

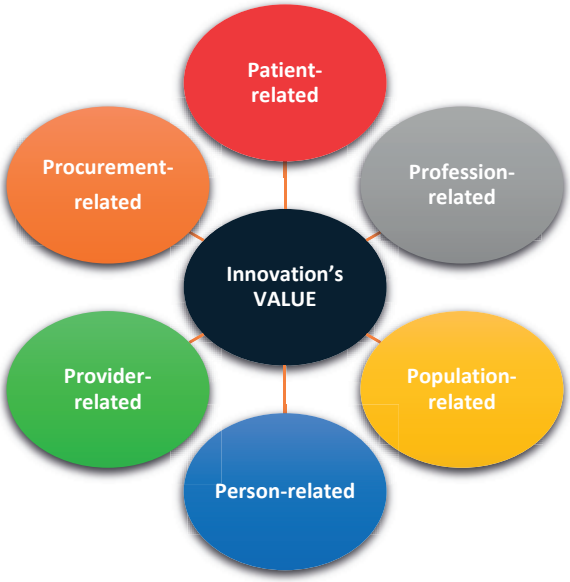

Figure 1. *Perceived attributes of value of an emerging medical technology.*

Medical innovations raise concerns about sustaining the affordability of publicly-funded health care systems. Innovation in medical technology has contributed to improving life expectancy and reducing mortality over the last fifty years (Cutler & McClellan, 2001). However, it has been a principal driver of health care expenditure growth, which is faster than that of gross economic growth. Although the precise magnitude is difficult to identify, many studies indicate that progress in medical technology is responsible for a substantial part of the annual increase in health care expenditures in recent decades, averaging at about 50 per cent (Bodenheimer, 2005; Koopmanschap et al., 2010; Sorenson et al., 2013).[5] Even use of technologies that are considered cost-effective – i.e.,

5 In the first decade of the 21st century, growth in prescription drugs and devices, together with increased hospital charges, administrative costs, and professional services, accounted for more than 90 per cent of cost increases in the total US health care expenditure (Moses et al., 2013).

acceptable costs for the health outcomes produced per unit of output – may not translate into a reduction in health care expenditure mainly due to the growth in the quantity of services (Bodenheimer, 2005; Gelijns & Rosenberg, 1994) or shifting the frontier of medical conditions that can now be treated but which were previously undetectable/untreatable.

On the other hand, financial redistribution arrangements within publicly-funded health care systems are not simply (third-party) cash-redistribution arrangements. They make health care services accessible to everyone when in need, without them bearing significant financial burden (Saltman, 2004). They represent social solidarity as a deeply-rooted 'way of life' grounded at the core of civil society and social welfare; and as such they require technologies, services, and citizens' behaviour to contribute to the best interest of the population (Saltman, 2004). The idea is to protect citizens from social catastrophes such as sickness and unemployment with the support of fellow citizens. Technically, this is arranged by means of pooling risks and financial cross-subsidy among citizens. Risk-pooling potentials within public health care systems make several types of social solidarity simultaneously possible, i.e., between sick and healthy citizens, the rich and the poor, the young and the old, men and women, and today's citizens with those of the future.

Many new forms of care may challenge social solidarity in that their large-scale, long-term risks and benefits in improving population health are uncertain during introduction, as are the distribution of gains and the fraction of the population that may benefit (Gelijns et al., 2005; Karaca-Mandic et al., 2017). These uncertainties can jeopardise public support for maintaining a publicly-funded health care system, hence shaking the pillars of social solidarity. Ethical suitability in terms of how an innovation shapes the ideals of social service delivery, the definitions of state of health and disease, patterns of allocation of public resources, health care outcomes, and human well-being/life are also often unclear and under-examined (Daniels et al., 2016; Hofmann, 2015; Lucivero, 2016) (Cf. also chapters four and five).

For all these reasons, an innovation's value to society at large may then be at stake in policy and practice relating to technological innovations in health care; what is referred to in this dissertation as the 'public problem' of medical innovations, or as Lehoux puts it in the title of her book 'the problem of health care technology' (Lehoux, 2006). As shown in chapter three, what is contested is not only how to deal with the problem of medical technology but also the nature

of the problem itself and what constitutes 'value'. It is, therefore, important to recognise that advanced medical innovations, even highly specialised devices that seem at first glance just clinical or technical apparatuses, do have public significance. It would be gratifying to see that this dissertation is, in the first place, interpreted as providing support for conveying such a message.

VALUE-DRIVEN TECHNOLOGY INTRODUCTION

In response to these challenges of new medical technology, health care systems (i.e., scholars and public authorities on behalf of tax-payers) have been calling for a more value-driven introduction of medical innovations in order to generate the most favourable impact of both the innovations themselves and the resources spent (Henshall & Schuller, 2013; KNAW, 2014; Berwick, 2016). The value-driven introduction of an innovation, then, renders public legitimisation of decisions and actions made in the innovation ecosystem. The concept of legitimisation generally relates to the processes of justification by giving reasons; and legitimacy of decisions refers here to the state of being widely acknowledged as 'rightful' (Saretzki, 2012). The general public can, thus, recognise the 'moral authority' of the decider and subject themselves voluntarily to choices as having been rightly made (Bærøe & Baltussen, 2014). In this sense, public legitimisation of medical technology is based on the practice of attaining 'reasonableness' of an innovation's public value, i.e., providing adequate, well-justified reasons. This involves 'value judgments'[6] on social *desirability* and practical *plausibility* of claimed benefits, respectively the 'why' and the 'how' of new technology (Demers-Payette et al., 2016; Lehoux, 2006; Lucivero, 2016) (see chapters four and six).

This dissertation adopts a broadly-defined notion of value, i.e., value in relation to decision-making. As described by Mesthene, the notion of 'value' refers to the conceptions of desirable states of affairs that are utilised as criteria for

6 Value judgment has been described within the context of public policy as a prudent effort to appraise the societal worth of a course of action. It is an instance of ethical argumentation that involves examining the persuasiveness of diverse reasons in the course of deciding on certain choices. Value judgment, therefore, relies on reaching reasonableness. It is not to be confused with ideological commands or emotional appeals (Dunn, 2012). An illustrative example of value judgment is as follows: 'care provision in an ambulatory setting is more efficient than in hospital. Accordingly, the former is preferable to the latter because it increases the aggregate satisfaction of members of the community, in accordance with the principle of the greatest good for the greatest number'.

preference or choice, or as justifications for (proposed) action. Desirability in a general sense is a central constituent of this conception of value that, in turn, forms motivations, interests, and goals based on one's valuation of risks and benefits (Mesthene, 2003). The broad view on value taken in this dissertation encompasses two specific notions of value, namely 'consumer surplus' and 'value for money'[7], used respectively within the context of service economics and within health care markets. Within the former context, the value of a service is regarded as a cognitive construct: as the customer's/user's perception of the surplus of benefits over sacrifices needed to purchase and consume a service (van de Klundert, 2009). Within the context of health care markets, value is, as Michel Porter puts it, 'the health outcomes achieved per dollar spent' (Porter, 2010).

Taking a wide-angle view on a medical innovation's value

How to address the 'public problem' of medical innovations and legitimise their value to society at large? The core premise of this dissertation is that exploring the social dynamics of introducing a new medical technology provides us with an in-depth understanding of how its actual value is constructed and this helps enhance the public legitimacy of introducing an innovation into the health care system. The social interactions that emerge and stabilise when introducing medical innovations are representatives of their eventual impact because they enable certain discourses/actions and constrain others (Latour, 2005; Lucivero, 2016); and accordingly they also mobilise resources in certain directions rather than in others. That social interactions and inter-personal networks play an important role in introducing new technology was shown as early as fifty years ago in the pioneering study of the diffusion of tetracycline in clinical practice during the 1950s (Coleman et al., 1966). In view of the increasingly complex and dynamic nature of innovation processes, the study of contemporary innovation's social dynamics becomes even more important.

Thus, to study the construction of an innovation's value, we need to broaden our gaze from the innovation in isolation to the innovation within the context of use. This requires 'wide-angle' visualisation of the innovations, whereby the unit of analysis/assessment is the innovation ecology rather than a certain technological

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7 Value of a certain health care intervention is then defined in terms of individuals' (or others acting on their behalf) 'willingness to pay' to acquire more health care or other goods or services.

object. Borrowed from photography, a wide-angle view is ideal for 'capturing the whole of the scene'. It offers 'greater depth of field' and 'opens up perspective to include more relevant entities' (Digital Photography Review website). A wide-angle view of a medical technology introduction helps us unravel the diversity and dynamism of innovation processes and reveal the complex web of interactions that constitute its real-life value. Insights from Science, Technology, and Society (STS) studies can equip our gaze with a suitable wide-angle lens to explore an innovation's value thoroughly. STS is an interdisciplinary field of academic study rooted primarily in the social sciences. By examining the mutual influence of science, technology, and society, STS can help us link techno-scientific developments with public (health) policy.

As mentioned previously, the core of this dissertation is to regard medical technology introduction as a social phenomenon. This view is best represented by theoretical perspectives developed within STS scholarship, particularly, the social construction of technology and the constructive mode of technology assessment (CTA) (Bijker & Pinch, 2012; Pinch & Bijker, 2012; Rip et al., 1995). According to this view, the impact of (new) technology cannot be studied/assessed in isolation. Technology and society are not mutually exclusive of one another; instead, they influence and shape one another. In other words, living with technology influences the way we live in the world. Theoretically, the mutual shaping of technology and society merges the view that the impact of technology is exclusively the result of individuals interactions (i.e., social determinism) with the view that the impact is predetermined purely by the technology itself (i.e., technological determinism) (Lehoux, 2006).

(Re)connecting an innovation's dynamics with technology assessment

The knowledge infrastructure that hosts perspectives to address the public problem of medical innovation is Health Technology Assessment (HTA). This policy-oriented field of research emerged in the 1970s as a knowledge-based tool to regulate the introduction and diffusion of health care technologies with the emphasis on societal perspectives (Banta, 2001; Lehoux, 2006; Lucivero, 2016). Since then, HTA has received increasing support in many publicly-funded health care systems throughout the world as an essential element in developing policies and informing decision-makers so they make legitimised choices. A broad array of academic institutions, arm's-length government advisory agencies, and non-profit research organisations are involved in producing HTA, typically by conducting systematic reviews of published scientific

evidence, cost-effectiveness analyses, and sometimes analyses of ethical, legal, organisational and social aspects of health care technologies.

As of the 1990s, the HTA's mandates, means, and methods have been shaped and closely tied to the notions of evidence-based medicine and rational priority setting, while measuring clinical effectiveness and cost-effectiveness formed the foundation of assessments (Lehoux, 2006; Lehoux & Blume, 2000). Since then – and to date – mainstream HTA has come to be seen as being preoccupied with the objective of quantification of clinical and economic effect (Moreira, 2012). The object(ive) of assessments has gradually been narrowed down to the technology detached from its real-world context; HTA has steadily *branched-off* from the main strand of Technology Assessment with its original idea of contributing to setting an innovation *agenda* by relating technological changes to societal problems. Moreover, HTA has faced a division into technical 'assessment' and societal 'appraisal', with the former receiving more attention in HTA development (Baltussen et al., 2017; Blume, 2009; Blume, 2013; Garrido et al., 2010; van Est & Brom, 2012). As a result of the increasing dissemination and uptake of such HTA reports, healthy criticism has called for 'greater reasonableness' in dealing with the public problem of health technology, for instance, by providing decision-makers with a more comprehensive insight into the actual benefits and societal consequences of a new technology. In particular, scholars have pointed out the 'sociological' and 'normative' shortcomings of current HTA for legitimising technological developments in health care (Giacomini et al., 2013; Lehoux, 2006; Lucivero, 2016; Moreira, 2012). More recently in the development of HTA and in response to these critics, attention has been paid to the importance of the mission (the 'social mandate') and epistemology (knowledge base) of HTA within a broader public arena (Giacomini et al., 2013; Lehoux, 2006; Lucivero, 2016).

This dissertation aims to respond to these calls by conducting a wide-angle investigation of the social dynamics of technology introduction, while addressing anew the 'pressing need' to consolidate HTA's foundation by integrating concepts and findings from the field of STS, and methods from the field of anthropology (Lehoux, 2006; Moreira, 2012).

THE FOCUS OF THIS DISSERTATION: UNDERSTANDING AND CONNECTING

The dissertation adopts the approach of *techno-anthropology*. This is an emergent, interdisciplinary research area within the field of STS that focuses on human-technology interactions and relations (Børsen, 2013). This approach is based on a qualitative, problem-oriented examination of human-technology relationships to address societal problems, and applied to health care, in relation to the triple goal of public health care systems (i.e., better health, better care, lower total costs) (Botin et al., 2015). Techno-anthropology is inspired by anthropological research methodology, the hallmark of which is the in-depth pursuit of cultural beliefs, sense-making practices, social interactions, incentives and expressions, organisational structures, and regulatory frameworks. Classical anthropological research had originally focused on studying indigenous cultures. In recent decades, however, this research has been implemented, among others, to studying (modern) scientific and technological cultures.

Techno-anthropological research typically consists of two interrelated steps. According to Børsen, the first step focuses on an in-depth exploration and analysis of the stakeholders' (dissenting) arguments, perspectives, and positions. The examination can include technology design, driving forces of innovation spread, changes brought about through the use of an innovation, how a new technology is given meaning, how it is deployed, and how it relates to the wider political-economy of the health care system. The second step involves debate on how the analyses of policy-relevant techno-scientific dissents can inform decision-makers to make judgments about concrete societal and ethical dilemmas regarding new technologies (Børsen, 2013).

In congruence with these two aims, the objective of the study is twofold: (*a*) gaining a broad understanding of the value of a new therapeutic medical device based on the ways in which value is perceived and constructed in practice, and (*b*) integrating such understanding into existing HTA frameworks to better address the public problem of medical innovations (see also figure 2). The project focuses in particular on diverse value perspectives in practice. Rather than simply compiling a range of opinions, I aim to elicit interpretatively what *matters* to stakeholders and to position the different views on value in relation to one another and with reference to the broader objectives of the health care system. The study thus takes on a joint *descriptive-communicative* orientation by carrying out a real-world investigation of diverse perspectives on an innova-

tion's value and harnessing this harvest in order to stimulate public debate and a participatory assessment of new technologies. The ultimate goal of the project is to enhance public legitimisation of introducing new medical technology and to maintain the socially-responsible embedding and deployment of medical innovations. I first empirically explore the social dynamics of technology introduction focusing on one in-hospital innovation, the *da Vinci*® surgical robot, a state-of-the-art technology that enables minimally invasive operations from a distance. I then examine the implications of this empirical understanding on the role, methodology, and (future) direction of technology assessments, and how we can make HTA better connected to innovations' social dynamics.

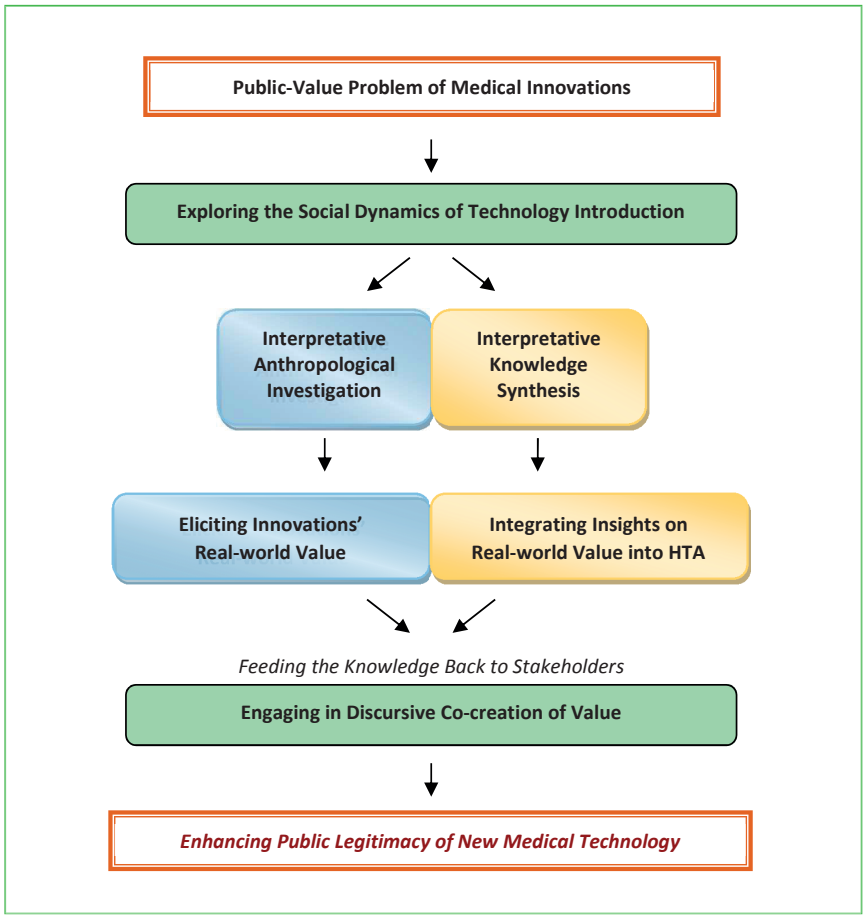

Figure 2. *Conceptual logic of the dissertation.*

STUDY DESIGN AND METHODOLOGY

The study was designed flexibly and pragmatically in accordance with the two above-mentioned objectives. It involves an explorative case study, namely the introduction of robotic surgery, and an interpretative analysis of multiple strands of literature on technology assessment (see also figure 2). The da Vinci surgical robot provides a 'rich case' for examining a new technology in real-life and studying the social dynamics of its introduction. This innovation, a promising, expensive, complex and contested device, has been in the diffusion phase in recent years and has been received enthusiastically by the surgical community worldwide. The richness of this innovation as a choice for case study became clear to me as early as in 2008 when – at the outset of my research on robotic surgery – a urologic surgeon whom I approached for an orientation chat started our conversation by stating:

> You probably know the advantages of the robot, don't you? Do you know the political advantages or the real ones? Of course, the non-political answer is that it's just a joystick … to reach the prostate which is hard to access, so surgery becomes more precise and so on … but you know, politics are always there.

That was when I made up my mind to explore these 'politics' of which he spoke.

From a methodological point of view, a case study design helps us go beneath the skin of a social phenomenon, e.g. the introduction of a medical innovation, and gain a detailed understanding of it. A case study can be the method of choice for an in-depth examination of complex interactions underlying a phenomenon in its 'real-life' context (Yin, 1994). The case studies presented in this dissertation (chapters two and three) involved in-depth, qualitative exploration of stakeholders' knowledge and perspectives on the introduction of da Vinci surgery. These case studies are examples of techno-anthropological research described above. The researcher immerses him/herself in rich data often collected from (participant) observation, in-depth interviews, and multi-source document analyses to provide a 'thick description' of the social phenomenon being studied. This investigative logic can best explore the rationales (the 'why') and processes (the 'how') of a social phenomenon (Green & Thorogood, 2005; Lehoux, 2006).

A broad understanding of the social dynamics of technology introduction can, then, pave the path for subsequent conceptual analyses as to what such an understanding could mean to the policy and practice of introducing medical innovations and how it can enrich the knowledge-base of technology assessment. As described by Faulkner, the rise of first-hand research evidence in healthcare accords with the widely documented move towards a more heterogeneous mode of knowledge-production, which is trans-disciplinary, attentive to the context of application, oriented towards innovation ecosystem/networks, and reflexive to societal concerns (Faulkner, 2009; Gibbons et al., 1994).[8] In line with this development, the case studies in the dissertation are followed by a subsequent knowledge synthesis design based on an integrated assessment of existing research fields (see also chapters four and seven).

The knowledge synthesis approach used in this dissertation is problem-oriented, amounting to assessing medical innovations as a policy problem or – as Giacomini et al. put it – a 'technology-as-policy analysis' (Giacomini et al., 2013). It involves constructing new, coherent analytical insight – often with some degree of creativity and reflection on personal experiences – by integrating concepts from different strands of literature and disciplines to address a certain problem (Bammer, 2013; Noblit & Hare, 1988). Rather than having an aggregative intent – as in the case of systematic reviews of studies assessing a treatment effect, such knowledge syntheses are 'integrative' and 'interpretative', pertaining to the problem at hand, by adequately relying on literature from multiple research fields (Noblit & Hare, 1988). An interpretative knowledge synthesis as such is capable of supporting decision-makers with a broader understanding of a complex, real-world problem as well as informing them how to deal with uncertainties and consequences of actions (Bammer, 2013; Noblit & Hare, 1988). Interpretative knowledge syntheses also serve the purpose of knowledge translation by bridging existing knowledge (what is already known) and policy problems (diverse unknowns). Correspondingly, they respond to the recent considerable interest in 'knowledge brokering' (valorisation) by establishing 'synergies' between knowledge-producers and knowledge-users in an innovation's ecosystem (Bammer, 2013; Fournier, 2012; Kastner et al., 2012; Kothari et al., 2017).

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8 In innovations studies, the knowledge-base of technological innovation systems are referred to as 'knowledge helices' or 'mode 2 knowledge', 'mode 3 knowledge', etc. For example, the 'quadruple helix' mode of knowledge production involves the co-production of knowledge through university-business-government-civil society relations.

WHAT IS TO COME: OUTLINE OF THE DISSERTATION

After this introduction, the second chapter explores in-depth the adoption of robotic surgery in the Dutch health care system at an earlier stage of its diffusion. This is followed in chapter three by a thick description of the value profile of the same innovation, particularly its evidence basis, after the early diffusion phase. The case study of robotic surgery highlights the public significance of medical technology, namely, uncertainties in their social desirability and actual impact during the introduction phase. In chapter four I examine how we can elicit an innovation's betterment and deal with uncertainty of the value profile of complex in-hospital innovations. Chapter five presents a perspective on the purpose of HTA, with a plea to integrate the wider/public aspects of value into HTA to meet the needs of the population. Chapter six is a methodological commentary explaining what an assessment of an innovation's social desirability and practical plausibility – respectively the 'why' and the 'how' of value – entails. The final chapter provides a synopsis of the study, a discussion on its contribution, and concluding remarks.

Chapters two to six of this dissertation are based on separate articles published in international peer-reviewed journals and tailored in their content and length to the specific audiences and requirements of those journals. These chapters can be read stand alone and as such, some overlap may exist between them.

REFERENCES

Bærøe, K., Baltussen, R. (2014). Legitimate healthcare limit setting in a real-world setting: integrating accountability for reasonableness and multi-criteria decision analysis. *Public Health Ethics,* hu006.

Baltussen, R., Jansen, M.P.M., Bijlmakers, L., Grutters, J., Kluytmans, A., Reuzel, R.P. et al. (2017). Value assessment frameworks for HTA agencies: the organization of evidence-informed deliberative processes. *Value in Health*, 20(2), 256-260.

Bammer, G. (2013). *Disciplining Interdisciplinarity: Integration and implementation sciences for researching complex real-world problems*. ANU E Press.

Banta, D. (2001). The management of healthcare technology from a national perspective. *International Journal of Healthcare Technology and Management*, 3(2-4), 177-190.

Berwick, D.M. (2016). Era 3 for medicine and health care. *Journal of American Medical Association*, 315(13), 1329-1330.

Bijker,W.E., & Pinch,T. (2012). Preface to the anniversary edition. In: W.E. Bijker, T.P. Hughes, T. Pinch, & D.G. Douglas (Eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*. MIT Press, Boston, p.X-XXIV.

Blume, S.S. (2009). Assessing health technologies in a changing world. *International Journal of Technology Assessment in Health Care*, 25 Suppl 1 276-280.

Blume, S.S. (2013). Medical innovations: Their diffusion, adoption, and critical interrogation. *Sociology Compass*, 7(9), 726-737.

Bodenheimer, T. (2005). High and rising health care costs. Part 2: technologic innovation. *Annals of Internal Medicine*, 142(11), 932-937.

Børsen,T. (2013). Identifying interdisciplinary core competences in Techno-Anthropology: interactional expertise, social responsibility competences, and skills in anthropology-driven design. In: T. Børsen, & L. Botin (Eds.), *What Is Techno-Anthropology?* Aalborg University Press, Aalborg, pp. 35-66.

Botin,L., Bertelsen,P., & Nøhr,C. (2015). Challenges in improving health care by use of health informatics technology. In: L. Botin, P. Bertelsen, & C. Nøhr (Eds.), *Techno-anthropology in Health Informatics: Methodologies for Improving Human-technology Relations*. IOS Press, Amsterdam, pp. 3-13.

Coleman, J.S., Katz, E., Menzel, H. (1966). *Medical innovation: A diffusion study.* Bobbs-Merrill Indianapolis.

Consoli, D., Mina, A., Nelson, R. R. et al. (2016). *Medical Innovation: Science, Technology and Practice.* Routledge.

Cutler, D.M., McClellan, M. (2001). Is technological change in medicine worth it? *Health Affairs*, 20(5), 11-29.

Daniels, N., Porteny, T., Urrutia, J. (2016). Expanded HTA: enhancing fairness and legitimacy. *International Journal of Health Policy and Management*, 5(1), 1.

Demers-Payette, O., Lehoux, P., Daudelin, G.v. (2016). Responsible research and innovation: a productive model for the future of medical innovation. *Journal of Responsible Innovation*, 3(3), 188-208.

Dunn, W.N. (2012). *Public Policy Analysis: An Introduction.* New York: Taylor & Francis.

Etzkowitz, H., Leydesdorff, L. (2000). The dynamics of innovation: from national systems and "mode 2" to a triple helix of university-industry-government relations. *Research Policy*, 29(2), 109-123.

Faulkner, A. (2009). *Medical Technology into Healthcare and Society: A Sociology of Devices, Innovation and Governance.* Basingstoke: Palgrave Macmillan.

Fournier, M.F. (2012). Knowledge mobilization in the context of health technology assessment: an exploratory case study. *Health Research Policy and Systems*, 10(1), 10.

Garrido, M.V., Gerhardus, A., Rottingen, J.A., Busse, R. (2010). Developing health technology assessment to address health care system needs. *Health Policy*, 94(3), 196-202.

Gelijns, A., Rosenberg, N. (1994). The dynamics of technological change in medicine. *Health Affairs*, 13(3), 28-46.

Gelijns, A.C., Brown, L.D., Magnell, C., Ronchi, E., Moskowitz, A.J. (2005). Evidence, politics, and technological change. *Health Affairs*, 24(1), 29-40.

Giacomini, M., Winsor, S., Abelson, J. (2013). Ethics in health technology assessment: understanding health technologies as policies. *Healthcare Management Forum*, 26(2), 72-76.

Gibbons, M., Limoges, C., Nowotny, H. et al. (1994). *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies.* Sage.

Green, J., Thorogood, N. (2005). *Qualitative Methods for Health Research.* London: Sage publication.

Henshall, C., Schuller, T. (2013). Health technology assessment, value-based decision making, and innovation. *International Journal of Technology Assessment in Health Care*, 29(4), 353-359.

Hofmann, B.M. (2015). Too much technology. *British Medical Journal*, 350(h705).

Janssen, M. (2016). *Situated Novelty: A Study on Healthcare Innovation and Its Governance.* Dissertation: Erasmus University Rotterdam.

Karaca-Mandic, P., Town, R.J., Wilcock, A. (2017). The effect of physician and hospital market structure on medical technology diffusion. *Health Services Rsearch*, 52(2), 579-598.

Kastner, M., Tricco, A.C., Soobiah, C., Lillie, E., Perrier, L., Horsley, T. et al. (2012). What is the most appropriate knowledge synthesis method to conduct a review? Protocol for a scoping review. *BMC Medical Research Methodology*, 12 114.

KNAW (2014). *Evaluation of New Technology in Health Care. In Need of Guidance for Relevant Evidence.* Amsterdam: Royal Netherlands Academy of Arts and Sciences (KNAW).

Koopmanschap, M., de Meijer, C., Polder, J. (2010). *Determinants of health care expenditure in an aging society.* Netspar Panel Paper 22. Tilburg: Tilburg University.

Kothari, A., McCutcheon, C., Graham, I.D. (2017). Defining integrated knowledge translation and moving forward: a response to recent commentaries. *International Journal of Health Policy and Management*, 6(5), 299-300.

Latour, B. (2005). *Reassembling the Social: An Introduction to Actor-network Theory.* Oxford: Oxford University Press.

Lehoux, P. (2006). *The Problem of Health Technology: Policy Implications for Modern Health Care Systems.* New York: Routledge.

Lehoux, P., Blume, S. (2000). Technology assessment and the sociopolitics of health technologies. *Journal of Health Politics, Policy and Law*, 25(6), 1083-1120.

Lucivero, F. (2016). *Ethical Assessments of Emerging Technologies: Appraising the Moral Plausibility of Technological Visions*. Cham: Springer International Publishing.

Mesthene,E. (2003). The social impact of technological change. In: R.C. Scharff, & V. Dusek (Eds.), *Philosophy of Technology: The Technological Condition*. Blackwell, Oxford, pp. 617-637.

Moreira, T. (2012). *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum.* London: Routledge.

Moses, H., Matheson, D.H., Dorsey, E.R., George, B.P., Sadoff, D., Yoshimura, S. (2013). The anatomy of health care in the United States. *Journal of American Medical Association*, 310(18), 1947-1964.

Noblit, G.W., Hare, R. D. (1988). *Meta-ethnography: Synthesizing Qualitative Studies.* Sage Publication.

Pinch,T., & Bijker,W.E. (2012). The social construction of facts and artifacts. In: W.E. Bijker, T.P. Hughes, T. Pinch, & D.G. Douglas (Eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*. MIT press, Boston, pp. 11-44.

Porter, M.E. (2010). What is value in health care? *New England Journal of Medicine*, 363(26), 2477-2481.

Prasad, V.K., Cifu, A. S. (2015). *Ending Medical Reversal: Improving Outcomes, Saving Lives*. Baltimore: JHU Press.

Rip,A., Misa,T.J., & Schot,J. (1995). Constructive technology assessment: a new paradigm for managing technology in society. In: A. Rip, T.J. Misa, & J. Schot (Eds.), *Managing Technology in Society*. Pinter Publishers, London, pp. 1-12.

Rye, C.B., Kimberly, J.R. (2007). The adoption of innovations by provider organizations in health care. *Medical Care Research and Review*, 64(3), 235-278.

Saltman,R.B. (2004). Social health insurance in perspective: the challenge of sustaining stability. In: R.B. Saltman, R. Busse, & J. Figueras (Eds.), *Social Health Insurance Systems in Western Europe*. Open University Press, pp. 3-20.

Saretzki, T. (2012). Legitimation problems of participatory processes in technology assessment and technology policy. *Poiesis & Praxis*, 9(1-2), 7-26.

Sorenson, C., Drummond, M., Khan, B.B. (2013). Medical technology as a key driver of rising health expenditure: disentangling the relationship. *ClinicoEconomics and Outcomes Research*, 5 223-234.

van de Klundert, J.J. (2009). *Value-Conscious Health Service Organisations*. Inaugural lecture, Erasmus University Rotterdam.

van Est,R., & Brom,F. (2012). Technology assessment, analytic and democratic practice. In: R. Chadwick (Ed.), *Encyclopedia of Applied Ethics*. Elsevier, Oxford, pp. 306-320.

Webster, A. (2007). *Health Technology and Society: A Sociological Critique*. New York: Palgrave Macmillan.

Yin, R.K. (1994). *Case Study Research: Design and Methods*. Thousand Oak: Sage Publication.

2 Understanding the value profile of the *da Vinci*® surgical robot during the early introduction phase

This chapter is a slightly extended version of the following article:
Abrishami, P., Boer, A., Horstman, K. (2014)

Understanding the adoption dynamics of medical innovations: Affordances of the da Vinci robot in the Netherlands.
Social Science & Medicine, 117: 125–133.

An operating room featuring the da Vinci® surgical system (©2017 Intuitive Surgical, Inc.)

ABSTRACT

This study explored the rather rapid adoption of a new surgical device – the da Vinci robot – in the Netherlands despite the high costs and its controversial clinical benefits. We used the concept 'affordances' as a conceptual-analytic tool to refer to the perceived promises, symbolic meanings, and utility values of an innovation constructed in the wider social context of use. This concept helps us empirically understand robot adoption. Data from 28 in-depth interviews with diverse purposively-sampled stakeholders, and from medical literature, policy documents, Health Technology Assessment reports, congress websites and patients' weblogs/forums between April 2009 and February 2014 were systematically analysed from the perspective of affordances. We distinguished five interrelated affordances of the robot that accounted for shaping and fulfilling its rapid adoption: 'characteristics-related' affordances such as smart nomenclature and novelty, symbolising high-tech clinical excellence; 'research-related' affordances offering medical-technical scientific excellence; 'entrepreneurship-related' affordances for performing better-than-the-competition; 'policy-related' affordances indicating the robot's liberalised provision and its reduced financial risks; and 'communication-related' affordances of the robot in shaping patients' choices and the public's expectations by resonating promising discourses while pushing uncertainties into the background. These affordances make the take-up and use of the da Vinci robot sound perfectly rational and inevitable. This Dutch case study demonstrates the fruitfulness of the affordances approach to empirically capturing the contextual dynamics of technology adoption in health care: exploring in-depth actors' interaction with the technology while considering the interpretative spaces created in situations of use. This approach can best elicit *real-life* value of innovations, values as defined through the eyes of (potential) users.

KEYWORDS

Technology adoption • Surgical device • da Vinci robot • Affordance • Science, technology and society studies • Qualitative ethnographic evaluation • Decision-making • The Netherlands

INTRODUCTION

The da Vinci robot is a new surgical device. Worldwide, it has been used most commonly for the surgical removal of cancerous prostate (Camberlin, Senn, Lays & de Laet, 2009) and more recently also for uterine cancers (ECRI, 2013). It is a remotely-controlled laparoscopic device for the surgical excision of cancerous (and surrounding) tissues. The da Vinci robot is to date the only robotic surgical system available on the market (Gleitsmann et al., 2012). Despite uncertainties in clinical added benefits and high costs (see below), it has been widely adopted in most Western countries and demand for it continues to rise (*ibid.*). How should one understand the rather rapid adoption of this innovative technology?

Many well-developed health care systems, particularly market-oriented systems, permit a more decentralised provision of health care innovations. Providers, patients and payers are frequently engaged in situations of choice on whether to adopt (i.e., whether to purchase and use), request, or reimburse new forms of care. As a result the take-up of innovations is a dynamic *process* involving multiple formal/informal decisions by a multitude of interactive actors (Greenhalgh, Robert, Bate, Macfarlane & Kyriakidou, 2005). Since the technology is embedded in the "wider social body" of the setting of use (Webster, 2007), adoption decisions are not bounded merely by the technical advantages of the innovation as a solo artefact. Adoption takes place at the interface of stakeholders, technology, and the stage (i.e., socio-organisational structures, assemblages, and networks). This way of conceptualising adoption processes draws on a constructivist perspective on technology, as developed in Science, Technology and Society Studies (STS). It entails that technology and society co-evolve and shape each other (Rip, 2001). It is oriented toward exploring both the material and rhetoric 'identities' of the technology in practice (Ulucanlar, Faulkner, Peirce, & Elwyn, 2013). As a 'sociotechnical' process (Bijker & Pinch, 2012; Ulucanlar et al., 2013), adoption represents a wider set of benefits within the 'social matrix' of use (Webster, 2007): what priorities are served by the technology, what actors can achieve by using it, and which symbolic meanings are attributed to those activities.

The aim of this article is to gain an understanding of the adoption dynamics of health care innovations by examining one specific case, namely, the da Vinci robot in the Netherlands. To grasp the contextual dynamics of robot adoption, we placed the concept 'affordance' centre stage. The article starts by introducing this concept after which we explain the case and the methodology. In present-

ing the results we show how five kinds of affordances play a role in the adoption dynamics. Analysing the case of the da Vinci robot in terms of affordances also serves to explore the fruitfulness of this concept as a conceptual-analytic tool for understanding the adoption of technological innovations in health care. In the conclusion, we reflect on the case study as well as on cross-applicability of the concept affordances in understanding real-life adoption practices.

UNDERSTANDING ADOPTION DYNAMICS BY MEANS OF AFFORDANCES

The concept 'affordance' is originally developed in ecological psychology by James Gibson in 1979 in an attempt to capture behavioural responses that can emerge in the interaction between an organism and its environment (Scarantino, 2003). Affordances can be in a nutshell expressed as: … "is for"… . The edge of a cliff, for instance, can be fall-off-able or jumpable depending on the circumstance (Scarantino, 2003). More recently, the concept has been used to study human-technology interaction in computer science and technology design. In these fields, affordances are described as capacities for action offered by technology and signified by actors within the context of use. For example, a jacket is *wearable* or a touchscreen display is *tappable*. It makes the actor opt to wear the one or tap the other. Similarly, a piece of paper is writable but also foldable (as in origami). In STS, affordances refer to the different meanings, promissory visions, and utility values that can be assigned to a technology according to the ways it is implemented in its context of use (Webster, 2004).

We argue that the affordances approach is a fruitful conceptual-analytic tool to understand adoption dynamics. Central to such an understanding is an exploration of the 'adoption space' and technology-actor-setting interrelations therein (Ulucanlar, et al. 2013). As a sociotechnical process and subject of a sociological investigation, adoption processes encompass *both* the material characteristics of a device (identified by pre-existing technical properties and initial promises) and the rhetorical practices/expectations of actors constructed within a particular socio-organisational setting of use. Lehoux argues that a subject-object dichotomy fails to capture the subtle nuances of human-technology interactions in constructing impact (Lehoux 2006). Affordances comply with this fluidity in capturing the technology-actor-setting interrelations. Firstly, they comprise 'perception-action couplings' (Scarantino, 2003). Affordances represent perceived promises (benefits) of an innovation. However, they are

not isolated mental abstractions. They provide grounds for individual decisions, architect situations of choice, and 'suggest' the choice (action) that should be made. More than simply being informative to adoption decisions, affordances are 'performative' as they stimulate and frame agentic adoption decisions (pro-) actively (Hutchby, 2001). Secondly, affordances can frame stakeholders towards specific *collective* sociotechnical practices. When shared within a network of stakeholders, perceived promises of a new technology – once internal to some individuals' intentions – are externalised and objectified (Garud & Rappa, 1994). They are recognised and available to 'convince' other actors even though the details necessary to warrant the promises being fulfilled in practice are missing (van Lente, 2012). This can create a 'consensual validation' (Garud & Rappa, 1994) of perceived promises, thereby making affordances performative at a collective level too. Third, the concept affordance enables us to capture the implicit drivers of (non-)adoption, which cannot be sharply demarcated from the knowledge-base conception of the value of the technology. This may reveal a symbolic/interpretative dimension of adoption, which often remains unarticulated and unapprehended within a formal evidence-based rationalisation (Ulucanlar et al., 2013). The affordances approach, therefore, enables us to understand the 'socio-cognitive roots' of adoption processes (Garud & Rappa, 1994), their 'generative forces' among users and potential adopters (Borup, Brown, Konrad & van Lente, 2006), and the *semantic utilities* of the technology as recognised by individual users within the context of use (see also Box 1).

As a conceptual-analytic tool, affordances draw closely on the insight gained from the sociology of expectations (Borup et al., 2006). They are both capable of describing technology dynamics by linking technical and social issues. They both embrace the promises of technology and their performative character. They attend to the importance of developing a conceptual-analytical vocabulary to better understand a 'strategic turn' in the technological innovations and investments of recent decades (*ibid*.). Affordances approach, we argue, can complement expectations studies by zooming-in on strategic adoption behaviours at the interface of actor, technology, and the setting of use. This approach responds to the call for 're-connecting' the promises with the practices constituting them (*ibid*.). In this regard, the affordances approach is more utilisation-focused in exploring sociotechnical (i.e., technology-actor-setting) interlinkages. The expectations approach is more appropriate for exploring the adoption of major generic technological innovations with wide varieties of application (e.g., nanotechnology), whereas the affordances approach might better explain technology adoption in a particular application field – where expectations may be more

fragile (*ibid.*) – e.g., a surgical device (such as the da Vinci robot) or an implantable device (such as deep brain stimulation). For the same reason, affordances approach may provide a more concrete focus on 'constructive usership' in technology introduction (Faulkner, 2009). The affordances approach can therefore be regarded as an *ecological* (situated) version of expectations studies capable of capturing local patterns of adoption and utilisation.

Box 1. ***Theoretical elaboration on the concept affordances and its fruitfulness***

The affordances approach enables us to capture implicit and symbolic utilities of the technology as signified by the actors in the context of technology adoption and use. It can elucidate the relation between technological 'scripts' (utility functions inscribed in the technology by design) and human's creative and agentic engagement with these scripts. By unpacking the socially-constructed utilities of the technology, this approach helps explain the drivers of adoption and in so doing, the strategic acting of adoption (e.g., an opportunity to advance research career by adopting da Vinci robot).

From the point of view of sociological theory, an analysis by means of the affordances perspective can escape the (linguistic) division between objective and subjective. Such division proves 'highly problematic' (Boroup et al., 2006) or even 'false' (Lahire, 2013; Elias, 1978) in so far as understanding social processes of technology adoption is concerned. In his 'figurational and process' sociological theory, Norbert Elias describes the 'indissociability' of the individual and the social when exploring social lives/processes with the aim of understanding (Lahire, 2013; Elias, 1978). He chooses a perspective to overcome the deficiency of language when facing the conventional ontological antinomies – e.g., individual-society or agent-structure (Elias, 1991; Quintaneiro & Mitre, 2006). He argues that it is important not to conceive of a social process as 'thing' which is somehow 'outside' of the individual or the structure. According to Elias, there is no individual isolated from society and vice versa. His analogy with dance is noteworthy: there is no dance as such separate from dancer or from the floor (*ibid.*). Similarly, there is no technology adoption – and no technology impact – dissociated from the adopter or the context. Figurational and process sociology aims at understanding social processes by exploring the links between the individual (i.e., the

Box 1. ***Theoretical elaboration on the concept affordances and its fruitfulness*** *(continued)*

actor, agency, subjectivity, subject of psychology) and society (i.e., the context, the structure, the institution, the system, the objectivities, subject of sociology) (Lahire, 2013). In a similar vein, Verbeek uses an analytical view to move beyond the human-technology (or subject-object) dichotomy when understanding the technology's role of 'mediating' human-world relationships (Verbeek, 2011). Verbeek argues that specific realities of technology adoption and human intentionality need to be understood – and located in – human-technology associations (*ibid.*). An analysis by means of affordances complies with Elias' process sociology as well as Verbeek's mediation approach in exploring the technology adoption as a socio-technical phenomenon, as a fluid process involving constant configurations and reconfigurations, as *culture*. The dynamism, symbolism, utility perceptions, and identities inherent in these 'real-life' social processes are not 'external' to the technology, nor to the individual actors. Likewise, there are neither entirely immanent in the technology, nor exclusive to the user (see also chapter seven).

In addition, the processes of technology adoption cannot be understood well by simply labelling complex interlinkages with terms borrowed from physical sciences. We would argue that conventional terms such as 'factors', 'elements', 'variables', or 'domains' fall short to capture the fluidity of these socially-constructed real-life processes. These terms involve forms of conceptual reductionism (e.g., commercial factors, marketing elements, organisational domain), and as such, have been rather unsatisfying in anthropological studies aiming at in-depth understanding (Lahire, 2013). They could be qualified tools in situations where a brief understanding is sufficient, e.g., in the form of categorisation or classification. Rather than serving as itemisation, affordances' are there to be explored, explained, and reflected upon. They can provide the 'why' and the 'how' of the factors *being* factors as such. For further elaboration, we refer readers to the criticisms on the Andersen model of health services utilisation in particular settings (see, e.g., Vingilis, et al., 2007). This widely-used model is based on an identification of predictors of health services utilisation and access under three sets of 'factors': predisposing, enabling, and need factors.

Box 1. ***Theoretical elaboration on the concept affordances and its fruitfulness*** *(continued)*

A major contribution of the affordances approach, we argue, is the very kind of understanding that it can bring to bear. This approach provides us with a situated (context-specific) and rich (in-depth) understanding of adoption dynamics. Such understanding offers opportunities for (self) *reflection* by providing a sketch of reality and shedding light on how (far) promises actually come true. It may also help us *anticipate* at an early stage of introduction the technology's further embedding in the health care system as well as its potential impact on, say, resource distribution based on recurrent patterns of technology use. Related to reflexivity and anticipation is the generalisability of the concept affordances. Affordances approach provides a situated insight, though with a 'conceptual generalisation' (Greenhalgh, et al., 2011; Green & Thorogood, 2004). This refers to certain ways of thinking about and making sense of the social practice of technology adoption that are of general relevance and can be transferable to other technologies/settings (see also chapter seven). Nonetheless, the very strength of the affordances approach may also be its weakness: providing a sophisticated understanding. This is particularly challenging for policy and practice, where a concrete and straightforward implication of such understanding is expected (see, e.g., the case study reported by Greenhalgh et al. 2011).

The theoretical underpinnings of the concept affordances as well as its implications need, nevertheless, further study. To our knowledge, there is little theoretical and empirical contribution available on use of this concept to analyse medical technology adoption. We hope this article will encourage further studies on this framework.

Understanding the technology-actor-setting dynamics of medical innovations is particularly important during the early diffusion phase. At this stage, the promises of the innovation are salient and the inquiry of impact (in the face of contingencies of effect) is pressing. Exploring affordances of the innovation at this phase provides insight into an array of processes that account for *both* shaping and fulfilling the adoption. However, this has remained an under-studied subject in studying the diffusion of health care innovations and in health technology assessment (HTA). In both research areas, little attention

has been devoted to the social dynamics of adoption, while such insight can be of importance to diverse stakeholders involved in technology development, assessment, and funding (Ulucanlar et al., 2013; Webster, 2007; Lehoux & Blume, 2000; Blume, 2009; Ashcroft, 2012). In fact very often, the unit of analysis has been the artefact as separated from the context of its use, or the individual adopters detached from their social networks and their agentic roles therein. On the other hand, empirical research to capture the adoption dynamics is scarce (Greenhalgh et al., 2005), particularly with a constructivist enquiry (Reuzel & van der Wilt, 2000) and more specifically for non-pharmaceutical innovations (Ulucanlar et al., 2013). This can be added to an overall generic paucity of descriptive research in health care practice and policy (Gagliardi & Dobrow, 2011). Such research would nevertheless provide valuable insight to (national) policy-makers involved in procurement and reimbursement decisions (Ulucanlar et al., 2013) or funding research, as well as technology developers and the developers of (clinical) practice guidelines.

THE CASE STUDY OF DA VINCI ROBOTIC SURGERY

The *da Vinci*® system was introduced in 2000 by an American firm called Intuitive Surgical Inc. It was produced on a commercial scale based on a concept initially developed within the American army, to provide the care while keeping doctors safely away from the battle field. The robotic surgeon is seated at a console at a distance from the operating table and controls the movements of the robotic arms remotely (figure 1). As mentioned before, adoption of this innovation was very swift. The worldwide installed base of da Vinci surgical systems had increased from less than 300 in 2004 to a thousand in 2008 (Camberlin et al., 2009) and had reached 2300 in 2011 (ECRI, 2013), thus sustaining an annual growth of more than 25% for the manufacturer (Gleitsmann et al., 2012).

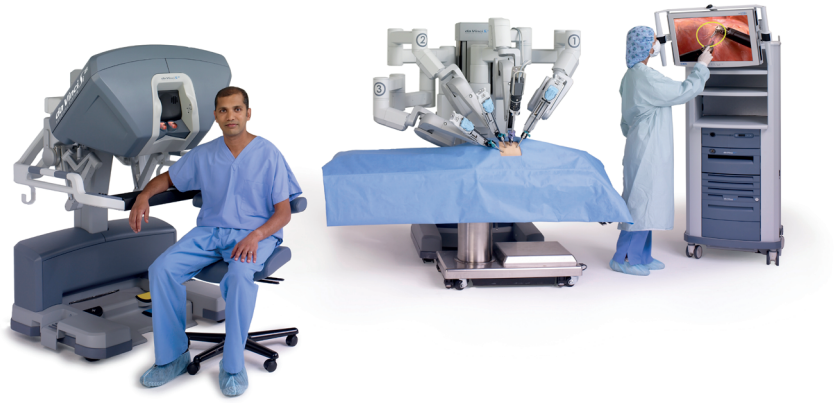


Figure 1. *The da Vinci surgical robot (©2017 Intuitive Surgical, Inc.).*

This study examined the application of the da Vinci robot for prostate operation. The operation is known as robot-assisted radical prostatectomy (hereafter referred to as RARP). In 2011, RARP comprised 31% of almost 360,000 robotic operations worldwide (ECRI, 2013). In the Netherlands, RARP is the most common robotic application accounting for circa 70% of all prostate operations (la Chapelle, Jansen, Pelger & Mol, 2013). Other alternatives for the surgical resection of cancerous prostate are: open radical prostatectomy (ORP) and laparoscopic radical prostatectomy (LRP). For decades, open prostatectomy had been the method of choice to remove a cancerous prostate (Lepor, 2005). ORP still remains the 'gold standard' therapy because of long-term experience and patient follow-up, thereby being a 'reference' in comparative studies on effectiveness, safety, costs, and outcome (Martínez-Salamanca & Romero Otero, 2007). LRP and RARP are minimally-invasive surgeries (MIS) as they are less invasive than open surgery for the same purpose and require a smaller incision to reach the target inside the body. The da Vinci robot allows the surgeon to carry out MIS remotely.

The added clinical benefits of RARP compared with other treatment options for localised prostate cancer are 'controversial' as a result of 'considerable uncertainty' surrounding the clinical research results and their meaning (Robertson et al., 2013; Novara et al., 2012; Heemskerk, Bouvy, & Baeten, 2014; Makarov, Yu, Desai, Penson & Gross, 2011). The recently-updated Dutch national guidelines on prostate cancer reported a lack of randomised studies comparing surgical and non-surgical treatment modalities (IKNL, 2013). Drawing on the current

state of scientific evidence, the guidelines mention slightly reduced functional morbidities and complications after RARP, but "no difference" between the oncological results of RARP, ORP, and LRP (*ibid*.). The clinical superiority of RARP remains difficult to prove as the treatment outcome depends to a large extent on the surgeon's experience, the rate of learning robotic surgery skills, the hospital's surgical volume, and the patient's risk portfolio on cancer spread (Robertson et al.,2013; Novara et al., 2012). The Dutch guidelines conclude in the section 'Best therapy for localised prostate cancer' that the treatment results "depend mainly on the risk group and not on the method of treatment" (IKNL, 2013, p. 76).

In terms of costs, the da Vinci system involves considerable capital investment and expenses. These include a purchase price of 1.3–1.7 million Euro (depending on the system version) plus a maintenance cost of about ten per cent of the catalogue price per year and the costs of reposables (instruments such as cutters, needle-holders, etc.) of about 2900 Euro per patient/operation (Gleitsmann et al., 2012; Camberlin et al., 2009). A newer (Si) model is also available with dual consoles at an additional cost of 380,000 Euro (ECRI, 2013). A Dutch hospital, which was debating whether to purchase a da Vinci system, estimated in their business case, the total cost (purchase, maintenance, materials, and personnel) at about one million Euro per year if the purchase price is to be set off over a period of five years (first author's personal contact 2009). The da Vinci robot's uncertain clinical added benefits amid its high expenses also suggest a 'considerable uncertainty' regarding its cost-effectiveness (Close et al., 2013).

The uncertainties seem incongruent with what is happening in practice: a sharp increase in its adoption. In the Netherlands too, the da Vinci robot was perceived as a highly promising innovation. By the end of 2007 – seven years after the first demonstration – five da Vinci surgical systems were operational in the Netherlands. Seven years later, as of February 2014, the installed base of da Vinci systems had almost quadrupled (19 systems in 18 hospitals, 15 of which were the Si model) and at least two other Dutch hospitals were contemplating purchasing the system (authors' calculation and contact with surgeons affiliated with those hospitals) (figure 2). Why are adopters so convinced? What are the affordances of the da Vinci robot?

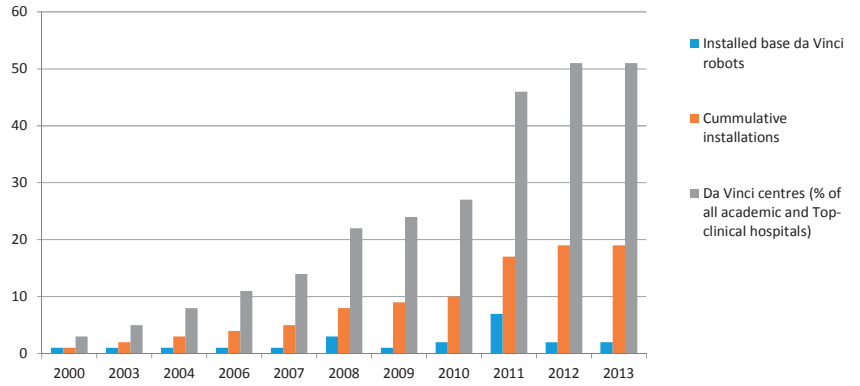


Figure 2. *Da Vinci system installations in the Netherlands.*

METHOD

Since affordances of the da Vinci robot are rooted in mutual interplay of technology, actors and the context of use, it is difficult to subject them to quantification and measurement. Exploring concepts such as this requires explicit *contextualisation* instead. This means a situated 'thick description' of the benefits of technology from the perspectives of diverse stakeholders and in relation to the various aspects of the setting of use. In fact, affordances themselves *denote* the methodology needed for studying them: an explorative qualitative method with a focus on perceptions, intentions, decisions, actions, interactions, and dynamics in a *real-life* context.

A fairly diverse range of data were searched for, gathered and studied between April 2009 and February 2014. HTA reports, manufacturer's website, medical congress websites, patients' forums and weblogs were reviewed. The empirical data is partly based on an elaborated policy research carried out in 2009 by the Health Care Insurance Board (CVZ), the Dutch government's advisory organisation on reimbursing forms of care. The lead author, an employee of CVZ, empirically explored the adoption of the da Vinci robot in the Netherlands (Abrishami, 2011). The policy report included 28 sessions of in-depth semi-structured (group) interviews performed in 2009 with diverse stakeholders throughout the Netherlands (table 1). The interviews made use of a 'purposive' sampling method by selecting information-rich respondents who could be expected to generate appropriate data (Green & Thorogood, 2004). Identify-

ing data had already been anonymised. The following section is based on a thematic analysis of the data from the perspective of affordances.

Table 1. *List of interviewees.*

Respondents	Interview sessions	Descriptions
Urologists	8	• Robot surgeon: 3 • Laparoscopic surgeon: 2 • (Only) ORP urologist: 3
Former patients with prostate cancer	4	• Operated with robot: 1 • Operated with usual laparoscopy: 2 • Board member of the Dutch Prostate Cancer Patients' Organisation: 1
Hospital managers	3	• Academic medical centre: 2 • Non-academic hospital: 1
Private health insurance companies	3	• Care purchaser and medical advisors of 2 major companies
Health care journalists	3	• Newspaper health care journalist: 2 • Freelance medical journalist: 1
National policy-makers	2	• Medical advisors of Dutch Health Care Authority (NZa) and the DBC (DRG-like) Maintenance Organisation
Hospitals' technical assistants	2	• Responsible for technical maintenance of the da Vinci robot
Organiser of international medical congresses	1	• At European level
Operation theatre nurse	1	• Assistant of a robotic urologist
Clinical epidemiologist	1	• Academic researcher
Total sessions of discussions	***28***	

THE AFFORDANCES OF DA VINCI SURGICAL ROBOT

In the analysis of our empirical data we were able to distinguish five categories of affordances of the da Vinci robot. These affordances are interrelated and they overlap, and it is in fact this interrelatedness that helps us understand why Dutch health care embraced the da Vinci robot and why it appeared almost impossible to escape this innovation.

I. Characteristics-related affordances

Characteristics-related affordances of the da Vinci robot are commonplace. They are proximal to its technical features and shared by nearly all stakeholders. First, there is the naming of the device: a robot. Smart nomenclature of the device played an important role in inducing an image of perfection among the stakeholders. While the da Vinci is a computer-assisted surgical device rather than a true robot and human surgeons still operate, the very words 'robot' and 'da Vinci' for a remotely-controlled laparoscopic device had considerable framing impact on stakeholders. As one patient put it, "the word 'robot', of course, sounds **magical** [strong verbal emphasis]. [It] suggests that things can't go wrong anymore".

Related to this was the novelty of the technology. The da Vinci robot was associated with what can be referred to as the newer-must-be-better mindset. Some respondents believed that the pursuit of the latest is a global trend nowadays, but that it is also a "typically Dutch" belief that distinctly applies to robotic surgery and many other emerging technologies. The very existence of state-of-the-art technology encourages the idea of the robot as being naturally superior to earlier technology. An urologist mentioned: "the patients [often] say, 'I do choose for the newest technology because I **deserve** it'".

The da Vinci robot has been enthusiastically received as a 'symbol' of providing advanced care (Paul et al., 2013). According to our empirical data, high-tech precision was central to this conception on the part of many potential adopters and patients. As such it was perceived as a surrogate for high quality care and articulated with a reaction of fascination. Technological precision formed the backbone of the manufacturer's promotion, reflected in its motto: "taking surgery beyond the limits of the human hand". This was also resonated in medical congresses and in patients' and surgeons' accounts. A patient put it as follows:

> … I believe that the machine [robotic device] can work accurately … It [a good cancer treatment result] is a matter of luck and everybody has to be lucky but the luck factor is reduced when a machine is used rather than the human hand.

The da Vinci robot is not only new, it is in keeping with the current 'spirit of time' in urology, namely, minimally-invasive surgery (MIS). The da Vinci robot emerged in a context where the popularity of MIS in urology continued to grow

tremendously among both patients and professionals. Urologists' prior experience with laparoscopy had made them rapid, albeit relatively late, adopters of the robot compared with the initial adopters such as neurosurgeons. The recent widespread shift toward MIS has been reported in the literature (Descazeaud, Peyromaure & Zerbib, 2007) and was known to many respondents, notably the urologists in this study. The da Vinci robot was conceived as "a perfect interface to transition" from ORP to MIS (Ghavamian, 2009, p. 864). The perception of MIS as 'the way to the future' created a strong incentive for a growing number of urologists (and hospitals) to consider switching to robotic surgery. An urologist, who himself operated on prostates using only the open method, described it decisively:

> Times have changed. Under the current *Zeitgeist* [the spirit of the time], the philosophy of urologic operation involves minimally-invasive laparoscopic techniques. The era of open surgery in urology is over. … The prostate **belongs** to the robot. It has already been decided worldwide.

The same process also applies to future generation of urologists, i.e., residents, for gaining experience in RARP (Robinson, Macneily, Goldenberg & Black, 2012). The shift towards MIS goes hand-in-hand with a shift in the learning environment of MIS training from learning by doing to learning by simulated reality (Hoogeveen & Burie, 2009). This provides an increasing number of potential surgeons with the possibility of learning MIS, including robotic surgery. Two academic MIS urologists stated that they no longer teach residents the conventional method of prostate operation. This has been signalled in medical literature as well: "[W]ill the new generation of urologists be able to perform radical prostatectomy without the robot?" (Descazeaud et al., 2007, p. 11).

Other device-specific affordances relate to the impact on the work place during operations. There was, for instance, the perceived ergonomic benefit. Da Vinci surgery provides a better ergonomic position and ease of operation for the surgeon than LRP or ORP (i.e., sitting more comfortably at a console while operating). Surgeons perceived this ergonomic advantage in reduced neck or back arthrosis, resulting in longer career prospects. The theatre nurse and the surgeon's assistant were enthusiastic about another technical feature: increased engagement with the operative field as the surgeon sits at a distance.

II. Research-related affordances

These affordances were brought forward mainly by surgeons, hospitals, technical universities and the manufacturer. They all have a stake in conducting and publishing research on the robot.

Surgeons in different fields have had a longstanding desire to report their experiences with new surgical devices and operative methods as randomised research is often not feasible. As of 2000, urologists' interest in publishing early experiences with the robot has caused an exponential increase in the number of scientific publications on this topic and several PhD dissertations. This was also associated with a proliferation of more specialised 'new' journals such as the Journal of Robotic Surgery sponsored by Intuitive Surgical (since 2007) and the International Journal of Medical Robotics and Computer-Assisted Surgery (since 2004) (Middelbeek, 2007). Urologists in this study expressed their desire to report their techno-surgical experiences in international journals in order to add a research profile to their clinical careers and also to maintain a forerunner role in evidence generation, for which there is an urgent need. According to one robotic urologist in an academic hospital, this was "a main goal" of purchasing the robot.

Medical and technical universities also displayed a shared institutional interest in robotic surgery research. They perceived robotic surgery as an interdisciplinary "knowledge exchange platform" for generating clinical-technical knowledge and expertise, a "marriage of the clinic and technique", in the words of one surgeon. In a joint initiative a Dutch academic hospital and a technical university invested heavily in fostering R&D, innovation, training and teaching evidence-based minimally-invasive (robotic) surgery. The initiative served as a large-scale research platform backed by national and European funds in order to achieve techno-surgical excellence. The intention of conducting research was by no means confined to academic hospitals. By virtue of conducting research with the da Vinci system, one district general hospital achieved entitlement as a tertiary teaching ('Top-clinical') hospital.

The manufacturer's interest in obtaining 'feedback' from academia contributes to the knowledge dynamics of the da Vinci robot further. Such knowledge can be used to develop the device incrementally as well as to promote it with the language of science. The manufacturer does so by facilitating, organising and sponsoring knowledge exchange forums. Da Vinci surgery has appeared a

recurring topic on the agenda of scientific and educational surgical congresses, and one that is quite often facilitated (partly) by manufacturer sponsorship. In the 2009 European Association of Urology (EAU) congress, Intuitive Surgical was present as a 'Gold Corporate Sponsor'. This sponsorship involved the provision of an unrestricted educational grant that required scientific sessions of the congress to focus on the topic of robot surgery (in particular, issues identified by the scientific board of EAU congress). These collaborative platforms offer room for producer-user interaction in the forms of a 'knowledge synergy' (Middelbeek, 2007). Besides the scientific meetings approved by the board of the congress, in the exhibition part of the congress there was also live surgery with the robot, organised by Intuitive Surgical. According to a member of the Sales & Marketing Department of EAU congresses, the urologists in attendance were "extremely excited".

The intense circulation of knowledge surrounding robotic surgery underpins coalitions of interest among surgeons, hospitals, and technical universities for knowledge production. Being recognised by potential adopters, the research-related affordances of da Vinci robot serves this mutual interest. It constructs a form of push-and-pull dynamics for evidence generation, academic reputation, incremental technical development of the device and/or operating methods, expansion of surgical indications, and research (career) advancement.

III. Entrepreneurship-related affordances

These affordances mostly related to surgeons, hospitals and insurers though it was also reported by other stakeholders. It corresponded to the device being adopted within a market-oriented care delivery system in the Netherlands.

Portrayed as a sign of clinical excellence and state-of-the-art surgery, the da Vinci robot provides a ground for and mediates competition between the stakeholders. It also stimulates differentiation and specialisation in this process. Adopting the da Vinci robot offers an opportunity to perform better than the competition by allowing a more specialised service delivery while enjoying a more privileged competitive position. A da Vinci operation assistant, also a member of the hospital's policy committee, described her hospital's policy to practice good entrepreneurship with the use of robot:

> We [the neighbouring hospitals and ours] have been fishing in the same pool, our city. But now the robot has emerged. We don't

> want to be just a general hospital, of which there are so many in this region … We are very active in promoting ourselves and attracting patients … We have already built a 'name' in robot surgery in this region … We want to be the **Ronaldo** in the world of hospitals.

The da Vinci robot can propagate competition among urologists, between hospitals, insurers or even between cities, regions, and countries. Once the competitive privileges of the robot are disseminated, an increasing number of surgeons and hospitals may feel under pressure to deliver da Vinci surgery. The promises of technology result in a socially-constructed shared obligation to adopt/use it. Many respondents recognised it and described it literally as a "pressure" (as opposed to a choice). A remarkable fear of missing out ('use it or lose it') among prospective users – particularly among the Dutch medical society (Heemskerk et al., 2014) – fuelled this process. There was also a feeling of retrospective regret for patients who had undergone ORP in the past. The felt pressure of provision had a border-crossing dimension as well. This was particularly pointed out by urologists who worked near the Dutch border. They were confronted with Belgian and German da Vinci centres attracting Dutch patients. One urologist stated:

> Since I work near the border, I have experienced the pressure that patients go to Germany or Belgium. I do not have the robot at the moment and I am **desperate**. I wish I had it. Although it is commercially driven, I am forced to operate with the robot.

It was a similar case with private insurers who saw themselves under pressure to contract RARP for the hospitals. This pressure they felt was despite the fact that they were allowed to make selective arrangements with regard to purchase, price and patient referrals. Insurers were asked why they were willing to contract RARP with so many hospitals and pay extra (30–40% in 2009) per operation. A medical advisor of an insurance company explained:

> Hospitals want to deliver the [new] care, and then they come to us for a contract. It also creates a good image for our company … that we are buying the best care delivered by the best doctors in an excellent urologic centre in the Netherlands. … We can say [this] to the media – and we have already said.

These pressures can impress upon an increasing number of stakeholders that, at least at a perceptive level, using the da Vinci robot is a 'must-do'. "Once this [competition] process has started in one insurance company or hospital, others soon start as well and it is difficult to stop this process", a care-purchaser of an insurance company confirmed.

IV. Policy-related affordances

These affordances came into the picture when the da Vinci robot was being explored within the sophisticated regulatory framework of health care innovations in the Netherlands. Examining national policies pertaining to the provision and financing of innovative care revealed the da Vinci robot's privileged position. We regard this regulatory situation as affordance of the device in so far as this stimulates its adoption and use.

In the Netherlands, the provision of RARP has been subject to market (supply and demand) regulation since 2009. A decision by the Dutch Health Care Authority (NZa) – the national regulator of all the healthcare markets in the Netherlands – switched RARP from the fixed-price (A-) segment to the freely negotiable (B-) segment of care. On the other hand, the therapy has not been subject to any national supply-side regulation such as the Exceptional Medical Procedures Act (WBMV). No public licence is required for the provision of RARP despite its high cost and sophistication. This means that all hospitals and insurers are free to adopt the robot and to arrange its implementation and finance.

At the same time RARP is collectively insured care based on the advice of CVZ (2007). Including this therapy in the national benefits package can mean a reduced financial risk of provision borne by the hospitals and/or the insurers.

But this is not all. The initial promises of RARP had already been set high in order to attract surgeons and patients in its country of origin (US) and in countries with no social health insurance system covering RARP. Studying patients' forums revealed some American patients' concerns about RARP not being (fully) covered by their insurance plans. "An uphill battle is in front of you … if you try to fight your insurer", described an ex-patient in a forum. For a Dutch patient, however, there is no such barrier because nearly all operation expenses are covered by insurance. Again this means a privileged position for da Vinci robot in the Dutch setting: users' relative insensitivity to the costs involved.

In this setting national policies on market regulation and reimbursement of RARP are translated down through the care delivery setting into a persuasive prospect for adopting and using the robot. To this should be added that no national training credentials are required prior to performing solo robotic surgery. Policy-related affordances are actually the result of a 'joint impact' of different national policies made disjointedly from one another. They cannot be traced without relating the technology to the context of use.

V. Communication-related affordances

The communication-related affordances of the robot relate mainly to patients and the public. These affordances involve the device's role in fostering promising discourses without juxtaposing them adequately against uncertainties. This process may significantly shape patient's choice of therapy and the public's impression and expectations.

While clinical studies have shown that da Vinci works best in case of a relatively young man with a truly localised tumour, for such patients one may also consider 'active surveillance', i.e., regular monitoring of the tumour with clinical and laboratory tests without doing surgery. However, urologists found it difficult to convince patients that active surveillance is a good option. A board member of prostate cancer patients' organisation also reported:

> I know from our association that if the doctor says: "Sir, you can wait … just come every three months for a check-up and monitoring", a lot of people think: "He just wants to get rid of me; he thinks I'm not important or I'm not rich enough, etc." This is how they see it, though in fact it's a very good option.

While minimal-invasiveness was highly valued over invasive (open) surgery, non-invasiveness was not, because it was very often readily regarded as 'doing nothing' and, according to a patient's weblog, interpreted as "a euphemism for denial or indecision".

On the other hand, the promotional motive of the manufacturer together with competitive motives of hospitals in offering robotic surgery backed the production and spread of massive direct-to-consumer information making promises about RARP. Citing its urologist, a hospital website informed patients using the title, "robotic surgery is a **blessing**". RARP alleviates the patient's urgent

concern following diagnosis that the cancer should be removed radically (i.e., entire removal) with a high-tech MIS technique. Both urologists and patients mentioned that the information depicting a promising image of the da Vinci system was pervasive and much easier to find than information about more conventional surgeries and about cancer recurrence or complications after RARP. Besides, there is no mandatory registry of patients' outcome to 'counterbalance' that promising image.

The da Vinci robot feeds the doctor-patient relationship in depicting itself as treatment of choice. Almost all urologists believed that most patients have already made their choice by the time they come to them. Patients have already been intrigued – in urologists' words "manipulated" or "framed" – by the robot. Patients, on the other hand, believed that the urologist's positive recommendation plays a central role in shaping their ultimate decision in favour of RARP. In the face of unproven (evidence-based) benefits, some patients regarded urologists' recommendations as being in their personal interest/preference projected through their professional authority. An insurance company advisor confirmed this: "Patients come to us to ask if we will pay for a new therapy, but it is the doctors who tell them to ask us". One patient described this as follows:

> It always starts like this: someone [the doctor] who adopts the new therapy wants to advertise it; otherwise they wouldn't have begun with it in the first place. So it's always coloured…I expected them to explain the advantages and disadvantages for any treatment option [in a balanced way] but there is always the question: "What would **you** do doctor?".

A robotic urologist emphasised that the long-term benefits of robotic surgery (specially cancer cure) are much less certain, yet often more relevant than its short-term benefits such as a reduced bleeding, a shorter stay at hospital, less pain, potency, cosmetics, etc. "Looking at the long-term outcomes," he concluded in a long interview, "open surgery is better than laparoscopic surgery [with or without a robot]". In the doctor-patient encounter, however, the discourse on RARP's short-term benefits was more pervasive. A board member of the patients' organisation described further:

> … you [the patient] want[s] to believe that the new therapy is effective; you are not interested in uncertainties … If the prostate has gone but the cancer has not, you had a bad diagnosis [treat-

> ment choice] before the operation. You have to choose a method that gives most guarantees over a longer period … If the tumour has to go away, so do the [penile] nerves too sometimes, then you can't get an erection; Period! The robot can't help you with that.

In addition to the professional arena and doctor-patient encounters, the da Vinci system has also been brought into the public sphere as a highly promising innovation. The features associated with the robot, 'state-of-the-art', 'high-tech', 'medical', 'innovation', 'minimally-invasive', 'surgery', and 'cancer', represent a high *news value* that enables journalists to write attractive stories about this 'topic of the day'. Reports on conventional therapies have made far fewer appearances in public spheres such as mass media. This was evident from many examples of TV programmes, news reports, Dutch newspapers and the journalists interviewed. The da Vinci robot offers health care journalists all the main features of so-called 'mainstream journalism' to write an attractive report for the general public: catchiness and seduction, exaggeration in presenting vague promises as facts, optimism, and responsiveness to the public's taste (Abrishami, 2011). This "high-tech 'tour de force'", the NBC News reported, is "the hottest trend in surgery. It's dazzling technology. It's promoted everywhere. There are television ads, glossy brochures and public demonstrations at science museums and shopping malls. Even president Obama was invited to test-drive the surgical robot" (NBC News, 14.06.2013).

Unless a serious complication or catastrophe is involved, according to our journalist respondents, there is often "no reason" or "no room" to be so critical and to write about the disadvantages and uncertainties of medical technologies for the public. The same applies to the regulation and finance of innovations. "It would be a somehow boring subject and no one would read it…Even an economic editor would not be interested in it.", said one respondent and continued a second one:

> Sometimes health care journalists write about new technologies too early … You get too many press releases about all sorts of new treatments and how promising they are. Some hospitals are very active in doing that. With the present [Dutch] market-like system, they have to sell themselves … There are a lot of questions about the use and effectiveness of these technologies. But, you know, the subject is very sexy: the robot, the laser, the genes.

Our journalists respondents believed that much of the public's interest and curiosity in a medical innovation is oriented towards its technical mechanism of action – or how the new thing works – rather than how *well* it works. Mainstream journalism responds to this taste and takes the same orientation. Similar to the doctor-patient setting, the articulation of uncertainties made less of an 'appearance' in public spheres as result of the communication-related affordances of the da Vinci robot.

DISCUSSION AND CONCLUSION

The concept affordances – namely, the perceived promises, meanings, and utility values of an innovative technology within the context of use – provides insight into how the da Vinci robot came to be adopted in the Netherlands so rapidly despite the many clinical and efficiency-related uncertainties. As the case study illustrates, the enthusiasm for demanding the da Vinci robot was driven by strong (i.e., interrelated and mutually reinforcing) affordances of the device signified on the part of the stakeholders. The affordances subsequently became performative. They shaped perceptions, built intentions, legitimised decisions, and guided actions in such a way that further legitimisation was no longer required. When widely shared, affordances may imply insisting that others *should* use or request the technology (van Lente, 2012). Affordances make the take-up and use of the robot sound perfectly rational and inevitable: a 'no-brainer' (Abrishami, 2011).

The case study shows that the constitutive force of affordances is not neutral, but has normative significance. The performativity of affordances directs actors towards realising the following interrelated promises: progress, precision, prestige, pioneering, performance, and profit. This path is created and sustained in the interaction between the artefact, the actors and the different institutional subsets of the context of use, namely, the treatment of patients, the market, and techno-surgical research. Widely-shared affordances can endorse and at the same time fulfil a stand-alone conception of excellence in health care in a *corporate-technical-productive* form. Other facets of excellence in service delivery may become submissive to this propagated, self-sustained conception at the level of both perception and action. Optimally allocating limited resources, considerations on equity in access, and the foregone opportunities of investing in other forms of care would then be of no immediate concern to those engaged

in adoption decisions/practices. The affordances approach helps explain this normative reconfiguration of excellence in service delivery.

The affordances approach is, we would argue, widely applicable. It can be used to investigate the (non-)adoption of various kinds of medical innovations (e.g., out-patient (wearable) medical devices, interventional imaging equipment, medical serious gaming, pharmacogenetic testing, etc.) or to explore a device's adoption processes across different health care systems. For instance with regard to the da Vinci robot, litigation-related affordances seem to exist in the US, where the device offers plaintiffs and law firms opportunities for initiating lawsuits on robotic-related injuries. Moreover, this approach may be used as part of a health technology assessment (HTA), inasmuch as it provides an *ex-ante* understanding of the innovation's potential *outcomes* based on recurrent patterns of adoption and early-stage utilisation. From a theoretical point of view, the affordances approach is more context-specific compared to expectations studies. It may be better suited to exploring local practices and human agencies. It could also contribute to 'cross-fertilisation' of three theoretical strands, namely Social Construction of Technology (SCOT), Actor-Network Theory and cultural theory (Bijker & Pinch, 2012).

Affordances may vary situationally, across innovations, and over time. Nevertheless, the *ecological* mode of investigation is central to applying this concept. This means exploring an innovation in the real world while considering the actors' interaction with the innovation and the interpretative spaces created in situations of use. An ecological investigation of the 'adoption space' (Ulucanlar et al., 2013) can, we believe, best elicit local utility values and 'identities' of medical innovations through the eyes of (potential) adopters. Strikingly, such an assessment of technology adoption brings along its own methodology for realising it: an in-depth qualitative ethnographic evaluation.

In sum, by using the affordances approach in studying the case of robotic surgery in the Netherlands, we feel we have contributed to an understanding of adoption dynamics by examining its socio-cognitive roots, the enacting (performative) forces, and the normative implications. We encourage further empirical studies involving this concept and its theoretical underpinnings to expand the knowledge of policy-makers, users, and innovators of the *real-life* value of medical innovations as seen through the eyes of (potential) users.

REFERENCES

Abrishami, P. (2011). *Da Vinci Surgery: Is it a No-brainer? Robot-assisted Prostate Surgery in the Mirror of Social Health Insurance*. Diemen: CVZ. www.zorginstituutnederland.nl (Accessed March 2014).

Ashcroft, R.E. (2012). Health Technology Assessment. In Chadwick, R. (Ed.), *Encyclopaedia of Applied Ethics* (second edition) (pp. 556-65). Oxford: Elsevier.

Bijker, W.E. & Pinch, T. (2012). Preface to the anniversary edition. In Bijker W. E., Hughes, T. P. & Pinch, T. (Eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (pp. x-xxiv). Cambridge: MIT Press.

Blume, S.S. (2009). Assessing health technologies in a changing world. *International Journal of Technology Assessment in Health Care,* 25(Supplement 1), 276–80.

Borup, M., Brown, N., Konrad, K. & van Lente, H. (2006). The sociology of expectations in science and technology. *Technology Analysis & Strategic Management,* 18 (3/4), 285-98.

Camberlin, C., Senn, A., Leys, M. & de Laet, C. (2009). *Robotgeassisteerde chirurgie [Robot-assisted surgery]: Health technology assessment*. Brussels: Belgian Health Care Knowledge Centre.

la Chapelle, C.F., Jansen, F.W., Pelger, R.C.M., & Mol, B.W. (2013). Robotchirurgie in Nederland: hoogwaardig bewijs voor effectiviteit ontbreekt. [Robotic surgery in the Netherlands: lack of high-quality proof of efficacy]. *Nederland Tijdschrift Geneeskunde,* 157, A5145.

Close, A., Robertson, C., Rushton, S., Shirley, M., et al. (2013). Comparative cost-effectiveness of robot-assisted and standard laparoscopic prostatectomy as alternatives to open radical prostatectomy for treatment of men with localised prostate cancer: a health technology assessment from the perspective of the UK National Health Service. *European Urology,* 64, 361-369.

CVZ (2007). *Adviesaanvraag: Laparoscopische prostatectomie met behulp van de da Vinci operatie-robot* [Request for advice: Laparoscopic prostatectomy with the help of da Vinci robot]. Diemen: CVZ. www.zorginstituutnederland.nl (Accessed March 2014).

Descazeaud, A., Peyromaure, M. & Zerbib, M. (2007). Will robotic surgery become the gold standard for radical prostatectomy? *European Urology,* 51(1), 9-11.

Elias, N. (1991). *The Society of Individuals*. Cambridge, MA: Blackwell publication.

Elias, N. (1978). *What Is Sociology?* New York: Columbia University Press.

ECRI Institute (2013). Da Vinci decisions. *Health Devices,* (1), 6-18.

Faulkner, A. (2009). *Medical Devices into Healthcare and Society: A Sociology of Devices,*

Innovation and Governance. Basingstoke: Palgrave Macmillan.

Gagliardi, A.R. & Dobrow, M.J. (2011). Paucity of qualitative research in general medical and health services and policy research journals: Analysis of publication rates. *BMC Health Services Research,* 11, 268-72.

Garud, A. & Rappa, M. (1994). A socio-cognitive model of technology evolution: The case of cochlear implants. *Organizational Science,* 5(3), 344-62.

Ghavamian, R. (2009). Robotic and open radical prostatectomy: Is there reason to be receptive to change now and in the future? *Expert Review of Anticancer Therapy,* 9 (7), 863-5.

Gleitsmann, K., Bunker, K., Kriz, H., Ryan, K., et al. (2012). *Robotic-assisted Surgery*. Portland: Center for Evidence-based Policy.

Green, J. & Thorogood, N. (2004). *Qualitative Methods for Health Research*. London: SAGE publication.

Greenhalgh, T., Russell, J., Ashcroft, R. E., & Parsons, W. (2011). Why national eHealth programs need dead philosophers: Wittgensteinian reflections on policymakers' reluctance to learn from history. *Milbank Quarterly, 89,* 533-563.

Greenhalgh, T., Robert, G., Bate, P., Macfarlane, F. & Kyriakidou, O. (2005). *Diffusion of Innovations in Health Service Organisations*. Massachusetts: Blackwell Publishing.

Heemskerk, J., Bouvy, N.D. & Baeten, C.G. (2014). The end of robot-assisted laparoscopy? A critical appraisal of scientific evidence on the use of robot-assisted laparoscopic surgery. *Surgical Endoscopy,* 28(4), 1388-98.

Hoogeveen, Y. & Burie, R. (2009). *MITeC Vision and Implementation*. Nijmegen: Radboud University Nijmegen.

Hutchby, I. (2001). Technologies, texts and affordances. *Sociology,* 35(2), 441-56.

IKNL (Comprehensive Cancer Centre the Netherlands) (2013). *Richtlijn prostaatcarcinoom*. [Guidelines on prostate carcinoma] (Draft version 2.0). http://www.radiologen.nl (Accessed March 2014).

Lahire, B. (2013). Elias, Fruid and human science. In: Dépelteau, F & Landini, T.S., (eds.), *Norbert Elias and Social Theory* (pp. 75-90). New York: Palgrave publication.

Lehoux, P. (2006). *The Problem of Health Technology: Policy Implications for Modern Health Care Systems*. New York: Routledge.

Lehoux, P. & Blume, S.S. (2000). Technology assessment and the sociopolitics of health technologies. *Journal of Health Politics, Policy and Law,* 25(6), 1083-1120.

Lepor, H. (2005). Open versus laparoscopic radical prostatectomy. *Reviews in Urology,* 7(3), 115–27.

Makarov, D.V., Yu, J.B., Desai, R.A., Penson, D.F., & Gross, C.P. (2011). The association between diffusion of the surgical robot and radical prostatectomy rates. *Medical Care,* 49(4), 333-9.

Martínez-Salamanca, J.I., & Romero Otero, J. (2007). Critical comparative analysis between open, laparoscopic and robotic radical prostatectomy: Perioperative morbidity and oncological results (Part I). *Archivos Espanoles de Urologia,* 60 (7), 755-65.

Middelbeek, R.J.W. (2007). *Robotchirurgie* [Robot surgery]. Unpublished Master's thesis, University of Amsterdam.

NBC News television broadcast (14.06.2013). *Robotic surgery is high-tech 'tour de force', but is it safe?* www.nbcnews.com (Accessed Augustus 2013).

Novara, G., Ficarra, V., Mocellin, S., Ahlering, T.E., et al. (2012). Systematic review and meta-analysis of studies reporting oncologic outcome after robot-assisted radical prostatectomy. *European Urology,* 62(3), 382-404.

Paul, S., McCulloch, P., & Sedrakyan, A. (2013). Robotic surgery: revisiting "no innovation without evaluation". *British Medical Journal, 346,* f1573.

Quintaneiro, T. & Mitre, M. (2006). The concept of figuration or configuration in Norbert Elias' sociological theory. *Teoria & Sociedade*, 12(1), 54-69.

Reuzel, R.P.B. & van der Wilt G.J. (2000). Health technology assessment and evaluation: Back to basics? *Evaluation,* 6(4), 383-98.

Rip, A. (2001). Technology assessment. In Smelser, N.J. & Baltes, P.B. (Eds.), *International Encyclopaedia of the Social & Behavioural Sciences* (pp. 15512-5). Oxford: Elsevier.

Robertson, C., Close, A., Fraser, C., Gurung, T., et al. (2013). Relative effectiveness of robot-assisted and standard laparoscopic prostatectomy as alternatives to open radical prostatectomy for treatment of localised prostate cancer: a systematic review and mixed treatment comparison meta-analysis. *BJU International,* 112, 798-812.

Robinson, M., Macneily, A., Goldenberg, L. & Black, P. (2012). Status of robotic-assisted surgery among Canadian urology residents. *Canadian Urological Association Journal*, 6(3), 160-7.

Scarantino, A. (2003). Affordance explained. *Philosophy of Science,* 70(5), 949-61.

Ulucanlar, S., Faulkner, A., Peirce, S., & Elwyn, G. (2013). Technology identity: The role of sociotechnical representations in the adoption of medical devices. *Social Science & Medicine,* 98, 95-105.

van Lente, H. (2012). Navigating foresight in a sea of expectations: Lessons from the sociology of expectations. *Technology Analysis & Strategic Management,* 24(8), 769-82.

Verbeek PP. (2011) *Moralizing Technology: Understanding and Designing the Morality of Things*. Chicago: University of Chicago Press.

Vingilis, E., Wade, T., & Seeley, J. (2007). Predictors of adolescent health care utilization. *Journal of Adolescence.* 30(5), 773-800.

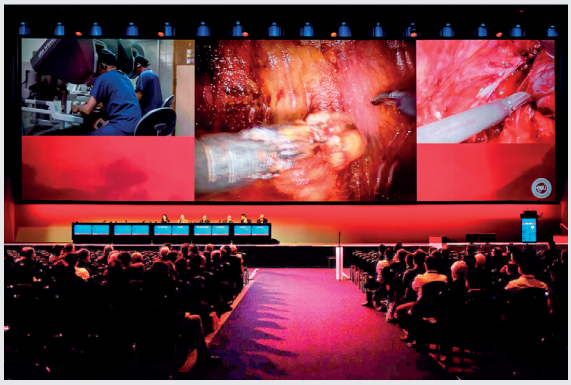
Webster, A. (2007). *Health Technology and Society: A Sociological Critique*. New York: Palgrave Macmillan publication.

Webster, A. (2004). Health technology assessment: A sociological commentary on reflexive innovation. *International Journal of Technology Assessment in Health Care,* 20(1), 61-6.

3 Understanding the value profile of the *da Vinci*® surgical robot beyond the early introduction phase

This chapter is based on the following article:
Abrishami, P., Boer, A., Horstman, K.

When the evidence basis breeds controversies: Exploring the value profile of robotic surgery beyond the early introduction phase.
Health Economics, Policy and Law (provisionally accepted).



Live Surgery session of the European Association of Urology Congress. 3D-4K (three-dimensional, ultra-high-definition) broadcast of live da Vinci® surgery (source: www.eau17.uroweb.org)

ABSTRACT

This article investigates qualitatively the value profile of the da Vinci® surgical robot after fifteen years of dissemination, practice, and research. We aimed to understand whether the swiftly-growing body of published studies on robotic surgery can now, i.e. beyond an early stage, guide decisions on the acquisition, procurement, and public provision of this innovation. We conducted a combined exploration of published studies (the formal arena) and stakeholders' perspectives (the discursive arena). Both arenas represent a crowded platform of diverse, often polarised arguments on the value of robotic surgery. What was unclear a decade ago due to lack of evidence is now unclear because of controversies about evidence. As a form of constructive technology assessment, this article outlines controversial value issues. Our analysis indicates the unlikelihood that the evidence basis – amid the mantra in the literature 'more research is needed' – will resolve the controversy, insofar as the value attributes that matter to stakeholders have not been well-targeted. The study underscores collective deliberation to resolve controversies in face of the continuing spread of complex medical innovation.

KEYWORDS

Computer-assisted surgery • Diffusion of innovation • Evidence-based medicine • Dissent • Health technology assessment • Value

INTRODUCTION

Computer-assisted, minimally-invasive surgery with the help of the *da Vinci*® robot is an expensive, though promising technological innovation. Since its inception in 2000, the da Vinci robot has spread widely throughout the world and its applications keep growing in volume, types of surgical procedures, organs of the human body, and surgical specialty fields. Over the last twelve years, worldwide system installations have increased more than twelve-fold, amounting to 4,150 units as of June 2017 (Intuitive Surgical Inc., 2017). And there is a high prospect of continuing growth in robotic surgery. A reported 16 per cent annual growth of robotic procedures is anticipated to double current levels within five years, portraying robotic surgery as a 'multibillion-dollar market opportunity' (Kelly, 2016).

Unlike pharmaceuticals, existing regulations of new medical device do not typically require substantial scientific evidence of effectiveness before market entry. Since a new therapy's value is largely uncertain at emergence, the demand for scientific insight to guide its dissemination remains high during the introduction phase. Fifteen years of dissemination and practice with da Vinci surgery have been accompanied with a swiftly-expanding body of peer-reviewed literature on this innovation. According to the manufacturer, who tracks publications, so far this amounts to more than 10,000 articles, with a current rate of over 150 publications per month (Intuitive Surgical Inc., 2017). One might expect, with the growing body of evidence, that justification for decisions on the acquisition, procurement, and (public) provision of robotic surgery improve. However as we will show, published studies have not provided uncontested guidance on whether the merits of robotic surgery – given the costs incurred – justify its spread/use in clinical care. Stakeholders in practice also present controversial views on the value of da Vinci surgery. In this article we explore the literature along with stakeholders' perspectives on this innovation to gain a better insight into unresolved value issues and their implications for further integration of robotic surgery into the health care system.

EXPLORING CONTROVERSIES AS A FORM OF CONSTRUCTIVE TECHNOLOGY ASSESSMENT

Controversy, i.e., the existence of diverse, sometimes contrary propositions that sustain a collective dispute (Venturini, 2010), is an integral, unavoidable

part of techno-scientific developments (Rip, 1987). Controversies on emerging technologies may benefit techno-scientific progress. Divergence of standpoints on a new medical technology's value profile may contribute to – or even serve as a driver of – its further developments (Lehoux et al., 2010; Maresca et al., 2014). However, controversies on emerging technologies render an important policy problem. They can readily translate into confusion, sophistication, and (opinion-based) arbitrariness of the action in question, i.e., introducing and using a new technology. Controversies also raise many ethical dilemmas about how to deploy the new technology responsibly (Geiger & Hirschl, 2015). According to Giere and McMullin, the problem of techno-scientific controversy is in fact the problem of justifying 'technological decisions' and different assessments of the reasons for action (Giere, 1987; McMullin, 1987). The unjustified introduction of new medical technology has repeatedly been demonstrated to be associated with poor outcomes (Geiger & Hirschl, 2015). Closure on controversies about medical innovations has, thus, priority from a public policy perspective. In the case of da Vinci surgery, Sundi and Han emphasise that the question 'is robotic surgery worth it, when it has already become widespread?' involves an 'important clinical and health policy dilemma in the contemporary era' (Sundi & Han, 2014).

To deal with such a dilemma, many health care systems have formally placed scientific knowledge of effectiveness and cost-effectiveness at the centre of governance of medical innovations. This science-based justification of the value of medical innovations has been a core attribute of health technology assessment (HTA) (Garrido et al., 2010; Goodman, 2013), whereby the state/health care system, health care professions, insurers, and medical technology industries seek the 'social legitimation' of new technology (Faulkner, 2009). The aim is to foster 'innovation of value', thereby optimising the population's health with the (limited) resources spent (Goodman, 2013; Henshall & Schuller, 2013). The quest for truth is, thus, germane when confronting/dealing with controversies about innovations (Lehoux et al., 2010). From this standpoint, controversies on the value of emerging medical technologies can be settled by means of formal scientific evidence, and often 'await' the establishment of such knowledge (Lehoux et al., 2010; McMullin, 1987).

This wait-and-see approach for justifying value has been challenged by studies from the perspective of science, technology and society (STS) (Martin & Richards, 1995; Martin, 2014; Pinch & Bijker, 2012; Rip, 1987; Sarewitz, 2004; Sismondo, 2008). Examining the mutual shaping of science, technology and

society, this scholarship has analysed, both theoretically and empirically, the dynamics of controversies about technologies, ranging from bicycles (Pinch & Bijker, 2012), vaccines, intravascular diagnostics (Maresca et al., 2014), to screening technologies (Lehoux et al., 2010), to name but a few. They highlight that techno-scientific controversies are never purely scientific nor purely technical, but often show a complex intertwinement of facts and values (Latour, 2004; Marres, 2015; Martin, 2014; McMullin, 1987; Moes et al., 2016; Pinch & Bijker, 2012; Venturini, 2010). Controversies about new technologies display 'interpretative flexibility' of an innovation's value (Pinch & Bijker, 2012; Sismondo, 2008). They display diverse knowledge claims, reasonings, problem framings, arguments, social alignments, vested interests, and symbolic (or cultural) values (Rip, 1987). STS scholarship reveals that the rise *and* fall of a techno-scientific controversy is related to these broader social dynamics rather than specific (formalised) scientific evidence (Rip, 1987).

STS studies on robotic surgery and other emerging medical technologies describe the social dynamics of their introduction. At an early introduction phase, when by definition few studies are available, scientific evidence has no pivotal role in guiding *actual* choices in technology introduction. Fed by the manufacturer's promotion, it is 'technology affordances' and 'technology identities' within the wider social context of its provision and use that constructs a powerful persuasive discourse to adopt and use robotic surgery, e.g., potentials to achieve high-tech clinical excellence, research and entrepreneurial advantages (Abrishami et al., 2014; Compagni et al., 2015; Ulucanlar et al., 2013). An 'isomorphic (peer) response' to the success stories of initial adopters of the da Vinci robot propagates its dissemination further despite persisting uncertainty about its science-based value profile (Compagni et al., 2015). When the evidence basis develops, so do these shared narratives, encompassing the innovation's as yet fledgling knowledge-base. Narratives remain performative by constructing a specific vision of an innovation's desirability, thereby paving a discernible path for further spread of the innovation (Abrishami et al., 2014; Lehoux et al., 2010). Moreover, the state of evidence is neither complete nor unambiguous, and what is considered certain and what is considered uncertain is, in itself, part of what is at stake (Rip, 1987). Scientific evidence is now available, yet it is unable to offer clear guidance on robotic surgery. As Frydenberg et al. argue, robotic surgery is already widely disseminated and this trend is irreversible "regardless" of the outcomes of future studies (Frydenberg et al., 2015).

Techno-scientific controversies are therefore an important locus for conducting health policy exploration, where scientific knowledge, socio-cultural meaning, and symbolic utilities integrate and are in the making (Martin & Richards, 1995). Since controversies carry conflicting 'valuations' of technology, exploring them can be considered a form of technology assessment that is 'utterly constructivist'; one that is reflective of the dynamics of introducing medical technology into the health care system and, as such, can serve the purpose of stimulating (public) debate about the innovation's social desirability (Abrishami et al., 2015; Venturini, 2010).

In this article we explore controversies on the value profile of da Vinci surgery after fifteen years of adoption, practice, and research. After explaining the study method, we analyse the current state of the debate on da Vinci surgery in the literature and then examine the perspectives of stakeholders involved in the introduction of this innovation in the Dutch health care system.

METHOD

This study is a multi-source qualitative exploration. We adopted the approach of 'mapping controversy from literature to actors' described by Venturini (Venturini, 2010). This approach involves observing and describing a range of oppositions around an innovation's value in two arenas: published studies (formal arena) and the perspective of stakeholders involved in deployment of the innovation (discursive arena). Little research has been conducted with such a combined analysis of the literature and stakeholders' perspectives, in particular, in studying the value of in-hospital medical innovations. This approach enables us to explore controversies about advanced technologies in their full complexity. Published studies provide first-level articulation, which a cartographer of controversy must 'dive into'. Stakeholders' perspectives on value then complement the mesh of statements circulating in a dispute (Venturini, 2010). As Rip argues, an integrated critical analysis of both the disputed techno-scientific knowledge and the social discourses on value will provides us with a means of technology value assessment that is more comprehensive than those formal methods of assessing the risk and benefits of new technologies that assume a separation of the scientific from the socio-cognitive aspects of value (Rip, 1987).

Empirical data were collected from literature, online documents, and interviews. We studied diverse resources in Dutch and English, including medical litera-

ture, HTA reports, medical magazines, live-surgery broadcasts, the press, and resources from the manufacturer, scientific associations, medical congresses, and the patients' association. The searching scheme was flexible, comprising a database search and snowball bibliography scanning. The databases Medline, Embase, JSTOR, PsychINFO, and Web of Science were searched, using broad search terms such as 'da Vinci', 'robot-assisted', 'benefit', 'prostate', 'cost', 'controversy', or their equivalents. Follow-up snowball citation searches were performed via Pubmed and Google Scholar. Relevant studies on da Vinci prostate surgery were identified based on a thematic analysis of the abstracts, categorised in two themes: 'in favour' or 'critical'. The aim of relying on studies was not to provide a systematic review of treatment effects, but to explore ongoing debates. We set the time span for our search pragmatically at three years before the date of writing this article (2013–2016). The first author also attended some prostate cancer patients' gatherings and Continuous Medical Education programs related to the topic. We then examined stakeholders' perspectives within the Dutch health care system, a publicly-funded, privately-operated health care system that has hosted the robotic surgery platform since its inception and has made this therapy (financially) accessible to citizens.

Semi-structured, in-depth (group) interviews were conducted with a wide range of stakeholders (table 1). The interviews made use of a 'purposive' sampling method by selecting information-rich respondents who could be expected to generate appropriate data (Green & Thorogood, 2005) and who would agree to being interviewed. Interviews were conducted between December 2015 and July 2016. An interview topic list was used to cover the same set of broad topics across different stakeholders. The questions remain, however, emphatically open-ended. Discussions were recorded, then transcribed verbatim. Transcripts were then checked for clarity and coherence and, in two cases, a respondent was contacted for clarification. The names of individuals and institutions have been anonymised. Interview transcripts were then systematically analysed, using a thematic content analysis approach (Green & Thorogood, 2005), and coded and categorised based on emerging themes and concepts. Given the large amount of data collected, we performed thematic analysis in three iterative rounds. We first identified an excerpt from the transcripts by compiling rich accounts capable of generating major themes. We subsequently used this interim excerpt to further categorise emerging themes and identify the reporting structure accordingly. We then returned to the main transcripts for a more detailed coding in accordance with the key themes and the reporting scheme already identified in

the interim round. Quotations in bold font indicate respondents' strong verbal/body-language emphasis.

Table 1. *List of interviewees.*

Respondents	Interview sessions	Descriptions
Surgeons	9	• Robotic surgeon: 4 • Non-robotic surgeon: 5 • Urologist:3, gastrointestinal surgeon: 4, vascular surgeon: 1, gynaecologist: 1 • Department head: 2
National policy-makers	5	• Senior advisors from the Dutch Ministry of Health, National Health Care Institute (ZIN), Dutch Health Care Authority (NZa), Health Care Inspectorate (IGZ), and Netherlands Organisation for Health Research and Development (ZonMw)
Private health insurance companies	3	• Medical advisors of 2 high market-share companies • Medical advisor of the umbrella association of health insurers
Hospital deans	2	• UMC: 1 • Non-academic tertiary hospital: 1
Urological cancer nurse specialists	2	• Works with robotic urologist:2 • Works in a non-robotic hospital: 1
Representative of Patients' Association	1	• A member of Dutch Prostate Cancer Patients' Association and former patient
Hospital business developers	1	• Health economists of 2 surgical departments of a UMC
Operating theatre nurse	1	• Experienced assistant of a robotic surgeon
Researchers/methodologists	1	• 2 HTA researchers of a UMC
Total sessions of interviews	***25***	

RESULTS

I. MAPPING CONTROVERSIES ABOUT ROBOTIC SURGERY IN THE LITERATURE

In this section, we analyse studies on the value of da Vinci surgery for the removal of prostate cancer (robot-assisted radical prostatectomy, RARP) published between 2013–2016. Prostatectomy is one of the pioneered fields of application of da Vinci surgery and, as such, the subject of a substantial body of studies. An analysis of the literature shows no closure of controversial issues on the value of robotic surgery compared with the alternatives, laparoscopic or open prostatectomy (LRP, ORP). What was unclear a decade ago due to lack of evidence is now unclear because of controversies about evidence. Below we describe two interrelated levels of controversies in the literature.

I.a. Contested study results on value

Across different study types, diverse conclusions have been made on the value of RARP. The bulk of research on robotic surgery is mainly comprised of retrospective or prospective case series, in which surgeons report a specific outcome of a selected group of their patients (Agha et al., 2015; Moran et al., 2013). Some studies are regarded as having higher strength: randomised clinical trials (RCT), systematic reviews & meta-analyses of case series, comparative effectiveness research (CER), HTA reports, and clinical practice guidelines (CPG). An RCT comparing RARP with LRP reports 'better functional results' (Porpiglia et al., 2013). However, a claimed first-ever RCT comparing RARP and ORP, conducted by Yaxley et al., published in a high-rank journal (Yaxley et al., 2016) and which received media attention e.g. (Bakalar, 2016), concludes 'similar functional short-term outcomes'. The authors recommend that patients choose an experienced surgeon rather than a surgical technique. Soon afterwards, the Robotic Urology Section of the European Association of Urology criticises this study as being "in contrast to the direction of surgical travel" and "different from the view of many of us" (Fossati et al., 2017).

Two systematic reviews of RCTs show that RARP is 'significantly better than LRP' at preserving potency and continence, while both conclude that there is 'insufficient evidence to support full implementation' (Allan & Ilic, 2016; Broholm et al., 2016). Two meta-analyses of case series conclude in favour of

RARP: 'reduced surgical morbidity', 'lower risk of positive surgical margin', and 'favourable peri-operative and functional outcomes' (Robertson et al., 2013; Seo et al., 2016). On the other hand, another systematic review concludes that 'available data were not sufficient to prove the superiority of any surgical approach in terms of functional and oncological outcomes' (De Carlo et al., 2014).

As for CER, a population-based study comparing RARP and ORP concludes that these are 'comparable' and claims that results of their study provide 'reassurance regarding the adoption of more expensive technology' (Hu et al., 2016). Another similar CER concludes 'comparable', but reports a statistically significant 'higher probability of complications' (Gandaglia et al., 2014). Likewise, two CERs with cost analysis conclude respectively: 'significant clinical benefits may justify higher total costs' (Turchetti et al., 2016); and 'higher costs do not seem to support the decision to introduce a robotic system' (Tedesco et al., 2016). Economic analyses conclude 'no' or 'extremely small' added value (QALY gains) of RARP, while also reporting uncertainty in cost-effectiveness 'mainly due to contradictory results on effectiveness' (Becerra et al., 2016). An Austrian HTA report concludes 'whether the benefits legitimises the high costs is highly questionable' and recommends 'hold off on the purchase of a surgical robot until other manufacturers will enter the playing field and the price will decrease' (Fischer & Kisser, 2015). The European CPGs on prostate cancer, and that of the Netherlands state that surgical approaches are 'equal' and do not recommend one over another (IKNL, 2016; Mottet et al., 2015). As for review articles and current-status viewpoints, controversy is sometimes readily apparent from the title. For instance: 'Robotic surgery in urological oncology: patient care or market share?' (Kaye et al., 2015). Also, consider 'The end of robotic-assisted surgery?' (Heemskerk et al., 2014) versus 'RARP: inching toward gold standard' (Sood et al., 2014). Some recent patient safety concerns have even been raised (Alemzadeh et al., 2016; Parsons et al., 2014), while many publications report that robotic surgery is clearly safe, and even has 'a better safety profile' (Sood et al., 2014). The inconclusiveness of the literature is subsequently reflected by other mediums of communication such as grey literature, online forums of professionals, discussion sessions of scientific congresses, weblogs, social media, and the press. An example is provided by three articles in the journal of the Royal Dutch Medical Association (*Medisch Contact*). The titles read: robotic surgery 'is not cost-effective' (Alderlieste, 2014), 'is just better' (van der Velde et al., 2014), and 'just as good as' (Broersen, 2016). A Dutch tabloid article, entitled 'Operation robot: beneficial help or expensive toys for surgeons?',

states that the rise in surgical robots has led to a "schism" among surgeons on the value of robotic surgery (Heijne & Witteman, 2014).

Findings from clinical practice registries also contribute to the inconclusiveness of study results. An example is the frequently-mentioned reduced blood loss and shorter hospital stay after robotic procedures compared with alternative resection methods. Real-world data from a non-mandatory quality registry of 4300 Dutch prostatectomy patients comparing RARP and ORP (between 2006–2013) show approximately 150 cc median reduction in blood loss with RARP, and a 2-day shorter hospital stay compared with ORP (van der Poel & Wijsman, 2013). The clinical significance of these findings is questioned by some studies. Likewise, ambiguity remains about the economic relevance of such a difference in hospital stay after RARP, or the achieved 0.8-day difference reported by Parsons et al. An Italian study, nonetheless, shows a reduction in hospital stay is economically relevant only when the difference exceeds 5 days (Franchini et al., 2015; Parsons et al., 2014).

I.b. Contested methods and protocols for studying value

Not only are the results of different studies on da Vinci surgery controversial, how studies are conducted is also contested. First, there are immense variations in the 'input' of studies, including patients' baseline profiles, tumour scores, tissue resection methods (e.g., pelvic lymph nodes resection), histopathological examinations of tumour specimens, data collection protocols, surgeons' experience, hospitals' volume profile, studies' time frames, system versions of the device used. In addition, there is a lack of agreed-upon/uniform ways of measuring and reporting results. The choice of comparator and the extent to which the chosen endpoints represent outcomes (e.g., oncological, functional, or quality of life outcomes) are also contested (Frydenberg et al., 2015). These disputes refer, at root, to the extent to which reported *differences* when using da Vinci robot can be regarded as clinically and/or economically relevant *advantages* attributable to the device. They sophisticate the interpretation of studies, thereby fuelling disputes on robotic surgery. See, e.g., (Fossati et al., 2017; Frydenberg et al., 2015).

Researchers also fiercely disagree upon methods/designs for assessing the value of da Vinci surgery. Randomised designs, to compare different treatment alternatives, are considered 'tremendously demanding' (Jones et al., 2015), while they are also regarded as unhelpful/irrelevant to clinical practice and

individual patient decisions (Allan & Ilic, 2016). Under the title 'the first RCT fuels debate rather than closing the question', Fossati et al. criticise RCT as not really testing the advantages of a surgical robot (Fossati et al., 2017). Likewise, while much evidence-synthesising takes place retrospectively, many consider the prospective CER as an appropriate method for assessing the value of robotic surgery (Gandaglia & Trinh, 2014; Jones et al., 2015). Observational studies, while criticised by some as being incapable of identifying comparative benefit (Booth & Tannock, 2014), are simultaneously embraced by others as 'the preferred method' to comparatively assess RARP (Greenfield & Sohn, 2013). One example is an observational study about returning to work faster after being operated on by robotic surgery – on the ground of minimal-invasiveness and faster recovery – compared with an open method. An earlier return to work is reported by a real-world nationwide Swedish cohort study (Plym et al., 2016), while a prospective – though single surgeon – study concludes the contrary: 'no significant difference' (Bier et al., 2016). Disagreement even exists on whether work disability (measured by sick-leave days) can be considered as an outcome representing a frequently promoted advantage of RARP, i.e. faster recovery (Gettman, 2016).

The above overview of the literature shows that published studies on RARP, including RCT's that are considered to meet the golden standard of research, do not provide uncontested guidance on the merits of da Vinci surgery, but serve rather as a breeding ground for disputes. This is manifest in recurrent concluding remarks such as 'rigorous evidence supporting robotic surgery is still lacking' and notably, 'more research is needed'. The literature demonstrates a fairly crowded platform of arguments and counterarguments with respect to the added value of da Vinci prostatectomy and the very methods for demonstrating value. A similar controversy can also be observed in other surgical fields. We briefly exemplify gastrointestinal surgery in Box 1 as a complement to our exploration.

Box 1. ***Debate on published studies on the use of surgical robots in gastrointestinal surgery***

Literature on the use of da Vinci robot in gastrointestinal surgery is, similarly to prostatectomy, disputed. Apart from the many debates, for instance in the forum of the American Society of Clinical Oncology (Glodé, 2014; Klapper, 2014), a recent case is noteworthy. In 2015, in its journal Surgical Endoscopy, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) publishes its position on the use of da Vinci system in gastrointestinal surgery. This assessment concludes that robotic surgery is 'safe, as effective, more costly, but not superior' to standard laparoscopic approaches (Tsuda et al., 2015). An accompanied editorial, then, states that "given the significance of the issue and the spectrum of strong opinions held regarding robotic surgery", the Journal decides to offer the manufacturer's medical director an opportunity to react. In her response, the manufacturer's medical director raises three main issues: that conventional laparoscopy is not an appropriate comparator; that "250 additional, relevant" publications are not included; and that the scope of cost calculation is narrow and "strongly misleading" (Curet, 2016). The editorial, nonetheless, reads: "these assessments are done in a very careful manner, with extensive literature review, debate, and discussion among the experts, at the committee level, and finally at the Society's Board of Governors' level. These documents are not produced lightly or capriciously. They are carefully considered and put forth as the Society's official opinion" (Talamini, 2016).

Considering the continuing controversies in the literature, we further explored the informal arena: the perspectives of stakeholders engaged in the introduction of da Vinci surgery in practice, including surgeons, hospital managers (provision), insurers (procurement), patients, policy-makers (regulation) and researchers (evidence generation) (see also table 1, list of interviewees). Open-ended interviews with the respondents, primarily focused on the prostate operation, revealed however a broader view on the da Vinci robot. How do stakeholders assess the (added) value of this innovation when scientific literature presents so many controversies? And how do they, eventually, relate to such literature?

II. MAPPING CONTROVERSIES ABOUT ROBOTIC SURGERY IN STAKEHOLDERS' PERSPECTIVES

In general, our respondents are very articulate about the topic. Many debates mentioned above resonate. Disputes involve respondents' disagreement with one another and/or their dissent from the current mainstream state of research and surgical practice. Stakeholders' narratives about da Vinci surgery reveal four interrelated dimensions to the controversies about this technology that continue to challenge justification of its introduction.

II.a. How to define and appreciate 'added' value?

A contested issue our respondents frequently mention is whether introducing da Vinci surgery needs to have demonstrated 'superiority' to alternatives or whether 'non-inferiority' suffices. Some respondents state that even if da Vinci surgery is not better than open methods, it is not worse either. "Unless it is proven that it is worse, we should move forward", says the dean of a University Medical Centre (UMC). "Not knowing the added value does not mean the device is not worthwhile", a surgeon says and his words are paraphrased by an insurance advisor and a representative of the Patients' Association. However, others argue that non-inferiority of robotic surgery is, irrespective of 'added' benefits and costs, insufficient for its spread. As one surgeon puts it: "We must first discern if it's proven technology … I can quickly train you and send you to the moon in a capsule. It is possible, feasible, but do we all do it? This [da Vinci] technique makes many things possible, but should we all use it? I don't think so … You should bring all considerations of added value into the equation and [this is something] we doctors seldom do". Similarly, dissent exists about the design of available comparative studies. Many respondents indicate that superiority research is scarce and available literature prominently involves "feasibility studies", often used to examine whether a new therapy can join the existing treatment arsenal. This design, two researchers and national policy-makers argue, is insufficient because costs are higher, advantages are insubstantial, and incremental improvements of alternative therapies are not taken into account. One robotic surgeon illustrates this by referring to the RAZOR study, an ongoing trial comparing open and robotic cystectomy. "It is powered as non-inferiority. I think we already know what they will conclude: 'not worse'", he says.

Diverse opinions exist as to whether da Vinci surgery involves just another variant of minimally-invasive operation or a distinctive/disruptive therapy. Issues

raised in this respect are ergonomic features, team communication, and tactile feedback. The ergonomic advantages gained from sitting at a console while operating is questioned by some respondents as 'replacing neck complaints with an imminent mouse arm' (i.e., repetitive strain injuries of the wrist and hand). A recent adopter says: "at the end of the day, you [as a surgeon] are tired, but it is a very different kind of tiredness". Team communication and situational awareness is another feature of the da Vinci surgery that, according to a robotic theatre nurse, differ from conventional surgery. "This is in contrast to those who think, 'it is just laparoscopy' … It is a **totally** different way of operating", she says. Tactile feedback is lacking during operating with the da Vinci robot. Many robotic surgeons do not regard tactile feedback as an important attribute of clinical added value. "Haptic feedback is just replaced with vision … It's like blind people having more sense of touch" says a da Vinci surgery proctor at the second Worldwide 24-hour Robotic Surgery Event (WRSE24, 2015). He describes that, similarly to those of the aviation industry and the sport sector, the robotic surgery's training programmes involve visual skills, increasingly relying on computer simulations and virtual reality techniques. Many non-robotic surgeons, however, regard the lack of tactile feedback as a 'major drawback' of the current da Vinci system. This has even been a basis for developing a whole new computer-assisted, minimally-invasive platform called Telelap Alf-X®, announced in 2016 as a potential rival of the da Vinci system.

Costs form, not surprisingly, another returning topic in the dispute about value. Dutch hospitals are free to purchase a surgical robot insofar as they can afford one (with or without financial supports from an insurer/investor). Many respondents regard the high investment and maintenance costs of robotic surgery as 'in the face of comparable benefits', the *only* value issue. Dissatisfaction with, in a surgeon's words, "an idiotically high price for such a humble benefit" is expressed and frequently attributed to the manufacturer's monopolistic position. The da Vinci robot is currently the only commercially-available console-based device approved for soft tissue surgery. Two da Vinci surgeons assertively refer to previous transitions from open to minimally-invasive surgery, notably gall bladder removal, which took place "without much fuss", as being a major transition but less costly. "I sincerely hope the costs [of a da Vinci robot] will eventually come down. If the costs come down, we will no longer have to convince anybody [that da Vinci surgery is better]. I **really** mean it", says a surgeon. A national policy-maker agrees that the discussion on robotic surgery is "purely about money". Another surgeon exemplifies the role of costs.

> For 40 years we used the supersonic Concord airplanes, but then we took a step back and reverted to using slower planes … Concorde may have been feasible and relatively safe, but it was not cost-effective. Operating with a robot is pleasant and feasible, but it is not that much better and it is more expensive. At a certain point, we need to take a step back, given the enormous pressure on our health care resources.

A robotic surgeon, on the contrary, claims in a public event about digital innovations that "we passed the point of no return as early as in 2014".

According to national policy-makers, insurers, and open-method surgeons, costs, despite being a core value issue, are often not taken into account in the actual valuation of new technology. A surgeon reflects on his profession:

> Surgeons are by their very nature gadget-aholics. They are at the forefront and always embrace the latest technology. I'm no different … [But] we medical specialists are (*a*) absolutely unaware of the costs we incur and (*b*) we always go for the best for our patients and therefore we believe that costs should not play a role, which is bullshit … we do too little cost-benefit analysis.

Another contested economic aspect is safeguarding a patient stream sufficient to achieve the break-even point on investment. We inquire about the patient streams of the head of a hospital's surgery department that recently started da Vinci surgery and the dean of a non-academic tertiary hospital who was considering purchasing. We made these inquiries against the background debate that there are already too many da Vinci robots operational in the Netherlands and some existing systems are said to be 'collecting dust'. Both respondents state that their business models have been carefully thought through and that adequate case load is guaranteed. The hospital dean explains:

> Surgical-oncology patients in the region all 'drain' here. We employ a variety of measures such as cross-hospital portfolio-exchange with a neighbouring hospital and reinforce a regional referral network … We want to serve what I call our biotope with respect to oncological surgery … By offering a top technique, by top surgeons from more than one specialty, with referral agree-

ments with doctors in the region, we will attract enough patients to cover the investment based on four days/week occupancy.

The business developer of another robotic surgery centre, however, casts doubt: "this equipment is far too expensive to be used on an eight-hour/day basis, if you [could] calculate it at 24/7. This utilisation rate for equipment costing more than two million Euros is, in my opinion, unjustified, yet we all do it".

II.b. Value for whom?

Value interpretations vary depending to who is considered as the device's actual beneficiary. Some respondents, referring to the ergonomic advantages of da Vinci surgery and disputed superiority of clinical outcomes, say it is surgeons who benefit from the device and not patients. "It is the doctor who is better off [ergonomically]. But we don't research this … We focus too much on clinical results and [in this respect] a robot is **fortunately** not better", says a laparoscopy surgeon. "What do you mean 'fortunately' not better?", we ask. "Well", he replies, "suppose doctors did worse without this instrument. Then you would truly be wondering what we [surgeons] are doing".

Related to the beneficiary is the question of the right indication. This is an important area of uncertainty and controversy. Some respondents express the idea that for many new techniques in surgery, the right indications are experimented on and established in a 'funnel' fashion. A new technique is first used broadly until it finally gets a "niche", where it has added value par excellence. A surgeon illustrates: "the microwave oven was introduced as a whole cook model … to cook **everything**. Nowadays I only use it to warm up a meal". Another surgeon explains: "when plates and screws were introduced for bone fractures in the 1950s, they were widely used. For everything! … Later, in the 1990s, we realised it was better not to fix certain bone fractures [surgically], but to use plaster cast or even just physiotherapy instead". Other respondents, however, argue that new techniques must follow a reverse-funnel entry; a new therapy must be used just for those who are the most likely to benefit.

A number of surgeons emphasise that da Vinci surgery is beneficial for 'only fairly complex cases', encompassing complex procedures (e.g., cystectomy) and complex patients (e.g., those with obesity or prior tissue adhesions). This is an instance of respondents' disagreement with the existing surgical practice. A patient representative, a urological oncology nurse specialist, and some

surgeons report a tendency in practice to select "easy patients" especially during learning phase. "Depending on how far the surgeon is on the learning curve", said a urologist during a session on training at the second WRSE24, "the patients selected for robotic procedures differ … Types of mistakes differ too" (WRSE24, 2015). One oncology nurse states: "If you only operate T1/T2a [early stage] tumours, then you will have better [oncologic] results. This says nothing about the outcome". Two surgeons argue that some new procedures are being performed by surgical robot because it is "just available" at their hospital. They also describe "pressure" from higher management to "offer" robotic surgery for surgical specialties/procedures that "had not been thought about before". At WRSE24, a urologist nevertheless states: "at our department, we use robot for all urological procedures except circumcision". Related to the right indication, yet another issue is raised: "who should be operated on with robot differs per geographical region", says a surgeon. "It is easier for a Dutch patient to attend consecutive sessions of radiotherapy than a patient in a vast country such as Australia".

Little disagreement is expressed by our respondents on the surgeon's experience being constitutive of value. However, diverse views do exist as to whether a good outcome should be attributed to the device or to the operator. This is how an experienced non-robotic laparoscopist puts it:

> The robot is just a device for an average surgeon to reach good results, as good as the results a top surgeon can reach without the device… The surgical margin of my prostatectomy series without a robot is lower than the average with the robot … So if you ask me, 'do you need a robot to carry out a good operation?', I say, 'no'. I don't need one. Does it mean that the robot is a useless device? No! … Perhaps the robotic surgeon's results would have been worse without the robot. You don't know … You'd better invest in very good operators.

According to an oncology nurse, when the results of patients undergoing da Vinci procedures are good, they often attribute the results to the method of surgery. However, if the results turn out less satisfactory, e.g. a disappointing level of continence, these results are often attributed to the experience of the surgeon who has not mastered the robot well. In addition to diverse value perspectives, a surgeon's baseline skills, a steep learning curve to build up robotic surgery

experience (often takes several years), and training methods also contribute to disputes on the locus of value of da Vinci surgery.

II.c. Is value evident?

Our respondents repeatedly point out two core characteristics of robotic surgery: minimal invasiveness and high-tech innovativeness. As characteristics of the device, these are commonplace and undisputed. However, they are controversial in the sense that they are perceived by some respondents, including some robotic surgeons and policy-makers, as stand-alone value attributes, in themselves, sufficient to drive the device's entry, while being contested by others as insufficient for its widespread introduction into the health care system. That da Vinci surgery involves a minimally-invasive operation is considered by one surgeon as being rooted in the non-maleficence principle: "everything that can be done minimally-invasively should be done so … this is fulfilling our professional duty of 'first do not harm'". Similarly, the fact that robotic surgery is a promising technological innovation is said to be, in itself, a sufficient argument in favour of its spread. "It's progress", says a robotic surgeon. "You have to recognise that this platform is highly potential … that can push your limits … I think it is unstoppable … Progress has a price, [but inevitably] you have to progress … It is difficult for me to explain a €2M investment and how to manage the health care budget … [but] when Google, J&J, Medtronics, etc. are all investing in using a computer between your hands and patient – because this is the concept – it will result in new things we currently don't even see". Another surgeon agrees: "I understand the question, 'what are the results and what are the costs', but you have to invest in innovation … It's of course a very vague question, 'how much should innovations cost', and surgeons won't be happy facing such a question [but] we have to go with the flow of this evolution in our profession …. You should not leave this area unexplored". A laparoscopist surgeon describes it with an analogy:

> Long ago, people travelled [from Netherlands] to Indonesia by boat. No one even thinks about it nowadays, except for fun/adventure. Everybody travels by airplane now. Well, suppose we had said, when airplanes were being developed: 'Stop!'; 'Too expensive!' … It was indeed expensive, as only the happy few could afford to fly by airplane, whereas everybody travels by plane these days and it is indeed an awful lot cheaper now.

We shall now describe another recurring topic: the influence of marketing on controversies. We observe no disagreement among our respondents that this innovation has been subject to intensive promotion from both the manufacture and adopting hospitals. This has been documented by research too (Abrishami et al., 2014; Gandaglia & Trinh, 2014; Kaye et al., 2015). Policy-makers, insurers, hospital managers, patient representative, and even some robotic surgeons frequently refer to the device as a "marketing tool", "glamour", "hospital's business card" that is "indeed used as such". A urologist recalls a colleague saying: "we purchased a system from part of our [hospital] budget earmarked as 'promotion budget'". "The da Vinci robot continues to spread", says a policy-maker, "and ultimately to become established not because it is better, but because it is in much closer alignment with marketing". A surgeon continues, "this da Vinci has employed fantastic sales techniques that have created almost a **clan**, I'd say … [that] those who join, feel they belong to an exceptional club". Intensive advertising on the device sophisticates the quest for value and fuels controversies in that it blurs the boundary between objective information and seductive promotion. An HTA researcher and a surgeon explain respectively:

> … It's just marketing push, technology push … they receive CE marking, [then] good marketing, and they sell. [It] doesn't have to be effective; it doesn't have to be sustainable … It's really a weaving error in the [innovation entry] system.

> There's damn little good evidence. It is usually just the sales pitch they [da Vinci surgeons] make: 'I [my patients] have less incontinence, less impotence', etc. I think survival is by far the most important [purpose] in cancer surgery … Well, selection bias exists. The easiest tumours are done with the robot, yet it is shocking that I found higher positive surgical margins.

He is referring to an interim report of the Dutch prostatectomy registry which revealed a statistically significant 'higher' percentage of positive surgical margins after RARP compared with ORP, while the median tumour size was comparable (van der Poel & Wijsman, 2013). A higher margin rate is associated with a higher chance of tumour recurrence and an increased need for secondary radiation therapy (Yossepowitch et al., 2014).

Another striking view on value, a constituent of controversies, is intuitive perception on the part of users. Many da Vinci surgeons share the idea that the device's

value is evident from their own experience (practice). Users are convinced of value, even if it remains evident only to them and they cannot justify the claimed value to others. "You are convinced because you can see the benefits with your own eyes … I have no doubt about added value, even though I cannot readily translate it into outcomes and published studies", says one robotic surgeon and another one continues with marked emphasis on his last three words:

> [Opponents say] 'there is no good evidence', but there is plenty of good evidence that we see in practice and I think we are not going to get much further in finding evidence … We do see [the device's value] in daily practice, **I**[do], **here**, **locally**.

Not surprisingly, this view is frankly open to interpretation and disagreement as expressed by a non-adopter recalling a debate with a da Vinci-using colleague. "… he said [to me], 'it is better in 'my' hands, so don't nag!'. Well, I don't regard this as an argument. It might mean you're really bad at open surgery … You can argue either way".

The words 'believer' and 'non-believer' in robotic surgery are literally spoken by many respondents. Two surgeons and a national policy-maker respectively describe the situation.

> … It starts with a vision you believe in, that computer assistance makes surgery better. I believe it so much that I'm quite totalitarian in my mind about it.

> In the beginning, data are sparse or fairly diverse. In surgery we have been through this with all [new] techniques. … It's [like] **religion** … You're going to do something that is expensive. You don't **know** whether it is better; you **believe** it is better … Do you believe in acupuncture? My partner, who is an anaesthetist and has travelled the world, says 'acupuncture works; I cannot explain it but it works'. Anaesthesiologist, mmm, scientifically trained, very critical, and yet he believes … You [first] start to believe and then you try to prove it, and it turns out that some issues are very hard to prove.

> "Surgical robot exudes enormous faith in technology, so it gives an aura of adding – even without proof – a 'placebo' if you like … [or] the homeopathy of the technique".

A policy-maker describes that the inconclusiveness of the literature contributes to the conception of value remaining belief-driven. He describes the controversies in published studies as "scientific deadlock". In search of value in the literature, he continues, "you are not going to find very good answers. You are torn between contested conclusions. It is actually believer versus non-believer [situation]". A representative of the Patients' Association explains that this believer/non-believer situation actually corresponds to being an owner or not an owner of the da Vinci robot:

> I speak to enough urologists every week … It is simply whether they have one or not that makes the difference … They contradict one another until the moment the urologist without a robot gets one. I have experienced it quite often … Before they start: "no added value"; after they get one: "it's much better"… I haven't heard the opposite.

Once value is conceptualised as belief-driven, the debate stretches to encompass the role of personal interests in shaping such beliefs. Again many respondents express the view that personal interests contribute to polarising views and fuelling controversies. An experienced non-robotic surgeon describes how personal interests divide adopters and non-adopters of robotic surgery into two "extremes", since both groups have personal interests.

> A lot of confirmation bias exists. It is in users' interest to advocate [that] robotic surgery is an awesome technique. These are people who have loud mouths, who are convinced of their own abilities … who say nothing if they have regrets later, and who say to you as a critic, 'you are just a whiner'. It is also in the interest of those who cannot use it, for whatsoever reason, to overthrow it.

II.d. Which patterns of provisions achieve value?

A prominent feature of the controversies is whether the provision of robotic surgery must be concentrated or expanded. Strikingly, almost all respondents strongly state that too many da Vinci surgery centres currently exist in the Netherlands (22 units or 1.3 per million of the population as of June 2016). Many respondents hold the view that providing this therapy "should have been" conditional on tracking and generating robust evidence of actual outcome, and until then, there should be a capacity cap on the number of hospitals

offering it. We also heard this from those who have recently joined the club, often without us mentioning this topic in interviews. It is "the responsibility of academic hospitals" to generate evidence of effect and cost-effectiveness *prior to* a widespread roll-out, many emphasise, notably national policy-makers and insurers. Our respondents refer to the widely held idea that concentrating non-emergency, highly-specialised care in a few high-volume units, known as 'centres of excellence', could drive outcome, reduce costs, and facilitate profession-led credentialing/training. Again, a great majority of respondents contrast this with current practices grounded on a market-oriented, competition-driven care provision system.

The dean of a UMC raises a distinction underlying the controversies: "There's a difference between a business model based on high volume and one based on research and future developments". Many other stakeholders, similarly, refer to the dispute on whether introducing new complex technique/procedure is an "academic task" or "entrepreneurship". Referring to current state of practice, one surgeon mentions: "The [health] Minister wants hospitals to compete with one another. Yes please! A robot is an ideal means for competing". An insurance advisor adds: "Our care system has left it to market mechanisms, not realising that we are creating overcapacity [while attempting to create a level playing field]". By means of a selective contracting/procurement, health insurers are able to stimulate concentration of complex specialised care, thereby driving value. Such value-based procurements entail contracting high-volume centres and eventually phasing out low-volume, low-quality ones. According to two insurance advisors, this heavily interferes with competition, which demands equalising volume across numerous suppliers.

> As insurers, we should stimulate the concentration of high-complex care … We should prevent a regressing-to-the-medium situation … [but] too many doctors want to provide these forms of care at a minimum volume … [Moreover] if we incite centralisation, after a certain point, the ACM [The Netherlands Authority for Consumers & Markets] would say, 'Stop! You are making new cartels'.
>
> We witnessed a lot of opposition from doctors when trying to set a minimum norm for bariatric surgery [thus not contracting hospitals below the norm]. Robotic surgery is even more complex.

A business developer of a UMC further explains: "Within the vicinity of our hospital [closer than seventy kilometres] there are two [other] robotic surgery centres. They are not friends with each other that can agree on a single centre [they are rivals] … They cannot **both** concentrate RARP based on a business case of [say] >400 RARP per year each, because they do not have that many patients. Yet they are doing it". One policy-maker, nevertheless, emphasises the political infeasibility of a national certificate-of-need policy for concentrating RARP: "A capacity cap would act as a **toxin** to the [market-oriented] health care system … this has to be a last resort, like chemotherapy in cancer". He also mentions the suggestion of nine Dutch hospitals to limit RARP to two nationwide centres. Though it receives publicity, it also triggers disputes from other centres that this should be collectively agreed upon by the profession, not imposed by the 'fewer-robots camp' (van Balken, 2016).

Controversies about the value of da Vinci surgery are also partly related to the ambiguity of the cumulative volume norms used to define an appropriate large-scale provision. No agreement exists on how many da Vinci surgery centres – be it per population, indication, or otherwise – are deemed appropriate. As mentioned earlier, some respondents, in particular insurers, find that 22 hospitals would be 'too many', while others feel differently, like one national policy-maker who says: "Not all surgeries are done robotically … Not all 100 [Dutch] hospitals have a robot. We are just approaching a quarter. Is this a problem? Who feels this is a problem?".

This section ends with presenting a related issue subject to dispute, namely, the threshold number of RARP per surgeon/hospital per year. It varies enormously, i.e., from 20 for basic proficiency, to 100–250 for maintaining competency, up to 700 for plateauing outcomes (Frydenberg et al., 2015; Geiger & Hirschl, 2015). A representative of the Patients' Association shares this experience:

> As the Patients' Association, we wanted to state our position on minimum norms. I asked many urologists, 'What would be a reasonable number?'. Well, this didn't help, because every doctor mentioned his/her own figure. Dr. [X] said, 'You have to perform RARP at least 70 times' and he does 75. Dr. [Y] said 130 and he performs around 130 … In our publications we mentioned the norm of the NVU [Dutch Association of Urology], commenting that we think it is too low.

The NVU has issued a minimum quality norm of "20 radical prostatectomy surgeries per location, per year" (NVvU, 2015). The vision document of the Patients' Association advocates "at least 35 radical prostatectomies, using the same technique, per urologist, with a fixed operation team" (Prostate Cancer Foundation, 2013).

CONCLUSION

Fifteen years of rapid dissemination, practice, and research with da Vinci surgery have resulted in a growing body of studies, which is inconclusive for guiding decisions on the acquisition, procurement, and large-scale provision of robotic surgery. Similarly, the perspectives of stakeholders involved in introducing robotic surgery in the Dutch health care system present a crowded platform of diverse, often polarised narratives on the value of da Vinci surgery. As a form of constructive HTA, the article outlined value issues that are at stake (table 2 on the next page). In both arenas, namely published studies and stakeholders' perspectives, disagreements involve everything from leaf to root: from study results, to designs, methods, and purposes of studies, right down to what the very concept of 'value' constitutes. Mapping controversies on robotic surgery reveals, in reconstruction, the foundational roots of the dispute. Controversies rest on a multitude of visions that are – in varying degrees – affiliated with the *innovation-based*, *market-based*, *fact-based*, or *outcome-based* ideals of technology introduction. Different 'genres' of dissent are messily intertwined; controversy is all-pervading; value varies widely and the jury is still out. We sum it up.

Table 2. *Mapping controversies about the value of da Vinci surgery after the early introduction phase.*

	Dimensions of controversy	Main points of dispute
Observed in the literature	Clinical and economic effect	• Incongruent study results • Research designs, methods, and protocols to assess value
Conveyed by respondents	How to define and appreciate 'added' value?	• Surgical robot better or not-worse? • Surgical robot me-too or disruptive? • Cost-efficient or expense-neutral?
	Value for who(m)?	• The recipient of value: surgeon or patient? • The generator of value: surgeon or gadget?
	Is value evident?	• Innovativeness as *raison d'être*? • Information-driven or promotion-driven? • Evidence-driven or belief-driven?
	Which patterns of provisions achieve value?	• Concentrated or expanded provision? • Research-based or entrepreneurship-based? • How much volume to achieve value?

A combined exploration of the literature and stakeholders' perspectives reveals discrepancies between the attributes of value targeted in these two arenas. Some issues that matter to stakeholders and are repeatedly subject to contestation among them (summarised in table 2) remain largely under-examined by the evidence basis. Issues regarding professionals' learning skills & comfort, personal interests, patients' expectations, 'local' outcomes data, institutional entrepreneurship, cumulative volume, foregone opportunities in care provision, business models, implementation know-how, knowledge-production & knowledge-transfer gains, litigation-avoidance, and publicity are all *real* constituents of the value profile of robotic surgery and many other advanced medical technologies like interventional targeted-therapy techniques, diagnostics, imaging equipment, etc. (Abrishami et al., 2015; Compagni et al., 2015; Faulkner, 2009). These are, however, insufficiently addressed by existing assessments. Our analysis indicates the unlikelihood that the evidence-based will resolve the controversy, insofar as the actual value attributes that matter to stakeholders have not been well-targeted. This has a significant research-policy implication. It is unlikely that the path recommended by many articles, 'more research is needed' – at least more research of the same type, can answer the question, 'is robotic surgery worth it?'. The results of this study are congruent with a vast array of STS studies, on, e.g., artificial hips (Faulkner, 2009), prostate-specific or prenatal screening (Lehoux et al., 2010), and silicone breast implants (Jacobson,

2000), which show that scientific evidence cannot, in itself, bring closure in controversies about the value profile of emerging innovations (Kyratsis et al., 2014; Martin, 2014).

If the hope of more scientific evidence to settle disputes is – for the time being – rendered unlikely, how does one deal with policy problems arising from controversies, i.e., to justify decisions on technology introduction? These problems may well be tackled if diverse stakeholders involved in technology introduction manage to work out a shared understanding of the 'social desirability' of the innovation (Lehoux et al., 2010; Venturini, 2010). This is in congruence with the current shift from an output-based to a value-based health care. It demands engaging in deliberation to collectively identify (added) value by appraising an innovation's benefits and risks to all stakeholders. Elsewhere we provided guidance for engaging in such a multi-stakeholder appraisal of in-hospital technologies (Abrishami et al., 2017). Stakeholders can learn from one another and compromise on the most prudent solution to balance diverse value perspectives (without necessarily ending the controversy). It can also help generate more relevant evidence for guiding patients decisions, technology spread, and procurement arrangements. Integrating such collaborative endeavours into formal HTA frameworks is a parallel priority.

Striving to settle controversies remains, nevertheless, a collective responsibility. If this is inadequately acknowledged and not acted upon in due time, the underlying value issues will probably remain unresolved, irrespective of future publications. Controversies on da Vinci surgery may evolve and persist, as in the case of electronic foetal monitoring, a high-tech, high-cost alternative to obstetric auscultation, which is still subject to controversy – and the call for more research – after decades of routine use (Nelson et al., 2016; Sartwelle et al., 2015). Alternatively, controversies may fade away over time, *not* because value issues have been *resolved* but because contestations may be *silenced* as the da Vinci robot continues to spread and more critical voices join the 'users club'. When a growing number of hospitals adopt the device, having found a way to break-even on expenses, and when it is used more frequently and for more indications, it gradually becomes routinised in surgical practice and embedded into the health care system. Robotic surgery could then become standard treatment without stakeholders *really* knowing, 'is robotic surgery worth it?'.

REFERENCES

Abrishami, P., Boer, A., Horstman, K. (2017). Value in co-creation: Subjecting innovative in-hospital technologies to multi-stakeholder appraisal. *International Journal of Hospital-Based Health Technology Assessment*, 2017(1), 12-30.

Abrishami, P., Boer, A., Horstman, K. (2014). Understanding the adoption dynamics of medical innovations: affordances of the da Vinci robot in the Netherlands. *Social Science & Medicine*, 117 125-133.

Abrishami, P., Boer, A., Horstman, K. (2015). How can we assess the value of complex medical Innovations in practice? *Expert Review of Pharmacoeconomics & Outcomes Research*, 15(3), 369-371.

Agha, R., Fowler, A.J., Lee, S.Y., Gundogan, B., Whitehurst, K., Sagoo, H. et al. (2015). A systematic review protocol for reporting deficiencies within surgical case series. *BMJ Open*, 5(10), e008007.

Alderlieste, L., (2014). Robotchirurgie niet kosteneffectief (Robotic surgery not cost-effective). https://www.medischcontact.nl/ Accessed 1 January 2017.

Alemzadeh, H., Raman, J., Leveson, N., Kalbarczyk, Z., Iyer, R.K. (2016). Adverse events in robotic surgery: a retrospective study of 14 years of FDA data. *PloS One*, 11(4), e0151470.

Allan, C., Ilic, D. (2016). Laparoscopic versus robotic-assisted radical prostatectomy for the treatment of localised prostate cancer: a systematic review. *Urologia Internationalis*, 96(4), 373-378.

Bakalar, N., (2016). Robotic surgery for prostate cancer may offer no benefits over regular surgery. http://well.blogs.nytimes.com/2016/07/28/robotic-surgery-for-prostate-cancer-may-offer-no-benefits-over-regular-surgery/ Accessed 1 January 2017.

Becerra, V., Avila, M., Jimenez, J., Cortes-Sanabria, L., Pardo, Y., Garin, O. et al. (2016). Economic evaluation of treatments for patients with localized prostate cancer in Europe: a systematic review. *BMC Health Services Research*, 16(1), 541.

Bier, S., Hennenlotter, J., Rausch, S., Aufderklamm, S., Martzog, J.C., Stenzl, A. et al. (2016). Return to work and normal daily life activity after open and robot-assisted radical prostatectomy: a single surgeon analysis. *Urologia Internationalis*, 96(3), 280-286.

Booth, C.M., Tannock, I.F. (2014). Randomised controlled trials and population-based observational research: partners in the evolution of medical evidence. *British Journal of Cancer*, 110(3), 551.

Broersen, S., (2016). Robot opereert prostaat net zo goed (Robot operates prostate just as good). https://www.medischcontact.nl/ Accessed 1 January 2017.

Broholm, M., Hansen, I.O., Rosenberg, J. (2016). Limited evidence for robot-assisted surgery: a systematic review and meta-analysis of randomized controlled trials. *Surgical Laparoscopy Endoscopy & Percutaneous Techniques*, 26(2), 117-123.

Compagni, A., Mele, V., Ravasi, D. (2015). How early implementations influence later adoptions of innovation: social positioning and skill reproduction in the diffusion of robotic surgery. *Academy of Management Journal*, 58(1), 242-278.

Curet, M.J. (2016). A response to the SAGES TAVAC assessment of the da Vinci surgical system. *Surgical Endoscopy*, 30(3), 805-806.

De Carlo, F., Celestino, F., Verri, C., Masedu, F., Liberati, E., Di Stasi, S.M. (2014). Retropubic, laparoscopic, and robot-assisted radical prostatectomy: surgical, oncological, and functional outcomes: a systematic review. *Urologia Internationalis*, 93(4), 373-383.

Faulkner, A. (2009). *Medical Technology into Healthcare and Society: A Sociology of Devices, Innovation and Governance*. Basingstoke: Palgrave Macmillan.

Fischer, S., Kisser, A. (2015). *Roboterassistierte Chirurgie (Robot-assisted surgery). Report Nr. 84*. Vienna: Ludwig Boltzmann Institute for Health Technology Assessment.

Fossati, N., Wiklund, P., Rochat, C.H., Montorsi, F., Dasgupta, P., Sanchez-Salas, R. et al. (2017). Robotic and open radical prostatectomy: the first prospective randomised controlled trial fuels debate rather than closing the question. *European urology*, 71(3), 307-308.

Franchini, F., Borsari, M., Frigieri, F., Castano, C., Voci, C. (2015). Prostatectomy: a comparison of cost-benefit analysis between open surgery and robotic techniques. *Value in Health*, 7(18), A452.

Frydenberg, M., Murphy, D.G., Moon, D.A., Lawrentschuk, N. (2015). Robotic assisted radical prostatectomy versus open retropubic radical prostatectomy: where do we stand in 2015? *Cancer Forum*, 39(3), 173-179.

Gandaglia, G., Sammon, J.D., Chang, S.L., Choueiri, T.K., Hu, J.C., Karakiewicz, P.I. et al. (2014). Comparative effectiveness of robot-assisted and open radical prostatectomy in the postdissemination era. *Journal of Clinical Oncology*, 32(14), 1419-1426.

Gandaglia, G., Trinh, Q.D. (2014). Models of assessment of comparative outcomes of robot-assisted surgery: best evidence regarding the superiority or inferiority of robot-assisted radical prostatectomy. *The Urologic clinics of North America*, 41(4), 597-606.

Garrido, M.V., Gerhardus, A., Rottingen, J.A., Busse, R. (2010). Developing health technology assessment to address health care system needs. *Health Policy*, 94(3), 196-202.

Geiger, J.D., Hirschl, R.B. (2015). Innovation in surgical technology and techniques: challenges and ethical issues. *Seminars in Pediatric Surgery*, 24(3), 115-121.

Gettman, M.T. (2016). Assessing work disability after radical prostatectomy. *European urology*, 70(1), 72-73.

Giere,R.N. (1987). Controversies involving science and technology. In: H.T. Engelhardt, & A.L. Caplan (Eds.), *Scientific Controversies: Case Studies in the Resolution and Closure of Disputes in Science and Technology*. Cambridge University Press, Cambridge, pp. 125-150.

Glodé, M., (2014). Robot-assisted versus open radical prostatectomy: costs and benefits. https://connection.asco.org/ Accessed 1 January 2017.

Goodman, C. (2013). HTA and innovation of value: getting to know you. *International Journal of Technology Assessment in Health Care*, 29(04), 351-352.

Green, J., Thorogood, N. (2005). *Qualitative Methods for Health Research*. London: Sage publication.

Greenfield, S., Sohn, W. (2013). The complexities of comparative effectiveness research on devices: the case of robotic-assisted surgery for prostate cancer. *Journal of Comparative Effectiveness Research*, 2(4), 367-370.

Heemskerk, J., Bouvy, N.D., Baeten, C.G. (2014). The end of robot-assisted laparoscopy? A critical appraisal of scientific evidence on the use of robot-assisted laparoscopic surgery. *Surgical Endoscopy*, 28(4), 1388-1398.

Heijne, S., Witteman, J., (2014). Operatierobot: nuttige hulp of duur speeltje voor chirurgen? (Surgical robot: beneficial help or expensive toy for surgeons?). http://www.volkskrant.nl/ Accessed 1 January 2017.

Henshall, C., Schuller, T. (2013). Health technology assessment, value-based decision making, and innovation. *International Journal of Technology Assessment in Health Care*, 29(4), 353-359.

Hu, J.C., O'Malley, P., Chughtai, B., Isaacs, A., Mao, J., Wright, J.D. et al. (2017). Comparative effectiveness of cancer control and survival after robot-assisted versus open radical prostatectomy. *The Journal of Urology,* 197(1), 115-121.

IKNL, (2016). Richtlijn Prostaatcarcinoom (Guidelines on prostate carcinoma) (2.1). http://www.oncoline.nl/prostaatcarcinoom Accessed 1 January 2017.

Intuitive Surgical Inc., (2017). http://www.intuitivesurgical.com Accessed 1 January 2017.

Jacobson, N. (2000). *Cleavage: Technology, Controversy, and the Ironies of the Man-Made Breast.* New Brunswick: Rutgers University Press.

Jones,R.T., Mishra,M.V., & Showalter,T.N. (2015). Role for comparative effectiveness research in treatment decision making. In: A.P. Dicker, W.K. Kelly, N.G. Zaorsky, & E.J. Trabulsi (Eds.), *Prostate Cancer: A Multidisciplinary Approach to Diagnosis and Management*. Demos Medical Publishing, New York, pp. 247-258.

Kaye, D.R., Mullins, J.K., Carter, H.B., Bivalacqua, T.J. (2015). Robotic surgery in urological oncology: patient care or market share? *Nature Reviews Urology*, 12(1), 55-60.

Kelly, S., (2016). New crop of robots to vie for space in the operating room. http://www.reuters.com/article/health-robots-idUSL1N1AD24X?type=companyNews Accessed 1 January 2017.

Klapper, S., (2014). Robot-assisted radical prostatectomy: new findings fuel the ongoing debate. https://connection.asco.org/ Accessed 1 January 2017.

Kyratsis, Y., Ahmad, R., Hatzaras, K., Iwami, M., Holmes, A. (2014). Making sense of evidence in management decisions: the role of research-based knowledge on innovation adoption and implementation in health care. *Health Services and Delivery Research*, 2(6).

Latour, B. (2004). Why has critique run out of steam? From matters of fact to matters of concern. *Critical Inquiry*, 30(2), 225-248.

Lehoux, P., Denis, J., Rock, M., Hivon, M., Tailliez, S. (2010). How medical specialists appraise three controversial health innovations: scientific, clinical and social arguments. *Sociology of Health & Illness*, 32(1), 123-139.

Maresca, D., Adams, S., Maresca, B., van der Steen, A.F. (2014). Mapping intravascular ultrasound controversies in interventional cardiology practice. *PloS One*, 9(5), e97215.

Marres, N. (2015). Why map issues? On controversy analysis as a digital method. *Science, Technology & Human Values*, 40(5), 655-686.

Martin,B., & Richards,E. (1995). Scientific knowledge, controversy, and public decision-making. In: S. Jasanoff, G.E. Markle, J.C. Petersen, & T. Pinch (Eds.), *Handbook of Science and Technology Studies*. Sage, Newbury Park, pp. 506-526.

Martin, B. (2014). *The Controversy Manual*. Sparsnas: Irene Publishing.

McMullin,E. (1987). Scientific controversy and its termination. In: H.T. Engelhardt, & A.L. Caplan (Eds.), *Scientific Controversies: Case Studies in the Resolution and Closure of Disputes in Science and Technology*. Cambridge University Press, Cambridge, pp. 49-92.

Moes, F., Houwaart, E., Delnoij, D., Horstman, K. (2017). Contested evidence: a Dutch reimbursement decision taken to court. *Health Economics, Policy and Law,* 12(3), 325-344.

Moran, P.S., O'Neill, M., Teljeur, C., Flattery, M., Murphy, L.A., Smyth, G. et al. (2013). Robot-assisted radical prostatectomy compared with open and laparoscopic approaches: a systematic review and meta-analysis. *International Journal of Urology*, 20(3), 312-321.

Mottet, N., Bellmunt, J., Briers, J. B. et al. (2015). *Guidelines on Prostate Cancer*. European Association of Urology.

Nelson, K.B., Sartwelle, T.P., Rouse, D.J. (2016). Electronic fetal monitoring, cerebral palsy, and caesarean section: assumptions versus evidence. *BMJ*, 355, i6405.

NVvU, (2015). Kwaliteitsnormen prostaatcarcinoom (Quality norms for prostate carcinoma). https://www.nvu.nl/en-us/kwaliteit/kwaliteitsnormen.aspx Accessed 1 January 2017.

Parsons, J.K., Messer, K., Palazzi, K., Stroup, S.P., Chang, D. (2014). Diffusion of surgical innovations, patient safety, and minimally invasive radical prostatectomy. *JAMA Surgery*, 149(8), 845-851.

Pinch,T., & Bijker,W.E. (2012). The social construction of facts and artifacts. In: W.E. Bijker, T.P. Hughes, T. Pinch, & D.G. Douglas (Eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*. MIT press, Boston, pp. 11-44.

Plym, A., Chiesa, F., Voss, M., Holmberg, L., Johansson, E., Stattin, P. et al. (2016). Work disability after robot-assisted or open radical prostatectomy: a nationwide, population-based study. *European Urology*, 70(1), 64-71.

Porpiglia, F., Morra, I., Chiarissi, M.L., Manfredi, M., Mele, F., Grande, S. et al. (2013). Randomised controlled trial comparing laparoscopic and robot-assisted radical prostatectomy. *European Urology*, 63(4), 606-614.

Prostate Cancer Foundation, (2013). Visie: kernpunten en kwaliteitscriteria (Vision: key issues and quality criteria for good prostate cancer care in the Netherlands). https://www.kanker.nl/uploads/file_element/content/5847/Kwaliteitscriteria_prostaatkanker.pdf Accessed 1 January 2017.

Rip, A. (1987). Controversies as informal technology assessment. *Knowledge*, 8 349-371.

Robertson, C., Close, A., Fraser, C., Gurung, T., Jia, X., Sharma, P. et al. (2013). Relative effectiveness of robot-assisted and standard laparoscopic prostatectomy as alternatives to open radical prostatectomy for treatment of localised prostate cancer: a systematic review and mixed treatment comparison meta-analysis. *BJU international*, 112(6), 798-812.

Sarewitz, D. (2004). How science makes environmental controversies worse. *Environmental Science & Policy*, 7(5), 385-403.

Sartwelle, T.P., Johnston, J.C., Arda, B. (2015). Perpetuating myths, fables, and fairy tales: a half century of electronic fetal monitoring. *The Surgery Journal*, 01(01), e28-e34.

Seo, H.J., Lee, N.R., Son, S.K., Kim, D.K., Rha, K.H., Lee, S.H. (2016). Comparison of robot-assisted radical prostatectomy and open radical prostatectomy outcomes: a systematic review and meta-analysis. *Yonsei Medical Journal*, 57(5), 1165-1177.

Sismondo,S. (2008). Science and technology studies and an engaged program. In: O. Hackett, M. Amsterdamska, M.E. Lynch, & J. Wajcman (Eds.), *Handbook of Science and Technology Studies*. MIT Press, Boston, pp. 13-32.

Sood, A., Jeong, W., Peabody, J.O., Hemal, A.K., Menon, M. (2014). Robot-assisted radical prostatectomy: inching toward gold standard. *The Urologic Clinics of North America*, 41(4), 473-484.

Sundi, D., Han, M. (2014). Limitations of assessing value in robotic surgery for prostate cancer: what data should patients and physicians use to make the best decision? *Journal of Clinical Oncology*, 32(14), 1394-1395.

Talamini, M.A. (2016). SAGES Assessment on the da Vinci Surgical System. *Surgical Endoscopy*, 30(3), 803-804.

Tedesco, G., Faggiano, F.C., Leo, E., Derrico, P., Ritrovato, M. (2016). A comparative cost analysis of robotic-assisted surgery versus laparoscopic surgery and open surgery: the necessity of investing knowledgeably. *Surgical Endoscopy*, 30(11), 5044-5051.

Tsuda, S., Oleynikov, D., Gould, J., Azagury, D., Sandler, B., Hutter, M. et al. (2015). SAGES TAVAC safety and effectiveness analysis: da Vinci Surgical System. *Surgical Endoscopy*, 29(10), 2873-2884.

Turchetti, G., Pierotti, F., Palla, I., Manetti, S., Freschi, C., Ferrari, V. et al. (2016). Comparative health technology assessment of robotic-assisted, direct manual laparoscopic and open surgery: a prospective study. *Surgical Endoscopy* aheadofprint Jun 17.

Ulucanlar, S., Faulkner, A., Peirce, S., Elwyn, G. (2013). Technology identity: the role of socio-technical representations in the adoption of medical devices. *Social Science & Medicine*, 98 95-105.

van Balken, M., (2016). Stammenstrijd (Tribal fight). https://www.medischcontact.nl/ Accessed 1 January 2017.

van der Poel, H., Wijsman, B. (2013). Prostatectomie kwaliteitsregistratie: de afgelopen jaren (Quality registry of prostatectomy: the past years). *Verenigingsnieuws*.

van der Velde, S., Broeders, I., van Hillegersberg, R., Ruurda, J. (2014). Met een robot opereren gaat gewoon beter (Operating with a robot is just better). *Medisch Contact* (45), 2208-2210.

Venturini, T. (2010). Diving in magma: How to explore controversies with actor-network theory. *Public Understanding of Science*, 19(3), 258-273.

WRSE24, (2015). Live surgery broadcast. http://wrse24.org/wrse24/ Accessed 26 October 2015.

Yaxley, J.W., Coughlin, G.D., Chambers, S.K., Occhipinti, S., Samaratunga, H., Zajdlewicz, L. et al. (2016). Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. *The Lancet*, 388(10049), 1057-1066.

Yossepowitch, O., Briganti, A., Astham, J.A., Graefen, M., Montironi, R., Touijer, K. (2014). Positive surgical margins after radical prostatectomy: a systematic review and contemporary update. *European Urology*, 65(2), 303-315.

4 Value in co-creation: Subjecting innovative in-hospital technologies to multi-stakeholder appraisal

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ABSTRACT

This article addresses how we can account for a value-driven introduction of in-hospital innovations when value is prone to – sometimes considerable – uncertainty. The contribution of multi-disciplinary, evidence-informed multi-stakeholder deliberation (MSD) to deal with value issues is examined. Despite a widespread recognition of multi-stakeholder participation in health care policy-making, it is still uncommon in the decision-making setting involving in-hospital technologies. An 'interpretative knowledge synthesis' method has been adopted. This approach involves constructing a conceptual cross-disciplinary analysis by drawing on different strands of literature from Health Technology Assessment (HTA), public policy, and Science and Technology Studies. The authors describe that during introduction of in-hospital innovations, the social value of these technologies is at stake and that the formal evidence basis of the innovation is, by itself, inadequate to legitimise their introduction. It is then explained how MSD can help maintain public legitimisation of new technology. By sustaining mutual learning about what matters to one another, stakeholders can take their understanding of value upstream, towards value to society at large. MSD, then serves as a platform for 'value in co-creation': engaging in discursive appraisal of an innovation's value. Concrete guidance is proposed for a multi-stakeholder appraisal of value as part of business/implementation planning in order to responsibly introduce new technologies in hospital setting. A collaborative endeavour to co-create value attends to current processes of decentralised, market-oriented introduction of in-hospital innovations. The aim is to legitimise dissemination, realise a socially-desirable impact from limited resources, and act collectively to mitigate uncertainties during the course of implementation.

KEYWORDS

Diffusion of innovation • Hospital-based health technology assessment • Evidence-based medicine • Stakeholder participation • Clinical governance • Leadership • Deliberation • Value

INTRODUCTION

An important characteristic of many contemporary well-developed health care systems is the influx of innovative medical technologies that have contributed to improving life expectancy, while at the same time, increasing health care costs (Bodenheimer, 2005; Cutler & McClellan, 2001). Hospitals are an important entry point for many new medical technologies. In order to generate most favourable impact for populations, while maintaining the affordability of publicly-funded health care systems, public authorities on behalf of tax-payers have been calling for a value-driven introduction (i.e., acquisition, use, dissemination, and insurance coverage) of medical innovations (Gray & El Turabi, 2012; Henshall & Schuller, 2013; Institute of Medicine, 2010; KNAW, 2014).

In many health care systems, scientific evidence of safety, efficacy, and cost-effectiveness are set as the centrepiece of value legitimisation and have been formally operationalised in health technology assessment (HTA). HTA serves as a 'gate-keeping' regulatory regime for the introduction of beneficial medical innovations (Faulkner, 2009; Garrido et al., 2010). Although evidence of clinical utility (including safety and cost-effectiveness) is essential, the value-driven introduction of an innovation renders, in addition, a wider legitimisation of adoption choices and implementation plans with reference to the innovation's societal desirability, health system benefits, and ethical acceptability. This wider legitimisation of in-hospital technology introduction is, however, a demanding task because how these innovations create value to society is not straightforward. Consider complex, highly-specialised new technologies such as: computer-assisted (robotic or semiautomatic) surgical platforms; imaging equipment (e.g., ultra-high resolution CT/MRI scanners); targeted therapy equipment and interventions (e.g., proton beam therapy, trans-vascular tumour therapy); new anaesthetic machines, sterilisation devices, intra-operative instrumentations (e.g., vessel-sealing systems); medical interventions involving implantable devices (e.g., wireless pacemakers, artificial joints, endovascular stents, etc.). These innovations are technically and symbolically appealing. Yet, as argued in this article, their real-world value is often subject to considerable 'all-pervading' uncertainty during its introduction (Culyer, 2009). Complexity of implementation, ambiguous scope of added benefit or harm, dependency of outcomes on the learning curve, capital-intensiveness or higher costs compared with their alternatives, 'distance' between resources used and aggregate health outcomes gained by means of the technology, and as yet unfulfilled promises in clinical practice constitute important sources of value uncertainty.

We examine in this article the fruitfulness of participatory, deliberative approaches for legitimising choices in in-hospital technology introduction and for dealing with value uncertainty. The article is structured as follows. After describing the methodology, we discuss the rationale for participatory approaches and explain how the formal evidence-based frameworks fall short to legitimise choices in in-hospital technology introduction. In presenting our analysis, we briefly reflect on a concrete example, namely, the introduction of robotic surgery. We then argue how deliberations between technology developers, care providers (including potential adopters and rejecters), researchers (evidence producers), technology assessors, payers, regulators, and representatives of patients and the public on the value of complex medical innovations helps legitimise their adoption and optimise their actual impact. Finally, we discuss the practical implication of deliberative practices and propose concrete actionable guidance to support value-driven introduction of emerging in-hospital technologies.

METHODS

The article has adopted a literature-based 'interpretative knowledge synthesis' method. It involves constructing an analytical perspective by relying on different strands of literature. New insights are generated by means of seeking encounters with diverse studies – often with some degree of creativity – to develop a coherent analysis, also referred to as 'lines-of-argument synthesis' (Barnett-Page & Thomas, 2009).

Interpretative knowledge synthesis has its roots in qualitative research tradition and interdisciplinary knowledge production (Bammer, 2013; Noblit & Hare, 1988). Qualitative research syntheses can provide us with pragmatic insights so we can address a certain problem and, as such, they are valued for their potential to inform health policy and clinical practice issues (Campbell et al., 2003; Thorne et al., 2004). Interpretative knowledge syntheses can, thus, serve the purpose of cross-disciplinary knowledge translation in the space between clinical governance and health policy. The problem-oriented character of such synthesis also allows 'synergies' to be established between knowledge producers (e.g., HTA agencies) and knowledge users (e.g., policy makers) (Bammer, 2013; Kothari et al., 2017; Noblit & Hare, 1988).

Approach

Interpretative knowledge synthesis is an endeavour distinct from 'evidence synthesis' by means of (systematic) literature reviews (Thorne et al., 2004). Conventional systematic reviews are often conducted to quantitatively summarise the evidence from available studies with the aim of obtaining precise estimates of treatment effect (Montori et al., 2003). In an interpretive knowledge synthesis, the aim of consulting the literature differs. Primary studies are not used to test or quantify the association between two events related to a clinical experiment. They are used as resources for further conceptual analysis of a given social/policy problem.

Compared with epidemiological systematic reviews, interpretative knowledge synthesis approaches are more flexible; their design and methods are less developed and there are relatively fewer completed syntheses available from which to learn (Thorne et al., 2004). The HTA community is also less familiar with the methodology as it is debated predominantly in the fields of education and anthropology (Lehoux, 2006). Although different terms have been used to label qualitative knowledge synthesis methods, e.g. 'meta-narrative' or 'narrative synthesis' (Kastner et al., 2012), the overarching purpose is to substantiate the analysis being developed with adequate explanations (Noblit & Hare, 1988). This interpretative task is often fulfilled by means of 'analytic abduction', i.e., making creative inferences across diverse studies against a background of developing a certain problem-oriented argument (Timmermans & Tavory, 2012). Argument formulation and data collection are, therefore, not seen as separate but iterative and double-fitting processes (Dixon-Woods et al., 2006).

The search strategy and the collection of studies in an interpretative knowledge synthesis are driven by considerations of content relevance, i.e., identifying the most relevant studies that could contribute to generating new accounts on the formulation of a certain problem and/or a proposal for dealing with it. The validity of such pragmatic syntheses relies on providing a coherent, well-reasoned, and nuanced analysis rather than on probabilistic sampling of primary studies or pre-defined uniformity of the collected data (Thorne et al., 2004).

Conduct

Drawing on the literature from HTA, public policy, and Science and Technology Studies (STS), we provide an interpretative analysis of the value 'problem'

of new in-hospital technologies (Giacomini et al., 2013; Lehoux, 2006). Our search and selection strategy were driven by the so-called 'purposive sampling' method (Green & Thorogood, 2005): by selecting articles that are considered relevant in contributing to the article's core arguments. Relevant articles were retrieved up to July 2017 using the 'pearl-growing' technique, i.e., literature screening by means of bibliography scanning and snowball citation searching. Databases that could be expected to generate a high yield on HTA, public policy, and STS literature were initially searched. These included Medline, Embase, JSTOR, PsychINFO, and Web of Science. Further relevant articles in English and in Dutch were identified by follow-up snowball searches via Pubmed and Google Scholar during the study period (December 2015-July 2017). This allowed a wider search scope including methodological commentaries from European HTA agencies and technology assessment knowledge centres, resources of two European consortia (MedTechHTA and AdHopHTA), and resources of Dutch scientific medical associations. The search continued until 'saturation' was reached. Selected studies then helped develop the article's structure and simultaneously refine further literature search and selection.

The same iterative approach also drove the development of guidance described later in the article (table 1 on page 118). It proposes to deal with the value challenges explained in the first part of this article. This guidance, which is the result of our analytic abduction (Timmermans & Tavory, 2012), involves a conceptual aggregation of value issues that foster grounds for multi-stakeholder appraisal of in-hospital innovations. It emerged in the process of a constant, recursive move between the data (diverse studies) and the concept under development (the value problem of in-hospital innovations). In addition, we reflected on our experience at the National Health Care Institute – the Dutch HTA advisory organisation – as assessor of some in-hospital innovations (e.g., minimally-invasive surgical devices, targeted therapy techniques) or as observers of stakeholders' discussions about others (e.g., wireless heart pacing systems, intra-arterial thrombolytic techniques, proton-beam therapy, etc.). The development of this guidance was inspired and informed by such cross-case experience. The guidance is hence a proposal, awaiting application in practice, validation, adjustment, and improvement.

In what follows, we present a conceptual analysis that has been constructed in an iterative journey of constantly 'puzzling out' the data and our observations.

NECESSITY OF SOCIAL LEGITIMISATION OF IN-HOSPITAL INNOVATIONS

Our analysis departs from the recently well-received guiding framework of Responsible Research and Innovation (RRI). This framework has been developed at the intersection of innovation science and policy in Europe and beyond to allow the proper embedding of scientific and technological advances in society (von Schomberg, 2013). Von Schomberg sketches a vision on RRI, in which realising the 'right impacts' takes centre stage in demonstrating the public value of innovation trajectories. Participation in an interactive (collective) debate is, then, integral to any RRI endeavour, whereby stakeholders become mutually responsive to the added benefits, societal desirability, and ethical acceptability of the innovation process and its marketable products (Von Schomberg, 2013). This view holds that the value-driven introduction of medical innovations renders a *collective* responsibility (rather than distinctive role responsibilities) on the part of stakeholders involved in product development, provision, evidence generation, procurement, and reimbursement of new forms of care (Abrishami et al., 2015; Clark & Weale, 2012; Lucivero, 2016).

The importance of stakeholder participation for social legitimisation of health care decisions has been recognised in both the scholarly literature and the practices of many health care authorities (Betten et al., 2013; Boivin et al., 2014; Culyer, 2006; Drummond et al., 2013; Husereau et al., 2016; Kreis & Schmidt, 2013; Lehoux et al., 2009). Drawing on public and patient engagement, participatory approaches are applied to decision-making settings involving macro-level policies on coverage/reimbursement of health services, resource allocation, and priority setting in the forms of appraisal committees, citizen juries, etc. Participatory approaches have also been examined to evaluate the merits of life science innovations (e.g., synthetic biology, genomics, brain mapping technology, etc.), public health interventions (e.g., breast cancer screening), and health system reforms (Abelson et al., 2013; Betten et al., 2013; McMaster Health Forum). However, existing research and practice both fall short in addressing participatory approaches in the decision-making setting involving the adoption and implementation of (complex) in-hospital innovations. In this setting, organising interactive discursive sessions with a multitude of stakeholders to appraise the societal desirability of an innovation and interrogate decisions in technology introduction is uncommon and, as such, an under-examined area for research (Sampietro-Colom et al., 2015).

Observing diverse strands of literature on technological innovations has led us to distinguish at least three characteristics of the innovation dynamics that provide compelling reasons to consider stakeholder participation for social legitimisation (appraisal) of in-hospital innovations: uncertainty in realising expected values, dispersed responsibility for technology dissemination, and the shortcoming of existing evidence-based justifications.

I. Value uncertainty

STS scholars and, sometimes, health services researchers examine technological innovations within the broader social context of their use in order to explain how the 'socio-technical' practices shape the actual impact of a technology (Rip et al., 1995; van Est & Brom, 2012). From this standpoint, many emerging in-hospital innovations generate value uncertainties because of their inherent socio-technical complexity (rather than exclusively technical sophistication). See Box 1 for a more detailed explanation. Technologies with socio-technical complexity are associated with diverse users' involvement, interface with other technologies, a high degree of interpretation in the context of use, and different configurations in implementation, resulting in a variety of outcomes in practice. They can be referred to as 'configurational technologies' (Faulkner, 2009).

Box 1. ***The dynamics of configurational technologies in the context of use***

The dynamics of configurational technologies provide explanation on how in-hospital innovations can be generative of uncertainties, thereby sophisticating the enquiry of value:

- Configurational innovations breed new challenges and needs 'precisely' while seeking to resolve or meet existing ones (Lehoux, 2006; Webster, 2007)
- The technology's adoption and implementation involves a multi-level, service-level innovation. The innovation is diffused as 'hard core' (a discrete 'product'), while cutting across several 'services' in its wider soft periphery (Rye & Kimberly, 2007; Sugarhood et al., 2014)
- Implementation is 'open-ended' and varies from set-up to set-up, with diverse pathways through which innovation use may lead to benefits and risks (Faulkner, 2009; KNAW, 2014; Webster, 2007)

Box 1. *The dynamics of configurational technologies* *(continued)*

- The technology takes on various socio-technical 'identities' and offers different 'affordances', i.e., it can serve different purposes, convey various symbolic meanings, and offer diverse utility values within the complex context of use (Abrishami et al., 2014; Ulucanlar et al., 2013)
- The 'transformative potential' of the innovation may cause large-scale unexpected changes and disrupt existing practices and relations (Nuffield Council on Bioethics, 2012)
- The innovation's technical features are evolving, as are the regulations involving market access, finance, and provision of the innovation (Gelijns & Rosenberg, 1994; Lehoux, 2006)
- The beneficiaries are diverse and the intended use is subject to ongoing change in practice (Faulkner, 2009; KNAW, 2014).

Many expected values could be at stake during introducing a configurational technology into clinical practice. Promises representing the merits of the innovation are to be fulfilled in future (Borup et al., 2006). The core and/or added clinical benefits have yet to be proven. The innovation's impact on health system sustainability is vague as it is unclear to what extent it infringes on any system objective – accessibility, good-quality care, and financial sustainability – relative to the others. Strikingly, from a health system perspective these objectives are considered 'incommensurable' in the sense that it is undesirable for the new technology to fulfil any objective at the substantial cost of another (Weale, 1998). Moreover, the aggregate health outcomes gained from resources spent on the new technology is difficult to trace because the innovation's technical output does not unequivocally lead to better population outcomes (Abrishami et al., 2015; Webster, 2007). Given the (extra)costs incurred, whether the innovation's budge impact will *eventually* be neutral to overall health care spending – let alone saving scarce resources down the road – is ambiguous. Ethical acceptability in terms of the innovation's aggregate impacts on social service delivery, resource distribution, and the ideals of human well-being may also be under-examined (Daniels et al., 2016; Daniels & van der Wilt, 2016). Dissemination of a certain technology can, in a self-perpetuating fashion, contribute to unrealistic hypes and expectations, widening disease categories, medicalisation, increased health anxiety, over-treatment, and inflated demands

dissociated from real health care needs of the population (Hofmann, 2015; Lucivero, 2016). After all, delivering actual value by means of configurational innovations depends on an immense array of elements within the context of use, external to the very technology such as a realistic consideration of one's own capacity, regional need for the service, research plans, patient stream, returns on investment, quality assurance, maintenance & upgrading, and training, to name but a few (Abrishami et al., 2015).

The *da Vinci*® surgical robot is a good example of a configurational technology that is prone to value uncertainty. It is a promising, expensive innovation offering minimally-invasive remote surgery. This innovation is received with enthusiasm and adopted rapidly by many hospitals worldwide. However, after more than a decade of use, its seemingly straightforward promises have not yet well translated into patient outcomes. The innovation's value profile including clinical benefits and cost-effectiveness compared with existing alternatives is considerably uncertain (Abrishami et al., 2014).

II. Dispersed responsibilities

A second reason to stimulate multi-stakeholder appraisal of an innovation's value stems from the fact that the responsibilities for configurational technologies are often dispersed among many actors. Decisions on the acquisition and use of in-hospital technologies are typically made in decentralised arrangements and at a hospital's discretion. In decentralised market-driven care provision systems, the burden of responsibility to legitimise whether and how the new technology should be adopted and used has been shifted from the macro-level (public authorities) to the local level (Berg et al., 2004; Ciani et al., 2012). These decisions, however, present highly consequential spin-off challenges within *and* beyond the adopting organisation, particularly in terms of pushing resources away from other forms of health care services (Gray & El Turabi, 2012; Hofmann, 2015; Rye & Kimberly, 2007). Within an adopting unit, investment on a certain technology could change the hospital's supply portfolio, resulting in eliminating a 'less lucrative' department. Beyond an individual hospital, pervasive adoption can establish an implicit prioritisation of both service provision and resource allocation.

With the loci of responsibility being institutionally dispersed while an innovation disseminates, the wider aspects of value remain untouched or under-examined (de Vries & Horstman, 2008; Rip et al., 1995; Webster, 2007). A lot of new

in-hospital technologies – sometimes even big-ticket items – are adopted in the absence or in advance of explicit, thorough assessments by public authorities (KNAW, 2014; Sampietro-Colom & Martin, 2016). The adopting hospitals, on the other hand, have local concerns, motivations, and value perspectives as they often operate in competitive settings, face direct-to-professional promotion, and deal with increasingly well-informed, demanding patients. Even if an individual adopting hospital has the so-called hospital-based HTA unit in place, assessing the societal desirability of new technologies often falls beyond the scope of such units (Gagnon et al., 2014; Sampietro-Colom & Martin, 2016). Hospital-based HTA is a growing worldwide initiative to support investment/procurement decisions and improve quality of care at a hospital level. It involves an assessment of the clinical, organisational, and economic aspects of a new technology from the distinctive value perspective of the adopting hospital (Sampietro-Colom et al., 2015).

The da Vinci surgical robot was adopted to achieve high-tech clinical practice excellence, research excellence, surgeon's comfort, and corporate advantages (Abrishami et al., 2014). The implications of rapid dissemination and pervasive use of this innovation such as resource re-distributional consequences or the foregone opportunities of investing in other health services are, however, hardly of immediate concern to the local adopters and users (Sampietro-Colom et al., 2015).

III. Limited evidence

The third reason to argue for MSD during in-hospital technology introduction is related to insufficient evidence of an innovation's value. Again the case of robotic surgery is illustrative, as it shows that the impact of the innovation in the real world is not well captured within formal justification frameworks. An extensive study on dissemination of this innovation in Italy conducted by Mele et al., concludes that the formal evidence basis is, by itself, inadequate to capture 'the marginal or even absolute benefits' of the innovation being introduced (Mele et al., 2014). Drawing on the literature, we argue in what follows that the evidentiary base of a configurational innovation does not provide full-blown insight legitimising choices in technology introduction. Three interrelated processes explain why public legitimacy of an innovation's value by means of formal evidence remains at stake.

III.a. Timeline of evidence-based justifications

First, medical innovations usually emerge in advance of an uncontested knowledge on how best to utilise them. The new technology is granted market entry by demonstrating technical equivalence and manufacturing performance, with no requirement of substantial value assessment. It is then adopted, diffused, and used prior to its evidence base being established (Institute of Medicine, 2010; Paul et al., 2013). This is somehow inevitable, as in order for evidence to be generated, the innovation must be used. Rigorous evidence of effect is often either not available at an early stage or insufficient for translating into an uncontested superiority (added-value) claim to legitimise decisions on take-up and use. The question 'is the new technology worth it?' often remains relevant and unanswered even after dissemination of the innovation (Institute of Medicine, 2010; Sundi & Han, 2014).

III.b. Tools of evidence-based justifications

The second challenge refers to the real-world relevance of the tools for legitimising value. Formal evidence-based assessments have not yet adequately captured the impact of an innovation in the real world. The comprehensive evaluation guidance of the Royal Netherlands Academy of Arts and Sciences (KNAW) clarifies that evidence concerning the benefits and risks of new technologies is often generated in an environment 'quite different' from that of real-world use (KNAW, 2014). The Academy calls for a 'network of evidence' approach, hence leaving one-size-fits-all approach. Evidence generation tools are primarily designed for an enquiry rooted in a causal verification of technical performance in a controlled, typically randomised examination. Such method is considered ideal when the effect to be assessed is – like the mechanism of actions of a drug –internal to the object of experiment. For instance, to demonstrate that an antihypertensive drug does indeed reduce blood pressure, one must extract a causal claim from the observed correlation between this drug and reducing the heart rate or dilating the vessels. Contextual factors will then need to be eliminated in order to increase confidence in the causal conclusion based on the correlational results of comparison.

Many emerging technologies, however, cannot be well framed in a test setting *ceteris paribus* (KNAW, 2014; Moreira, 2012; Netherlands Centre for Ethics and Health, 2007; Parkhurst & Abeysinghe, 2014). The impact of a medical technology is hardly internal to the technology in solo, detached from the context of use. Nor can the value be confined to the innovation's manufacturing standards and technical performance. It depends on the very external

contextual elements: precise indications for use, patients' baseline morbidity profile, treatment protocols, safety measures, care delivery pathways, providers' experience, training, hospital volume, the hospital's (sub)specialisations and scale profile, aggregate volume, and all the sociotechnical processes representing the context of service delivery (Abrishami et al., 2015; Institute of Medicine, 2010). De Vries and Horstman's analogy with the automobile is illustrative here (de Vries & Horstman, 2008). Medical innovations lend their values from their surroundings in much the same vein that the value of an automobile is geared to constructing suitable roads, building gas stations, passing traffic legislation, enforcing courteous driving behaviour, and organising all those countless other matters that we are inclined to take for granted when considering our cars as a 'useful' means of transport.

III.c. Tiers of evidence-based justifications

The third challenge involves the diversity of value perspectives. This is relatively untouched by formal evidence. Evidence is often generated assuming a 'demarcation' of hard-core knowledge and normative assumptions, while decision-making for technology introduction take place at the very junction of truth and vales (Clark & Weale, 2012; Lehoux et al., 2009; Parkhurst & Abeysinghe, 2014). Furthermore, an evidence basis by itself does not address how evidence is interpreted and actioned in practice (Kyratsis et al., 2014). Value is in the eye of the beneficiary that extends across a range of stakeholders. Who is the beneficiary/customer for medical innovations: Is it the receivers (patients), the operators (professionals), the researchers, the contractors (commissioners/insurers) or the public (tax/premium payers) (Abrishami et al., 2015)? Stakeholders – with often diverse interests, expertises, jargons, and disciplinary backgrounds – may have different general concepts of value, and in particular of the added value of an innovation (Drummond et al., 2013; Henshall & Schuller, 2013; KNAW, 2014). Subsequently they may engage in different presumptions and trade-offs when appraising the benefits and desirability of an innovation. This also applies to the choices on 'relevant' outcomes, endpoints, and measurement methods used to assess an innovation (Culyer, 2009; Drummond et al., 2005).

In addition, different tiers of value enquiry co-exist, particularly with complex innovations. These innovations are often used jointly with other in-hospital innovative services, the value of which is also the subject of testing and experimentation. Consider, e.g., a novel tissue resection method while performing robotic surgery (such as fluorescent-guided tissue resection), or a novel chemotherapy agent or tumour tracer while performing targeted cancer therapy. The novel

surgical method poses a distinctive assessment inquiry: 'is this new resection method better?', while concurrently interfacing with another value inquiry 'is robotic surgery better?'. Likewise, the added value of a novel chemotherapy agent, imaging contrast, tumour tracer, etc. – compared with the existing practice – involves a distinctive assessment, while also creating successive layers of value inquiry for targeted therapy. This interdependence of different innovative techniques sophisticates the evidence-based justification of value for each and for all together.

The above-mentioned challenges highlight the 'grey zone' of value-driven technology introduction, where achieving de facto value from introducing a new technology is uncertain, the innovation's wider consequences are not addressed well, and formal evidence falls short to capture diverse value perspectives in real world. Subsequently, social legitimacy of the technology being introduced remains at stake. In the case of the da Vinci robot, widespread adoption has taken place while its evidence basis is still 'conflicting' and inconclusive even in the pioneered fields of application, the resection of (cancerous) uterus and prostate (De Carlo et al., 2014; Sundi & Han, 2014; Wright et al., 2013). A call for generating further evidence seems unlikely to serve as a solution for the time discrepancy. Our recent exploration of the value profile of the da Vinci robot beyond its early introduction phase has shown that research, which has been conducted during fifteen years of using robotic surgery and published at an exponential rate has so far been unable to resolve the contest of its added value (see chapter three). And this is unlikely to occur in the near future as the technology and the practices involving it continue to evolve (Institute of Medicine, 2010; Paul et al., 2013).

In the following section we examine how participatory, deliberative processes can help enhance the legitimacy of choices in technology introduction.

THE CONTRIBUTION OF MULTI-STAKEHOLDER DELIBERATION

Systematic, multi-disciplinary, multi-stakeholder, evidence-informed deliberative processes (henceforth multi-stakeholder deliberation; MSD), have often been proposed as a tool for enhancing the social legitimisation of policies and decisions, in particular in complex, dynamic, and uncertain conditions (Swanson et al., 2010). Deliberation is an ancient practice, dating back to the *agora* of Athens and is still commonly used (Tyler, 2009). MSD can be defined as a

collective communicative process to examine an issue from different points of view (Tyler, 2009). MSD implies the consideration of different framings of risk and benefit to elicit 'best reasoned' choices (Boivin et al., 2014; Culyer, 2006; Swanson et al., 2010). Moreira describes deliberation – in his words, the 'Forum' – as a main mode of organising and coordinating contemporary health care systems, co-existing with the 'Laboratory' and the 'Market', i.e., platforms for effectiveness and efficiency respectively (Moreira, 2012). Under the heading "under what circumstances are deliberative processes [in decisions about health care technologies] likely to be of greatest use?", Culyer points out an array of situations, that all apply to configurational medical innovations, where a technology's societal legitimacy is uncertain/ambiguous (Culyer, 2009).

Multi-stakeholder deliberation has been addressed in a number of fields of study, most notably, adaptive governance (a branch of public policy) (Swanson et al., 2010), knowledge management (a branch of organisations studies) (Fong et al., 2007; Senge, 1990), change management (a branch of business leadership) (Heierbacher, 2007), and the Responsible Research and Innovation framework (a branch of STS) (Betten et al., 2013; van Est & Brom, 2012; Von Schomberg, 2013). In terms of theoretical foundation, MSD is linked to political theory of deliberative democracy and cognitive theory of judgment and decision-making (Tyler, 2009).

The fruitfulness of MSD in legitimising choices rests on its two interrelated key characteristics: democratic and epistemic representativeness (see also Box 2.). First, MSD can be held to ensure the participation and articulation of diverse voices. For introducing new in-hospital technology, this involves direct stakeholders (i.e., producers, providers, payers/planners, patients, the public) as well as intermediary stakeholders (depending on the circumstances, e.g., engineers/designers, technicians, nurse assistants, scientific journal editors, advocates/plaintiffs, advertisers, investors, journalists, research funders, policy makers, etc.). From this standpoint, MSD can be seen as a means of fostering a more democratic mode of governance, incorporating a key norm of civil society (i.e., representativeness) into expert-driven decision-making (Lucivero, 2016; Moreira, 2012; van Est & Brom, 2012). Second and related to this, is the epistemic benefits of deliberation. MSD provides a doorway for pluralising expertise: for engaging in different kinds of knowledge and different ways of knowing when interpreting and acting upon evidence to reach a decision (Kyratsis et al., 2014; Lehoux et al., 2009; Lucivero, 2016; Tyler, 2009). Legitimising the 'why' and 'how' of introducing complex technology may touch upon a variety of disci-

plines such as technology design, clinical science, safety and quality assurance, information technology, economics, implementation and evaluation sciences, entrepreneurship, business and organisation management, law (liability, patent, privacy), public health, sociology, and ethics of technology.

Box 2. ***Potentials of robust multi-stakeholder deliberation***

With reference to its democratic and epistemic benefits, MSD can assist stakeholders in taking well-informed, coordinated, and legitimised decisions on introducing emerging technology in situations of uncertainty and diversity of interests. Drawing on different strands of literature, we synthesise four inter-related potentials of robust MSD that account for such contribution.

I. Systems thinking and anticipation

In as far as technology introduction can be conceived as 'system innovation' (Sugarhood et al., 2014), MSD can serve as crucial *linkage* between different components of the health care system and different stages of innovation processes. Through striving for collaborative thinking, deliberation moves participants upstream to consider what matters to us all – 'from *me* language to *we* language' (Estlund, 2008). In their book entitled 'Dialogue', Ellinor and Gerard argue that through deliberation we can move from the idea that the solution lies in fixing parts of the system towards considering what needs to happen in the system as a whole. Dialogue stimulates us so we can 'see the forest for the trees'; and directs our attention to underlying uncertainties so we can 'find the source of fire rather than repeatedly firefighting' (Ellinor & Gerard, 1998; Korthals, 2011). In addition, deliberation provides stakeholders with a nuanced understanding of the interdependency of variables, even seemingly distant ones. This enables stakeholders to anticipate on an innovation's impact and devise solutions based on the relationships between decisions and their wider potential consequences (Tyler, 2009).

Box 2. ***Potentials of robust multi-stakeholder deliberation*** *(continued)*

II. Responsiveness to real-world dynamism

Subjecting an emerging technology to MSD reveals that value issues are often moving targets and in the making. Effective MSD enables us to treat the take-up and use of a complex innovation as a real-world 'societal experiment' rather than an inside-the-lab, theory-testing experiment (de Vries & Horstman, 2008). In such societal experiments, the state of knowledge on innovations' value is evolving. Plans and decisions, hence, remain unfinished – and corrigible over time, their 'rightness' subject to on-going reflection and deliberation.

This is an explicit acknowledgement of the difficulty of ascertaining how well an emerging technology works. This also implies a preparedness to deal with uncertainties collaboratively by tracing the 'known knowns', but also communicating the 'known unknowns', and attempting to envisage the 'unknown unknowns'.

III. Cumulative learning and knowledge exchange

Organisational and individual learning is a distinctive characteristic of MSD and a key issue in literature in which it is discussed. Acknowledging technology introduction as a knowledge-intensive societal experimentation implies that individuals and institutions can and must learn from one another (de Vries & Horstman, 2008). Learning implies: (*a*) willingness to understand the reasoning of others rather than just seeking 'confirmation' from the like-minded, (*b*) awareness of how one's decisions affect those of another, and (*c*) learning from knowledge domains other than one's own area of expertise. Much of dialogue is in fact about *listening*; listening to one another as well as to oneself (Ellinor & Gerard, 1998). Through MSD, different assumptions and decisional trade-offs in technology (e)valuation can be made debatable that might otherwise remain implicit (Lehoux et al., 2009). Moreover, new cumulative insights are generated as result of reflection on the past and exposure to diverse (value) perspectives (de Vries & Horstman, 2008; Ellinor & Gerard, 1998; Oborn et al., 2013). Unlike e.g. lobbying, authentic deliberation is not about 'winning' arguments but about reasoned exchange and mutual learning (Burgess et al., 2007).

Box 2. ***Potentials of robust multi-stakeholder deliberation*** *(continued)*

MSD can, therefore, provide an interactive basis for co-creating knowledge under conditions of uncertainty and contention (Betten et al., 2013; Greenhalgh, 2010; Oborn et al., 2013). It is also possible to achieve 'double loop' learning, which means learning how to learn and transfer knowledge on an individual, inter-organisational or intra-organisational level (Ellinor & Gerard, 1998; Oborn et al., 2013).

IV. Coordinated (creative) action

By their very nature, deliberative processes involve 'value-based reasoning for collective problem solving' (Abelson et al., 2013). Rather than being fancy verbose improvisations, deliberations serve to compromise on workable (re)solutions, thereby reducing misalignments in collective action, e.g., in introducing an innovation (Moreira, 2012).

They aim at co-creating value on the basis of a wider examination of risks and benefits. Drawn from both the potential for knowledge transfer and learning from diversity, MSD could facilitate the identification of 'best practice' (i.e., successful real-world examples) or novel, creative solutions to improve the business-as-usual (Betten et al., 2013; de Vries & Horstman, 2008; Fong et al., 2007). For instance, deliberation could help readjust strategies with respect to manufacturers' R&D, research funding, advertising, market access, procurement, etc.

To sum it up, robust MSD can enhance the quality of the 'social intelligence' bearing on decisions, thereby assisting in taking well-informed, more technically robust, and more democratically accountable actions in situations of uncertainty and diversity of interests. Further elaboration on MSD goes beyond the scope of this chapter as we aim to examine the contribution of MSD for public legitimisation of emerging in-hospital technology.

TOWARDS CO-CREATING VALUE OF IN-HOSPITAL INNOVATIONS

By subjecting the adoption and implementation of in-hospital innovations to MSD, a forum can be set up in which different rationales, presumptions, modes of knowing, voices, and value perspectives could become communicable. By means of deliberation on what matters to one another, stakeholders can take their understanding of value upstream, towards value to society at large. Such an *upstream understanding* might help reach consensus by reconciling different value repertoires (Drummond et al., 2013). However, considering the value uncertainties surrounding configurational technologies and diversity of interests, achieving consensus is not very likely. Deliberation is, in fact, much more about sustaining mutual learning and committing to collectively-devised solutions than about establishing consensus (Culyer, 2009; de Vries & Horstman, 2008). A critical societal appraisal of an innovation can take place by means of MSD, in which benefits and risks/costs of the innovation to all stakeholders are collectively explored, learnt, and compromised upon. Such a discursive endeavour to *jointly* legitimise 'why' an innovation's outcomes are desirable and 'how' the science and practice of the innovation can be optimised to fulfil the right impacts, is what we refer to as 'value in co-creation'.

Since facts, actualities, and values are tightly intertwined in technology introduction, appraisal of value invariably includes an appraisal of *evidence* too. Discursive processes, Culyer argues, are 'nearly always' required in understanding what is regarded as 'evidence' for making *good* decisions on new medical technologies (Culyer, 2009). On the one hand, this implies that evidence of efficacy and cost-effectiveness is hardly the 'base' on which decisions are taken; rather, these and other forms of evidence 'inform' decision-making through deliberative processes (Baltussen et al., 2017). On the other hand, an upstream vision on value compromised upon through deliberation can inform the generation of evidence, not least by examining what counts as *relevant* outcomes and how to enhance the practical relevance of assumptions underlying quantitative assessments. MSD also helps us overcome the time challenge in formal evidence-based justification by crossing it: by linking different stages of the innovation process, namely, the design, use, assessment, and regulatory stages (Korthals, 2011; Sugarhood et al., 2014). In parallel, MSD can also accommodates dialogue between the methodologies of generating evidence (i.e., knowledge exchange), typically between the formal HTA frameworks and the constructive technology assessment methods (Abrishami et al., 2015; Lucivero, 2016).

How does deliberation in the process of in-hospital technology introduction work in practice? Stakeholders can benefit from MSD, particularly for exerting the following efforts:

(i) developing business models and implementation plans,
(ii) developing plans for centralised and/or collaborative provision of advanced therapies,
(iii) managed entry and adaptive/conditional access,
(iv) developing clinical practice guidelines (CPGs) and benchmarks for appropriate use,
(v) incremental improvements of new technology in clinical practice, and
(vi) disinvesting/obsoleting existing alternatives.

These endeavours take place at the intersection of different value perspectives and require cross-stakeholder communications, thereby representing important loci of collective technology appraisal. In table 1 (page 118), we provide topics for an actionable discursive appraisal of in-hospital technological innovations.

Developing business models and learning from successful implementation plans foster a ground for MSD on value. As van Limburg et al. examine in the case of e-health technologies, making a socially-responsible business model is crucial to better understand what could be accomplished with the innovation and whether it is worth it (van Limburg et al., 2011). The Dutch Federation of Medical Specialists (FMS) has issued guidance for a 'careful' introduction of new interventions into clinical practice. The Federation has specified the following steps to develop a responsible introduction plan: inventorying prospective risks; identifying added benefits, expected volume, and budget impact; developing implementation protocol including training, data registry and monitoring; and evaluating actual outcomes (FMS, 2014). A related issue is devising value-based plans for concentrating the provision of expensive therapies or for group procurement on a more level playing-field in mono/oligopolistic market situations, cf. (Pronovost et al., 2017). These plans demand MSD since hospitals typically purchase technology in isolation. Care concentration and group procurement accommodate important value considerations such as scale-access trade-offs and outcome-based market demands that are relevant to a wide range of stakeholders.

Value considerations also provoke a model of shared decision-making as in the case of 'managed entry agreements' of innovative care. These agreements are a range of schemes devised to collaboratively deal with value uncertainties, e.g., price-volume agreements, cost-sharing, budget cap, monitoring registries, payment by results, risk-sharing, therapeutic plans, etc. (Husereau et al., 2014; Klemp et al., 2011). Another instance is 'adaptive' or 'conditional' access schemes for technology introduction such as Access with Evidence Development (AED) (Stafinski et al., 2010). These schemes are used to grant early access to potentially beneficial innovative care, while requiring the generation of enough and robust evidence to legitimise its public funding. A concurrent appraisal of the role and relevance of evidence is an important part of these endeavours.

A striking instance of value in co-creation is identifying which sub-populations of patients benefit from a new therapy the most (i.e., proper indications for using an innovation). The choices as to whom to offer the new therapy also determine the hospitals' return on investment based on patient stream (economic). Subsequently, this is geared to decisions on public funding of the innovation (social/economic), which in turn affect fairness/equity in resource allocation (ethical) and access to care (legal). This interconnectedness of the consequences of decisions during early stages of a new therapy denotes that the abovementioned disciplinary perspectives and stakeholders must be sufficiently represented to warrant that choices on eligibility to a new form of care are socially legitimised. With respect to incremental innovations, existing joint ventures such as industry-hospital partnerships can benefit from including more stakeholders particularly payers/HTA groups. Recent 'early dialogue' initiatives can, here, be inspirational. Early dialogues connect technology developers/sponsors and payers/coverage organisations to jointly examine at an early stage how to demonstrate an innovations' value later on (Backhouse et al., 2011; Demers-Payette et al., 2016). Examples are the US Food and Drug Administration's call for deliberation on evidence requirement in a pre-market phase (Food and Drug Administration, 2016) and the European SEED project (Shaping European Early Dialogues for health technologies).

Table 1. *Guidance for discursive appraisal of (complex) in-hospital innovations.*

Spectrum of Appraisal	Aspects of Value	Matters of Concern*
Desirability (*the 'why'*)	Societal desirability & Ethical acceptability	• How desirable are the promises of the innovation in question? What do we want from innovations and our health care resources? • How does dissemination of this innovation influence patterns of health services delivery, resource distribution, and the ideals of human well-being? • The forgone opportunity: why this innovation and not others? Who benefits and who loses from using it? What else can't we achieve?
	Necessity & Added benefits	• What constitutes a substantive *added* benefit? To what extent does the innovation's 'differentness' or 'newness' mean 'betterment'? • When and under which conditions should the new therapy be regarded as regular, and no longer experimental? • Examining wider industrial, knowledge-economic, and entrepreneurial benefits • Baseline assessment of cumulative need and identifying necessary scale/patterns of supply • Matching the innovation's output with actual needs and capacity: how much functionality is appropriate and what is the best way of acquisition of the necessary functionality (consolidated/group procurement, lease, outsource, etc.)? • How will the new device improve performance/outcome of the existing treatment pathway and reduce health care costs downstream?

Spectrum of Appraisal	Aspects of Value	Matters of Concern*
Plausibility (*the 'how'*)	Research governance (*Evidence in co-creation*)	• To which ends are we generating evidence or funding research on a given innovation? • Identifying *a priori* what counts as 'relevant' (versus high-level) evidence for demonstrating value and for informing patients' decisions • Clinical scoping: legitimising the choice of comparator, time-frame, target indications, and outcomes measures • Coordinating multi-centre evidence generation and evaluating research processes • Translating evidence into decision: developing CPGs (e.g., identifying target indications), and setting norms for appropriate use (e.g., quality standards and volume norms)
	Implementation	• Prospective risk inventory: making sense of and preparing for potential risks (e.g., regarding safety, patient outcomes, returns on investment, skill sets, and liability) • Exemplifying local 'best practices' (technical, clinical, financial, organisational, research, training, teamwork & coordination) • Deliberation on training & credentialing, scale issues (e.g., concentration versus differentiation), cross-stakeholder partnership, human resource implications (e.g., need for new competences), digital infrastructure, publicity, logistics, interoperability, coordination, etc. • Experience exchange and skill transfer between early adopters and potential/new users • Continual monitoring to learn how to optimise value

* *Topics are overlapping and may be discussed iteratively.*

As mentioned earlier, the proposed guidance is yet to be implemented in practice. The conceptual nature of guidance helps us define the 'learning needs' and the scope for value co-creation. It responds to the call for a flexible, non-one-size-fits-all value assessment framework for medical technologies (KNAW, 2014). This can, in turn, pave the path for developing an eventual 'roadmap' for value-driven introduction of in-hospital innovations. Another related application of guidance would be to identify pressing technology-specific value issues that need to be resolved in a particular local setting. In the case of robotic surgery, our recent exploration in the Netherlands shows, several unresolved value issues demand multi-stakeholder engagement and compromise, notably, what needs to be measured when demonstrating *added* clinical and economic benefits, how to consider entrepreneurial and ergonomic advantages, how to deal with the reshaping of hospital portfolios as result of dissemination of this innovation, how many robotic surgery centres are considered sufficient and at which minimum norms of surgical practice (see chapter three). These issues have, so far, been rarely addressed by published studies.

If assessing the impact of in-hospital technologies is shifted away from governments' task (Berg et al., 2004), while also being beyond the scope of individual local actors (Sampietro-Colom & Martin, 2016), where should this task be performed? We argue that different communities of practice performing at a meso-level can take on this collective responsibility because they can allow development of a shared understanding beyond the competitive settings, in which their individual members operate. Hospital federations, associations of university medical centres, professional/scientific medical societies, umbrella organisations of payers/health maintenance organisations and manufactures, or any (knowledge) network linking public and private institutions can host effective MSD. These associations have often experience with cross-stakeholder appraisal of new interventions (e.g., when developing CPGs) or they may already be consulted by national appraisals committees. Even in jurisdictions with no formal HTA establishment, it is fairly likely that these associations are already operational and can best take the lead for co-creating value. On the other hand, academic medical centres may reap the learning opportunities of MSD on in-hospital innovations as part of their residency trainings or Continuing Medical Education programmes. Industry and payers organisations can, in addition to acting as a stakeholder, support MSD by providing unrestricted grants, in similar veins to supporting forums in scientific congresses. Public authorities and national HTA agencies can stimulate value co-creation by providing these associations with expertise, funding, mediation, or oversight.

As for the tools to facilitate participatory deliberation, it would typically comprise foresight reports (e.g., horizon scanning, 'scenarios', or controversy mappings), iterative briefings, and panel discussions (Lucivero, 2016; McMaster Health Forum). There is nevertheless no blueprint, but room for a creative and efficient design of MSD, e.g. using digital communication methods, as long as fitness for purpose is well considered. Besides, pragmatic appraisal-support tools such as Multi-Criteria Decision Analysis (MCDA) are at our disposal. MCDA can help structure MSD, elicit stakeholders' value perspectives, reflect on socio-ethical underpinnings of decisions, address trade-offs, reach compromise, and document deliberations in a transparent manner (Baltussen et al., 2017; Goetghebeur & Wagner, 2017).

Value in co-creation through MSD: beneficial but not easy

Subjecting innovative technologies to a robust multi-stakeholder appraisal is fairly challenging. Deliberation is not a panacea, nor an easy exercise. Many processes could hinder conducting an effective MSD (Kahane et al., 2013). Participants (institutions and individuals) may be hesitant to engage in deliberation and reflection. Organisational readiness for pedagogic debate and a culture of listening could be lacking. Moreover, stakeholders may find it difficult to suspend their views – instead of promoting them – to learn from those, with whom they disagree; or they may perceive it as a threat to their individual/institutional credibility or power. Fear of taking away the arm's length, a conflict of interests (e.g., representing an association, while competing with peers or being involved in business with other stakeholders), the cognitive burden of facing no simple solutions, the burden of data provision, unfamiliarity with others' routines or disciplinary jargons, and trust can also play a thwarting role. After all, the topic of MSD, the innovation's value, is a complex, intellectually-intensive concept. Paradoxically, these barriers to engaging in an effective deliberation are in fact the very same reasons why deliberation can be fruitful or even necessary.

In addition, there are many practical issues when organising an effective MSD with respect to executive responsibility, recruitment, preparation, participation, moderation, and impact on timeline for decision making (Boivin et al., 2014; Burgess et al., 2007). Examples include how to conceive 'adequate' representation of disciplinary perspective; how to ensure participation of a robust mix of stakeholders across different stages of innovation; how to moderate the open articulation of diverse perspectives with no vested interest becoming dominant and no single voice ignored; how to prevent blaming or defensive conversa-

tions; how much capacity (time, money, and human resources) to allocate to allegedly non one-off deliberations; how often to organise MSD and with which deliberative techniques; how to handle ownership of deliberation outputs, (if applicable) media coverage, anonymity of perspectives, information-secrecy; and how to evaluate the success of deliberation (Flood, 2015; Rowe & Frewer, 2005). Notwithstanding, experiences with deliberative appraisal practices in national assessment and resource allocation settings, within the life sciences and public health, or in technological domains outside the health care sector (e.g., nanotechnology in Europe) are there to help design and conduct an effective MSD for introduction of emerging in-hospital technologies.

CONCLUDING REMARKS

This article touches upon stakeholder participation for the public legitimisation of complex in-hospital technological innovations. The contribution of multi-disciplinary, multi-stakeholder evidence-informed deliberation (MSD) for assessing the value of these technologies was examined. MSD allows a discursive inquiry into the societal desirability of a given innovation (i.e., 'why' introducing this technology) and its actual impact (i.e., 'how' to realise value in practice). In so doing, MSD serves as a platform for cumulative learning and, accordingly, for generating 'relevant' evidence to legitimise adoption, to ensure that the best outcomes are gained from limited resources, and to mitigate value uncertainties along the way of implementation. This co-creation of value is, we believe, the cornerstone of introducing complex in-hospital innovations responsibly.

Co-creating value, the article discusses, involves a collaborative endeavour that is well-attuned to decentralised health care systems, while also connecting micro-level decisions on in-hospital technologies with macro-level health policy considerations. Evidence-informed deliberative approaches that are open to a broad range of stakeholders' voices and modes of knowledge offer a participatory governance of emerging in-hospital technology without eliminating actors' volition in adoption decisions. This helps strengthen a democratic governance of these innovations. In addition, a shift from an output-based to a value-based introduction of emerging medical technology denotes an indispensable move from evidence-based medicine to evidence-informed multi-stakeholder deliberative decision-making. The article challenged afresh a taken-for-granted assumption that the adoption and implementation of emerging technologies render just technocratic a task. In the early stages, in-hospital technologies are

technically, symbolically, and economically attractive, whereas their actual worthiness is often not established. It is also during the same period that formal scientific evidence-based frameworks are unable to provide an uncontested justification for an innovation's added benefits or absolute values.

Our call for subjecting in-hospital technology introduction to multi-stakeholder appraisal implies not only eliciting the preferences of patients and the public, but also engaging in knowledge exchange and mutual learning. This aim of stakeholder participation well suits the distinctive task of introducing in-hospital innovation, an act that relies on a multitude of fairly specialised knowledge and expertise, from entrepreneurship, to risk management and clinical governance, to value assessment and outcome improvement. Deliberation with this objective facilitates cross-fertilisation of the stakeholders' know-how and enriches the knowledge-base of introducing complex new technology.

Whether an effective multi-stakeholder appraisal of in-hospital innovations could become a common practice for a value-driven introduction of emerging in-hospital technologies – amid practical difficulties – remains an empirical question. And the extent to which diverse stakeholders exercise this collective responsibility remains to be seen. No matter how near or far, the way to go for a value-driven entry of hospital innovations is to regard technology introduction as a prudent societal experimentation, in need of ongoing value evaluation and outcome optimisation. This entails building capacity, commitment, and competence for engaging in deliberation in order to learn how to align innovations' impacts with upstream societal objectives and how to compromise on workable solutions when *the* answer for value issues is inconceivable. We proposed guidance that helps define the scope for such a value-in-co-creation endeavour (cf. table 1 on page 118). We hope this article stimulates stakeholders' engagement in systematic deliberation on value of emerging medical innovations, notably prior to their widespread roll-out.

REFERENCES

Abelson, J., Blacksher, E.A., Li, K.K., Boesveld, S.E., Goold, S.D. (2013). Public deliberation in health policy and bioethics: mapping an emerging, interdisciplinary field. *Journal of Public Deliberation*, 9(1), 5.

Abrishami, P., Boer, A., Horstman, K. (2014). Understanding the adoption dynamics of medical innovations: affordances of the da Vinci robot in the Netherlands. *Social Science & Medicine*, 117 125-133.

Abrishami, P., Boer, A., Horstman, K. (2015). How can we assess the value of complex medical Innovations in practice? *Expert Review Pharmacoeconomics and Outcomes Research*, 15(3), 369-371.

Backhouse, M.E., Wonder, M., Hornby, E., Kilburg, A., Drummond, M., Mayer, F.K. (2011). Early dialogue between the developers of new technologies and pricing and reimbursement agencies: a pilot study. *Value in Health*, 14(4), 608-615.

Baltussen, R., Jansen, M.P.M., Bijlmakers, L., Grutters, J., Kluytmans, A., Reuzel, R.P. et al. (2017). Value assessment frameworks for HTA agencies: the organization of evidence-informed deliberative processes. *Value in Health*, 20(2), 256-260.

Bammer, G. (2013). *Disciplining Interdisciplinarity: Integration and Implementation Sciences for Researching Complex Real-world Problems*. ANU E Press.

Barnett-Page, E., Thomas, J. (2009). Methods for the synthesis of qualitative research: a critical review. *BMC Medical Research Methodology*, 9(1), 59-70.

Berg, M., Van Der Grinten, T., Klazinga, N. (2004). Technology assessment, priority setting, and appropriate care in Dutch health care. *International Journal of Technology Assessment in Health Care*, 20(01), 35-43.

Betten, A.W., Roelofsen, A., Broerse, J.E.W. (2013). Interactive learning and action: realizing the promise of synthetic biology for global health. *Systems and Synthetic Biology*, 7(3), 127-138.

Bodenheimer, T. (2005). High and rising health care costs. Part 2: technologic innovation. *Annals of Internal Medicine*, 142(11), 932-937.

Boivin, A., Lehoux, P., Burgers, J., Grol, R. (2014). What are the key ingredients for effective public involvement in health care improvement and policy decisions? A randomized trial process evaluation. *Milbank Quarterly*, 92(2), 319-350.

Borup, M., Brown, N., Konrad, K., van Lente, H. (2006). The sociology of expectations in science and technology. *Technology Analysis & Strategic Management*, 18(3-4), 285-298.

Burgess, J., Stirling, A., Clark, J., Davies, G., Eames, M., Staley, K. et al. (2007). Deliberative mapping: a novel analytic-deliberative methodology to support contested science-policy decisions. *Public Understanding of Science*, 16(3), 299-322.

Campbell, R., Pound, P., Pope, C., Britten, N., Pill, R., Morgan, M. et al. (2003). Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Social Science & Medicine*, 56(4), 671-684.

Ciani, O., Tarricone, R., Torbica, A. (2012). Diffusion and use of health technology assessment in policy making: what lessons for decentralised healthcare systems? *Health Policy*, 108(2), 194-202.

Clark, S., Weale, A. (2012). Social values in health priority setting: a conceptual framework. *Journal of Health Organization and Management*, 26(3), 293-316.

Culyer, A.J. (2006). NICE's use of cost effectiveness as an exemplar of a deliberative process. *Health Economics, Policy and Law*, 1(03), 299-318.

Culyer, A.J. (2009). *Deliberative Processes in Decisions about Health Care Technologies: Combining Different Types of Evidence, Values, Algorithms and People*. London: Office of Health Economics.

Cutler, D.M., McClellan, M. (2001). Is technological change in medicine worth it? *Health Affairs*, 20(5), 11-29.

Daniels, N., Porteny, T., Urrutia[corrected], J. (2016). Expanded HTA: enhancing fairness and legitimacy. *International Journal of Health Policy and Management*, 5(1), 1.

Daniels, N., van der Wilt, G.J. (2016). Health technology assessment, deliberative process, and ethically contested issues. *International Journal of Technology Assessment in Health Care*, 32(1-2), 10-15.

De Carlo, F., Celestino, F., Verri, C., Masedu, F., Liberati, E., Di Stasi, S.M. (2014). Retropubic, laparoscopic, and robot-assisted radical prostatectomy: surgical, oncological, and functional outcomes: a systematic review. *Urology Internationalis*, 93(4), 373-383.

de Vries,G., & Horstman,K. (2008). Learning from the work that links laboratory to society. In: G. de Vries, & K. Horstman (Eds.), *Genetics from Laboratory to Society. Societal Learning as an Alternative to Regulation*. Palgrave Macmillan, Basingstoke, pp. 171-190.

Demers-Payette, O., Lehoux, P., Daudelin, G.v. (2016). Responsible research and innovation: a productive model for the future of medical innovation. *Journal of Responsible Innovation*, 3(3), 188-208.

Dixon-Woods, M., Bonas, S., Booth, A., Jones, D.R., Miller, T., Sutton, A.J. et al. (2006). How can systematic reviews incorporate qualitative research? A critical perspective. *Qualitative Research*, 6(1), 27-44.

Drummond, M.F., Sculpher, M. J., Torrance, G. W. et al. (2005). *Methods for the Economic Evaluation of Health Care Programmes*. Oxford: Oxford University Press.

Drummond, M., Tarricone, R., Torbica, A. (2013). Assessing the added value of health technologies: reconciling different perspectives. *Value in Health*, 16(1 Suppl), 7-13.

Ellinor, L., Gerard, G. (1998). *Dialogue: Rediscover the Transforming Power of Conversation*. New York: Wiley.

Estlund, D. (2008). *Democratic Authority*. Princeton: Princeton University Press.

Faulkner, A. (2009). *Medical Technology into Healthcare and Society: A Sociology of Devices, Innovation and Governance*. Basingstoke: Palgrave Macmillan.

Flood, C.M. (2015). Scoping the shape of an iceberg: the future of public involvement in heath policy: reflecting on 'Public involvement policies in health: exploring their conceptual basis'. *Health Economics, Policy and Law*, 10(04), 381-385.

FMS, (2014). Leidraad NIKP (Guidance New Interventions in Clinical Practice). https://www.demedischspecialist.nl/ Accessed 1 March 2017.

Fong, P.S.W., Hills, M.J., Hayles, C.S. (2007). Dynamic knowledge creation through value management teams. *Journal of Management in Engineering*, 23(1), 40-49.

Food and Drug Administration, (2016). Request for Expressions of Interest From Coverage Organizations; Coverage Organizations Interested in Providing Input Regarding Private Payer Coverage to Medical Device Sponsors Who Request Their Participation in a Pre-Submission Meeting With the Food and Drug Administration. https://federalregister.gov/a/2016-03909 Accessed 1 March 2017.

Gagnon, M.P., Desmartis, M., Poder, T., Witteman, W. (2014). Effects and repercussions of local/hospital-based health technology assessment (HTA): a systematic review. *Systematic Review*, 3(1), 1-14.

Garrido, M.V., Gerhardus, A., Rottingen, J.A., Busse, R. (2010). Developing health technology assessment to address health care system needs. *Health Policy*, 94(3), 196-202.

Gelijns, A., Rosenberg, N. (1994). The dynamics of technological change in medicine. *Health Affairs*, 13(3), 28-46.

Giacomini, M., Winsor, S., Abelson, J. (2013). Ethics in health technology assessment: understanding health technologies as policies. *Healthcare Management Forum*, 26(2), 72-76.

Goetghebeur,M., & Wagner,M. (2017). Identifying value(s): a reflection on the ethical aspects of MCDA in healthcare decisionmaking. In: K. Marsh, M. Goetghebeur, P. Thokala, & R. Baltussen (Eds.), *Multi-Criteria Decision Analysis to Support Healthcare Decisions*. Springer, Cham, pp. 29-46.

Gray, M., El Turabi, A. (2012). Optimising the value of interventions for populations. *British Medical Journal*, 345(7877), 8.

Green, J., Thorogood, N. (2005). *Qualitative Methods for Health Research*. London: Sage publication.

Greenhalgh, T. (2010). What is this knowledge that we seek to "exchange"? *Milbank Quarterly*, 88(4), 492-499.

Heierbacher,S. (2007). Dialgoue and deliberation. In: P. Holman, T. Devane, & S. Cady (Eds.), *The Change Handbook*. BK Publication, San Francisco, pp. 102-107.

Henshall, C., Schuller, T. (2013). Health technology assessment, value-based decision making, and innovation. *International Journal of Technology Assessment in Health Care*, 29(4), 353-359.

Hofmann, B.M. (2015). Too much technology. *British Medical Journal*, 350(h705).

Husereau, D., Henshall, C., Jivraj, J. (2014). Adaptive approaches to licensing, health technology assessment, and introduction of drugs and devices. *International Journal of Technology Assessment in Health Care*, 30(03), 241-249.

Husereau, D., Henshall, C., Sampietro-Colom, L., Thomas, S. (2016). Changing health technology assessment paradigms? *International Journal of Technology Assessment in Health Care*, 32(4), 191-199.

Institute of Medicine (2010). *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation*. Washington (DC): National Academies Press.

Kahane, D., Loptson, K., Herriman, J., Hardy, M. (2013). Stakeholder and citizen roles in public deliberation. *Journal of Public Deliberation*, 9(2), 2.

Kastner, M., Tricco, A.C., Soobiah, C., Lillie, E., Perrier, L., Horsley, T. et al. (2012). What is the most appropriate knowledge synthesis method to conduct a review? Protocol for a scoping review. *BMC Medical Research Methodology*, 12 114.

Klemp, M., Fronsdal, K.B., Facey, K. (2011). What principles should govern the use of managed entry agreements? *International Journal of Technology Assessment in Health Care*, 27(01), 77-83.

KNAW (2014). *Evaluation of New Technology in Health Care. In Need of Guidance for Relevant Evidence.* Amsterdam: Royal Netherlands Academy of Arts and Sciences (KNAW).

Korthals, M. (2011). Deliberations on the life sciences: pitfalls, challenges and solutions. *Journal of Public Deliberation*, 7(1), 1-13.

Kothari, A., McCutcheon, C., Graham, I.D. (2017). Defining integrated knowledge translation and moving forward: a response to recent commentaries. *International Journal of Health Policy and Management*, 6(5), 299-300.

Kreis, J., Schmidt, H. (2013). Public engagement in health technology assessment and coverage decisions: a study of experiences in France, Germany, and the United Kingdom. *Journal of Health Politics, Policy and Law*, 38(1), 89-122.

Kyratsis, Y., Ahmad, R., Hatzaras, K., Iwami, M., Holmes, A. (2014). Making sense of evidence in management decisions: the role of research-based knowledge on innovation adoption and implementation in health care. *Health Services and Delivery Research*, 2(6).

Lehoux, P. (2006). *The Problem of Health Technology: Policy Implications for Modern Health Care Systems.* New York: Routledge.

Lehoux, P., Daudelin, G., Demers-Payette, O., Boivin, A. (2009). Fostering deliberations about health innovation: what do we want to know from publics? *Social Science & Medicine*, 68(11), 2002-2009.

Lucivero, F. (2016). *Ethical Assessments of Emerging Technologies: Appraising the Moral Plausibility of Technological Visions.* Cham: Springer International Publishing.

McMaster Health Forum, Programs. https://www.mcmasterhealthforum.org/home Accessed 1 March 2017.

Mele, V., Compagni, A., Cavazza, M. (2014). Governing through evidence: a study of technological innovation in health care. *Journal of Public Administration Research and Theory*, 24(4), 843-877.

Montori, V.M., Swiontkowski, M.F., Cook, D.J. (2003). Methodologic issues in systematic reviews and meta-analyses. *Clinical Orthopaedics and Related Research*(413), 43-54.

Moreira, T. (2012). *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum*. London: Routledge.

Netherlands Centre for Ethics and Health (2007). *Appropriate Evidence: Ethical Questions Concerning the Use of Evidence in Health Care Policy*. The Hague: Netherlands Centre for Ethics and Health (CEG).

Noblit, G.W., Hare, R. D. (1988). *Meta-ethnography: Synthesizing Qualitative Studies*. Sage Publication.

Nuffield Council on Bioethics (2012). *Emerging Biotechnologies: Technology, Choice and the Public Good*. London: Nuffield Council on Bioethics.

Oborn, E., Barrett, M., Racko, G. (2013). Knowledge translation in healthcare: incorporating theories of learning and knowledge from the management literature. *Journal of Health Organization and Management*, 27(4), 412-431.

Parkhurst, J.O., Abeysinghe, S. (2014). What constitutes 'good' evidence for public health and social policy making? from hierarchies to appropriateness. *Social Epistemology Review and Reply Collective*, 3(10), 34-46.

Paul, S., McCulloch, P., Sedrakyan, A. (2013). Robotic surgery: revisiting "no innovation without evaluation". *British Medical Journal*, 346(f1573).

Pronovost, P., Palmer, S., Ravidz, A., (2017). What Hospitals Can Learn from Airlines About Buying Equipment. Harvard Business Review. https://hbr.org/ Accessed 1 July 2017.

Rip,A., Misa,T.J., & Schot,J. (1995). Constructive technology assessment: a new paradigm for managing technology in society. In: A. Rip, T.J. Misa, & J. Schot (Eds.), *Managing Technology in Society*. Pinter Publishers, London, pp. 1-12.

Rowe, G., Frewer, L.J. (2005). A typology of public engagement mechanisms. *Science, Technology, & Human Values*, 30(2), 251-290.

Rye, C.B., Kimberly, J.R. (2007). The adoption of innovations by provider organizations in health care. *Medical Care Research and Review*, 64(3), 235-278.

Sampietro-Colom, L., Lach, K., Cicchetti, A. et al. (2015). *The AdHopHTA Handbook: A Handbook of Hospital-based Health Technology Assessment*. The AdHopHTA Project.

Sampietro-Colom,L., & Martin,J. (2016). Hospital-Based Health Technology Assessment: The Next Frontier. In: L. Sampietro-Colom, & J. Martin (Eds.), *Hospital-Based Health Technology Assessment: The Next Frontier for Health Technology Assessment*. Springer International Publishing, Cham, pp. 3-11.

Senge, P.M. (1990). *The Fifth Discipline: The Art and Practice of the Learning Organization*. New York: Doubleday.

Stafinski, T., McCabe, C.J., Menon, D. (2010). Funding the unfundable: mechanisms for managing uncertainty in decisions on the introduction of new and innovative technologies into healthcare systems. *Pharmacoeconomics*, 28(2), 113-142.

Sugarhood, P., Wherton, J., Procter, R., Hinder, S., Greenhalgh, T. (2014). Technology as system innovation: a key informant interview study of the application of the diffusion of innovation model to telecare. *Disability and Rehabilitation Assistive Technology*, 9(1), 79-87.

Sundi, D., Han, M. (2014). Limitations of assessing value in robotic surgery for prostate cancer: what data should patients and physicians use to make the best decision? *Journal of Clinical Oncology*, 32(14), 1394-1395.

Swanson, D., Barg, S., Tyler, S., Venema, H., Tomar, S., Bhadwal, S. et al. (2010). Seven tools for creating adaptive policies. *Technological Forecasting and Social Change*, 77(6), 924-939.

Thorne, S., Jensen, L., Kearney, M.H., Noblit, G., Sandelowski, M. (2004). Qualitative metasynthesis: reflections on methodological orientation and ideological agenda. *Qualitative Health Research*, 14(10), 1342-1365.

Timmermans, S., Tavory, I. (2012). Theory construction in qualitative research: From grounded theory to abductive analysis. *Sociological Theory*, 30(3), 167-186.

Tyler,S. (2009). Multi-stakeholder deliberation. In: D. Swanson, & S. Bhadwal (Eds.), *Creating Adaptive Policies: A Guide for Policy-making in an Uncertain World*. Sage, London, pp. 41-55.

Ulucanlar, S., Faulkner, A., Peirce, S., Elwyn, G. (2013). Technology identity: the role of sociotechnical representations in the adoption of medical devices. *Social Science & Medicine*, 98, 95-105.

van Est,R., & Brom,F. (2012). Technology assessment, analytic and democratic practice. In: R. Chadwick (Ed.), *Encyclopedia of Applied Ethics*. Elsevier, Oxford, pp. 306-320.

van Limburg, M., van Gemert-Pijnen, J.E.W.C., Nijland, N., Ossebaard, H.C., Hendrix, R.M.G., Seydel, E.R. (2011). Why business modeling is crucial in the development of eHealth technologies. *Journal of Medical Internet Research*, 13(4), e124.

von Schomberg,R. (2013). A vision of responsible innovation. In: R. Owen, J. Bessant, & M. Heintz (Eds.), *Responsible Innovation*. Wiley, London, pp. 51-74.

Weale,A. (1998). Ethical Issues in social insurance for health. In: T. Sorell (Ed.), *Health Care, Ethics and Insurance*. Routledge, New York, pp. 137-150.

Webster, A. (2007). *Health Technology and Society: A Sociological Critique*. New York: Palgrave Macmillan.

Wright, J.D., Ananth, C.V., Lewin, S.N., Burke, W.M., Lu, Y.S., Neugut, A.I. et al. (2013). Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. *Journal of American Medical Association*, 309(7), 689-698.

5 Health technology assessment to integrate appraisal of societal values

This chapter is based on the following article:
Abrishami, P., Oortwijn, W., Hofmann, B. (2017)

Ethics in HTA: Examining the "need for expansion".
International Journal of Health Policy and Management, 6(10): 551–553.

ABSTRACT

The article by Daniels and colleagues on expanding the scope of Health Technology Assessment (HTA) to embrace ethical analysis has received endorsement and criticism from commentators in this journal. Referring to this debate, we examine in this article the extent and locus of ethical analysis in HTA processes. An expansion/no-expansion framing of HTA is, in our view, not very fruitful. We argue that meaningfulness and relevance to the needs of the population are what should determine the extent of ethics in HTA. Once 'relevance' is the guiding principle, engaging in ethical analysis becomes inevitable as values are all over the place in HTA, also in how assessors frame research questions. We also challenge dividing the locus of ethical analysis into assessment and appraisal as this would detach HTA from its purpose, i.e., supporting legitimate decision-making. Ethical analysis should therefore be considered integral to the HTA process.

KEYWORDS

Health technology assessment • Ethical analysis • Organizational decision-making • Resource allocation • Value

INTRODUCTION

An editorial by Daniels and colleagues entitled, "Expanded HTA: Enhancing Fairness and Legitimacy" (Daniels et al., 2016), has set forth a debate accompanied by a number of successive commentaries in this journal (Byskov et al., 2016; Culyer, 2016; Jansen et al., 2017; Sandman & Gustavsson, 2016; Syrett, 2016). The debate addresses a core issue regarding the role of Health Technology Assessment (HTA) for legitimising decisions on health interventions. Central to the debate is a call to broaden the scope of HTA to embrace social and ethical issues such as equity and distributional impacts. The discussion also touches a longstanding, still unfinished, debate on the locus of such analyses within HTA processes: whether ethical appraisal of a health intervention is – in terms of content – separate from its technical assessment or interwoven with it. In this article we contribute to this debate with a view to examining the extent and locus of ethical inquiry in HTA.

TO EXPAND OR NOT TO EXPAND?

As we see it, "expansion" involves a problematic framing for the scope of HTA. Expansion entails surpassing a boundary. Likewise, a 'no-extension' argument, as Culyer makes (Culyer, 2016), involves the underlying assumption that we are deviating from a pre-existing assessment framework already demarcated by a specific discipline (medical science, epidemiology, health economics, or otherwise) and generally agreed upon within the HTA community. This view inevitably demands identifying where the boundary of expansion lies. For instance, in disagreeing with the suggestion of Daniels and colleagues to consider "matters other than safety and cost-effectiveness" in HTA, Culyer draws a line of 'unnecessarily' expanding HTA.

We reject a by-exclusion framing of HTA arisen from such an expansion/no-expansion argument, be it per domain or discipline, by calculation or deliberation, academic or non-academic, or otherwise. In our opinion, 'meaningfulness and relevance' to the needs of the population must be the prime criteria for determining the extent of HTA and for 'sufficiency' of analyses (Sandman & Gustavsson, 2016). As a tool to inform decision-making regarding health interventions, HTA must remain user-centred in the same fashion that airlines services must be tailored to the needs of passengers or health services to those of patients. The extent of an assessment (its evaluative scope) should, in turn, be

fit for the purpose of 'legitimising decisions' (Syrett, 2016), from both a practical and an epistemological point of view. A fit-for-purpose HTA is neither reductionistic nor unnecessarily exhaustive in terms of types of disciplinary perspectives, stakeholders involved, and the application of algorithmic calculations or deliberative processes. In a similar vein, an extensive elaboration of general ethical principles may in certain circumstances be rendered unnecessary, as equally may sophisticated modelling techniques. Notwithstanding, the health intervention in question should determine the content of HTA (Culyer, 2016).

TO EXPAND OR TO INTEGRATE?

Once 'relevance' is the guiding principle, it must be justified with adequate reasoning. Engaging in ethical analysis then becomes inevitable, thereby, *integral* to HTA processes. For example, HTA influences how pooled, but scarce resources eventually address the needs of the population; and the selection and/or exclusion of issues to address in HTA reports has normative bearings (Hofmann et al., 2014). If no significant ethical issue is conceivable for the health intervention at hand, an elaborate ethical analysis may not be necessary (e.g., in a case of a new me-too anti-cholesterol drug). Note: this is an if-clause. To ascertain the conditions of this 'if', the assessor will inevitably have to examine budget, distributional, and financial protection impact. Nevertheless, several surveys and reviews show that HTA reports seldom explicitly address ethical issues (Arellano et al., 2011; Daniels et al., 2016; Daniels & van der Wilt, 2016; DeJean et al., 2009; Droste & Gerhardus, 2003; Garrido et al., 2010). Some commentators in this journal reiterate this and endorse the integration of ethical analysis, including equity and fairness considerations into HTA. Culyer, however, argues that not all HTA reports need ethics; and that unveiling all specific ethical judgements would, in fact in itself, be unethical (Culyer, 2016). We agree with Culyer and others who assert that not all ethical aspects of all health interventions have to be addressed for every HTA (Grunwald, 2004). Ethical analysis is, again, better conceived in accordance to the 'relevance' argument. This would also prevent inconsistency, e.g., claiming that the job of assessors is to "populate the HTA process with ideas and evidence", while regarding the equity and distributional impacts of the health intervention as "excessive" (Culyer, 2016).

Moreover, the fact that ethics is already embedded in HTA processes – notably in terms of minimizing opportunity costs – does not guarantee adequate 'ethical

reasoning' or 'social learning' (e.g., regarding societal values beyond health gains that cannot be easily quantified) (Daniels & van der Wilt, 2016; Jansen et al., 2017). Nor does this preclude one from examining all the value judgements underlying calculative assessments, including the relevance of cut-off points, outcome measures, time frame, indirect medical costs or costs outside the health care system, cost-effectiveness thresholds, and trade-offs between advantages and disadvantages of different measurement methodologies, to name but a few (Hofmann, 2005; Hofmann et al., 2014). These choices and assumptions are often not made explicit in an HTA report. They, however, could nontrivially influence patterns of utilization and eventually resource (re-) distribution. The devil would then be in these details, challenging Culyer's idea of the intrinsic innocence of the tool: "Frequently what is wrong is not the tool but its users or the environment …". Aren't you then engaging in an ethical analysis with regard to justifying the scope and tool of the assessment? This is indeed separate from the fact that equity considerations in resource distribution are partly captured by 'a *correctly-perceived* idea of cost-effectiveness analysis in health care' (Culyer, 2016).

DIVISION OF LABOUR BETWEEN THE TWO CULTURES: CAN YOU KEEP YOUR HANDS OFF?

Ambivalence exists about where ethical issues should be handled: is it the task of decision-makers or do we want most of them integrated in HTA analyses? The same commentator, who argues that HTA frameworks should allow decision-makers to consider "all relevant, quantitatively and ethically significant issues", also asserts that "[i]t is not necessary – indeed it is unethical – to prescribe all the specific ethical judgments that may have to be made. That is not the job of analysts but of decision-makers and their advisers" (Culyer, 2016). In saying that HTA should not become prescriptive, Culyer notes that (*a*) scientific evidence should not be the 'sole basis' for making decisions and (*b*) responsibility and discretion rest on the decision-maker rather than the assessor. We agree and re-emphasise these points. However, we strongly doubt whether aiming at minimal 'meddling' with the job of decision-makers renders the assessments relevant or well-reasoned. The calculative assessments may either lose practical relevance or they may be regarded by the decision-maker and the public as prescriptive, not because their evaluative scope is adequate, but since they carry the connotation of being impartial or objective (Ashcroft, 2012). Acknowledging and explicitly addressing ethical issues along with technical assessment provide the

decision-maker with a more balanced/nuanced input for deciding on a certain course of action. Rather than prescriptively limiting the choices, such an ethical analysis clarifies existing choices made and the consequences thereof, even if it does not open up previously-neglected choices. It also feeds rather than discourages evidence-informed deliberative processes (Baltussen et al., 2016).

It is widely acknowledged that the division between assessors and decision-makers, between fact (assessment) and value (appraisal), and between technocratic and political legitimisation has made HTA processes fall short to properly address ethical issues (Baltussen et al., 2016; Daniels & van der Wilt, 2016; Garrido et al., 2010; Husereau et al., 2016; Jansen et al., 2017; Syrett, 2016). Such division could be incongruent with the relevance argument. To those who promote this division, it should not matter if the conclusions of the assessments – having been pushed in an algorithmic direction (Culyer, 2009; Culyer, 2016) – are ignored. It would, then, be defeating the purpose to expect legitimisation and transparency of decisions by means of HTA, while at the same time believing that assessors are only there to deliver evidence at the door. This leaves a lot of room for a decision-maker's *ad hoc* personal feelings/expedience/interest, raising the question of why HTA is needed in the first place.

Making decisions to optimize value (Daniels & van der Wilt, 2016) is indeed the authority and responsibility of decision-makers, its 'relevance and reasonableness' however, relies on the work of assessors. The choice is, as Daniels and van der Wilt put it, "between HTA remaining a source of incomplete advice …, thus risking an important kind of marginalization, and HTA … to provide as complete an assessment of a technology as possible" (P. 12) (Daniels & van der Wilt, 2016). You may have to choose: keeping your hands off or having an impact, because if HTA wants to have an impact on decisions, its hands may very well become openly involved.

CONCLUSION

We argue that the relevance to the decision at hand is what should determine the content of HTA. Ethical underpinnings of cost-effectiveness analyses do not, in themselves, assure adequate ethical reasonableness in an HTA. Ethical analysis is integral to the whole HTA process as it contributes to how HTA is defined,

interpreted, and acted upon. It includes equity and distributional considerations but also all value judgments inherently involved in assessments. To examine the extent and the role of ethical analysis in HTA, we may need to make up our mind: becoming detached from or catering to the needs of the population.

REFERENCES

Arellano, L.E., Willett, J.M., Borry, P. (2011). International survey on attitudes toward ethics in health technology assessment: an exploratory study. *Int J Technol Assess Health Care*, 27(01), 50-54.

Ashcroft, R.E. (2012). Health Technology Assessment. In: R. Chadwick (Ed.), *Encyclopaedia of Applied Ethics*. Elsevier, Oxford, pp. 556-565.

Baltussen, R., Jansen, M.P., Mikkelsen, E., Tromp, N., Hontelez, J., Bijlmakers, L. et al. (2016). Priority setting for universal health coverage: we need evidence-informed deliberative processes, not just more evidence on cost-effectiveness. *Int J Health Policy Manag*, 5(11), 615.

Byskov, J., Maluka, S.O., Marchal, B. (2016). The need for global application of the accountability for reasonableness approach to support sustainable outcomes: comment on "Expanded HTA: enhancing fairness and legitimacy". *Int J Health Policy Manag*, 5.

Culyer, A.J. (2009). *Deliberative Processes in Decisions about Health Care Technologies: Combining Different Types of Evidence, Values, Algorithms and People*. London: Office of Health Economics.

Culyer, A.J. (2016). HTA - algorithm or process?: comment on "Expanded HTA: enhancing fairness and legitimacy". *Int J Health Policy Manag*, 5(8), 501.

Daniels, N., Porteny, T., Urrutia, J. (2016). Expanded HTA: enhancing fairness and legitimacy. *Int J Health Policy Manag*, 5(1), 1.

Daniels, N., van der Wilt, G.J. (2016). Health technology assessment, deliberative process, and ethically contested issues. *Int J Technol Assess Health Care*, 32(1-2), 10-15.

DeJean, D., Giacomini, M., Schwartz, L., Miller, F.A. (2009). Ethics in Canadian health technology assessment: a descriptive review. *Int J Technol Assess Health Care*, 25(04), 463-469.

Droste, S., Gerhardus, A. (2003). [Ethical aspects of short health technology assessments: a systematic review]. *Zeitschrift für ärztliche Fortbildung und Qualitätssicherung*, 97(10), 711-715.

Garrido, M.V., Gerhardus, A., Rottingen, J.A., Busse, R. (2010). Developing health technology assessment to address health care system needs. *Health Policy*, 94(3), 196-202.

Grunwald, A. (2004). The normative basis of (health) technology assessment and the role of ethical expertise. *Poiesis & Praxis*, 2(2-3), 175-193.

Hofmann, B. (2005). On value-judgements and ethics in health technology assessment. *Poiesis & Praxis*, 3(4), 277-295.

Hofmann, B., Cleemput, I., Bond, K., Krones, T., Droste, S., Sacchini, D. et al. (2014). Revealing and acknowledging value judgments in health technology assessment. *Int J Technol Assess Health Care*, 30(06), 579-586.

Husereau, D., Henshall, C., Sampietro-Colom, L., Thomas, S. (2016). Changing health technology assessment paradigms? *Int J Technol Assess Health Care*, 32(4), 191-199.

Jansen, M.P., Helderman, J.K., Boer, B., Baltussen, R. (2017). Fair processes for priority setting: putting theory into practice: comment on "Expanded HTA: enhancing fairness and legitimacy". *Int J Health Policy Manag*, 6(1), 43.

Sandman, L., Gustavsson, E. (2016). Beyond the black box approach to ethics: comment on "Expanded HTA: enhancing fairness and legitimacy". *Int J Health Policy Manag*, 5(6), 393.

Syrett, K. (2016). Expanded HTA, legitimacy and independence: comment on "Expanded HTA: enhancing fairness and legitimacy". *Int J Health Policy Manag*, 5(9), 565.

6 How can we assess the value of complex medical innovations in practice?

This chapter is based on the following editorial:
Abrishami, P., Boer, A., Horstman, K. (2015)

How can we assess the value of complex medical innovations in practice?
Expert Review Pharmacoeconomics & Outcomes Research, 15(3): 369–371.

ABSTRACT

Rapid proliferation of medical innovations in the face of demographic changes and scarce resources is demanding a value-conscious entry of medical innovations into health care systems. An inquiry into value gains significance during the early diffusion phase of an innovation and becomes indispensable as the complexity of an innovation increases. In this editorial, we argue that a value assessment must pay attention to the social processes shaping the innovation's adoption and use, in particular, to the 'promises' of the technology and actual 'practices' with it. Promises and practices represent real-world value as they account for both outcomes and costs in practice. A systematic exploration of these loci of value, using insights from constructive technology assessment, enables us to make well-informed decisions on complex medical technologies.

KEYWORDS

Technology adoption • Complex medical innovation • Constructive technology assessment • Health technology assessment • Method • Outcome • Real-world value

INTRODUCTION

Rapid proliferation of medical innovations in the face of demographic changes and scarce resources is demanding a (more) value-conscious entry of medical innovations to enhance population health while maintaining the affordability of health care systems. We regard value as the worthiness of the actual impact of introducing the technology at the costs involved. As improving health care outcomes at reasonable costs is a 'health care imperative', an inquiry into the value of medical innovations has gained increasingly more relevance for all public and private stakeholders involved in the design, development, production, adoption, procurement, use, and assessment of innovations (Institute of Medicine, 2010; Porter, 2010).

In many contemporary health care systems, new medical technologies are being developed and put into use in a dynamic context comprising a diversity of stakeholders who are involved in a multitude of interrelated networks and constellations. At the same time, medical innovations are provided in increasingly decentralised arrangements with respect to their purchase, finance, use, or request. Stakeholders have been granted increasing discretion to decide on whether and how (often) an innovation should be used. The matter of decision-making involves a subtle interplay of factual knowledge and stakeholders' diverse value perspectives (Abrishami et al., 2014; Ashcroft, 2012; Boer, 2014; Borup et al., 2006). In the absence of a solid body of evidence during the early diffusion phase of an innovation, stakeholders' perspectives as to whether to adopt and how (often) to use inevitably gain significance. These perspectives, we argue, are important elements for a value assessment. They represent the innovation's perceived benefits and they shape certain patterns of adoption and practices with the innovation.

Take, for example, the *da Vinci*® surgical robot. While the costs are high and the evidence-based superiority is still unproven, this device is put in use in many countries. Our study of the adoption dynamics of the da Vinci robot reveals that it was adopted to achieve clinical practice excellence, scientific excellence, and entrepreneurship advantages (Abrishami et al., 2014). Surgeons and hospitals wanted to pioneer the provision of this high-tech high precision surgical platform – as a symbol of good care, while also conducting research and performing better than the competitor. On the same ground, insurers were also driven to contract this form of care for the insured. These perceived values have driven the introduction of this innovation. However, it is difficult to measure them in

a clinical experiment or a cost-effectiveness study. Assessing these attributes of value demands exploring the purposes, interests, and perspectives that guide adoption and use of technology in real world. This way of looking at the worthiness of an innovation signifies two interconnected loci of its value in its wider social world: the 'promises' of an innovation and the 'practices' involving that innovation. Promises and practices are representative of real-world value in that they shape why an innovation started to be used and how, thereby accounting for both outcomes and costs.

PROMISES: THE 'WHY' SIDE OF VALUE

Insights from the sociology of expectations and the philosophy of technology tell us how promises shape the potential of technological change. By definition, innovation is an intensely forward-looking enterprise with an emphasis on the creation of new opportunities and capabilities (Borup et al., 2006; Mesthene, 2003). Promises are representations of these opportunities as they provide stakeholders with 'reasons' for developing, adopting, and using an innovation. These denote what one wants to *achieve* by means of technology, the so-called 'affordances' of the innovation: which priorities are served by the innovation and which symbolic utilities stakeholders can attribute to those activities (Abrishami et al., 2014; Webster, 2004). They shape preference and choice, attract interest, justify behaviour, guide activities, foster investment, and mobilise resources (Borup et al., 2006; Mesthene, 2003). Promises and affordances depict certain images of a technology's desirability. They are, then, made *real* by actors in the context of use and – as such – are representative of the innovation's actual value.

PRACTICES: THE 'HOW' SIDE OF VALUE

Medical innovations lend their values from their surrounding context and from ways, in which they are put to use (Abrishami et al., 2014; Blume, 2013; Gelijns & Rosenberg, 1994; Ulucanlar et al., 2013). The impact of a medical technology can hardly be regarded as internal to the technology itself. Nor is its value confined to the innovation's manufacturing standards and technical performance, as signified, for instance, by a CE mark. De Vries and Horstman's analogy with the automobile is illustrative of this (de Vries & Horstman, 2008). The value of a medical innovation is related to the situations in which it is used, similar to

how the value of an automobile is geared to suitable roads, accessible fuel stations, effective traffic legislation, courteous driving behaviour, and many other details we are inclined to take for granted when considering an automobile as a desirable means of transport. Likewise, the value of medical innovation relies on the characteristics of the context of use, including considerations relating to patient (subgroup) selection, treatment protocols, care delivery pathways, providers' experience, hospital volume, a hospital's (sub)specialisations and scale profile, cultural repertoires of innovation, prevailing norms, and all detailed socio-technical processes ('how' questions) that represent a particular setting of service delivery (Henshall & Schuller, 2013; Institute of Medicine, 2010; KNAW, 2014).

PROMISES & PRACTICES OF COMPLEX MEDICAL INNOVATIONS

As the complexity of innovations increases, an inquiry into value becomes more pressing. "Value should always be defined around the customer", emphasises Porter (Porter, 2010), but who is the customer for complex innovations? Is it the receivers (patients), the operators (professionals), the contractors (commissioners/insurers), or the public (tax/premium payers)? Likewise, who takes the risk and who bears the burden? Considerable uncertainties are associated with both promises and practices in the case of complex, in-hospital, capital-intensive emerging technologies such as new imaging equipment, interventional image-guided targeted therapy techniques, computer-assisted (semiautonomous or robotic) surgical platforms, and implantable devices. Consider the following challenges during the early-diffusion phase:

- Sophisticated emerging technologies are symbolically and technically appealing, but expensive;
- The core and/or added clinical benefits are yet to be proven;
- Patient (sub)groups that could benefit the most have yet to be determined;
- Technical effects of the innovation (such as higher resolution imaging, more precise tissue targeting, or more accurate surgical resection compared with existing alternatives) do not easily translate into uncontroversial meaningful patient outcomes;
- The impact of a complex innovation on the deployment of public resources is difficult to trace as the exact amount of resources attracted by the innovation (thus, away from other services) often remains 'invisible' in the complex landscape of hospital finance (Boer, 2014);

- At the subsurface, a complex medical innovation often touches other in-hospital innovative services, the value of which is also the subject of testing and experimentation (e.g., a new tissue resection method while performing robotic surgery or a new chemotherapy agent or radiopharmaceutical while performing targeted therapy);
- The 'wider elements of real-world value' (Henshall & Schuller, 2013), namely, economic (entrepreneurial) and knowledge (research) yields are as yet unfulfilled, or, being difficult to measure, they are rarely assessed (Abrishami et al., 2014; KNAW, 2014).

Moreover, delivering value by means of complex innovations demands immense infrastructural adjustments and strategic decisions on a local level in terms of buildings and technical facilities, maintenance, Information Technology preparations, logistics, safety assurance and sterilization, human resource policy, personnel training, dealing with liability issues, publicity, return on investment, possible horizontal/vertical integration, engagement in public-private partnership for incremental development, interoperability and operational seamlessness, coordination, and last but not the least, setting up clinical trials and/or outcome registries to develop clinical practice guidelines and generate evidence on large-scale, long-term outcomes. On this perplex platform, exploring how promises come true and how practices perform is of key importance. The more complex the technology, the more detailed and diverse are the attributes of value that play a role within the setting of use.

ASSESSING PROMISES & PRACTICES: CONSTRUCTIVE TECHNOLOGY ASSESSMENT

Promises and practices render certain value propositions with reference to the nature, size, and plausibility of the benefits claimed (Campbell, 2012). The enquiry of value of medical innovations amounts to a systematic exploration of these attributes in the setting of technology use. The sociology of technology provides a methodological orientation for assessing the value of emerging medical technologies, namely, under the Constructive Technology Assessment (CTA) paradigm (Douma et al., 2007; Lehoux, 2006). However, such an approach is not well integrated into Health Technology Assessment (HTA) yet.

A constructive approach enables us to simultaneously capture the socio-organisational processes underpinning promises and practices in a single assessment.

This mode of investigating is pragmatic. The assessor tracks a certain technology systematically in a natural local setting. She/he describes in-depth the 'why' and the 'how' of the innovation as seen through the eyes of diverse stakeholders and potential users. The investigation also considers how evidence from existing clinical and economic studies are acted upon. Such an assessment provides us with a rich *understanding* of the innovation's value according to the ways it is adopted and used in real world. The aim is to stimulate debate and reflection on the social and ethical desirability of the innovation with reference to its actual benefits and eventual impact on resource (re)allocation. This critical societal appraisal may directly inform decision-makers or, indirectly, the design of clinical or economic assessments. In the case of robotic surgery, a constructive assessment 'constructs' how the promises and patterns of technology use may end up with service overuse, while also triggering a policy debate on how to counteract misallocation of resources as result of this value consequence.

CTA can be very informative in the early stage of complex emerging technologies (Abrishami et al., 2014; Douma et al., 2007; Lehoux, 2006). CTA can satisfy the needs of decision-makers by targeting the loci of value – promises and practices – in real world. Hence, CTA helps overcome the criticism leveled at mainstream HTA of commonly targeting technology in a stand-alone setting, detached from its real-life circumstances (Ashcroft, 2012; Battista, 2006; Blume, 2013; Faulkner, 2009; Lehoux, 2006; Ulucanlar et al., 2013). By accommodating a systematic exploration of the innovation's real-world value, CTA is well equipped to guide value-based decision-making on complex medical innovations in the early stages.

REFERECNCES

Abrishami, P., Boer, A., Horstman, K. (2014). Understanding the adoption dynamics of medical innovations: affordances of the da Vinci robot in the Netherlands. *Social Science & Medicine*, 117, 125-133.

Ashcroft,R.E. (2012). Health technology assessment. In: R. Chadwick (Ed.), *Encyclopaedia of Applied Ethics*. Elsevier, Oxford, pp. 556-565.

Battista, R.N. (2006). Expanding the scientific basis of health technology assessment: a research agenda for the next decade. *International Journal of Technology Assessment in Health Care*, 22(03), 275-280.

Blume, S.S. (2013). Medical innovations: Their diffusion, adoption, and critical interrogation. *Sociology Compass*, 7(9), 726-737.

Boer, A., (2014). Choices in Health Care: Truth and Values. Inaugural Lecture. http://www.bmg.eur.nl/fileadmin/ASSETS/bmg/Onderzoek/Oraties/Boer/Oratie_Bert_Boer.pdf Accessed 1 March 2016.

Borup, M., Brown, N., Konrad, K., van Lente, H. (2006). The sociology of expectations in science and technology. *Technology Analysis & Strategic Management*, 18(3-4), 285-298.

Campbell, B. (2012). How to judge the value of innovation: More evidence is needed but "promise" is important early on. *British Medical Journal*, 344(7858), 7.

de Vries,G., & Horstman,K. (2008). Learning from the work that links laboratory to society. In: G. de Vries, & K. Horstman (Eds.), *Genetics from Laboratory to Society. Societal Learning as an Alternative to Regulation*. Palgrave Macmillan, Basingstoke, pp. 171-190.

Douma, K.F., Karsenberg, K., Hummel, M.J., Bueno-de-Mesquita, J.M., van Harten, W.H. (2007). Methodology of constructive technology assessment in health care. *International Journal of Technology Assessment in Health Care*, 23(02), 162-168.

Faulkner, A. (2009). *Medical Technology into Healthcare and Society: A Sociology of Devices, Innovation and Governance.* Basingstoke: Palgrave Macmillan.

Gelijns, A., Rosenberg, N. (1994). The dynamics of technological change in medicine. *Health Affairs*, 13(3), 28-46.

Henshall, C., Schuller, T. (2013). Health technology assessment, value-based decision making, and innovation. *International Journal of Technology Assessment in Health Care*, 29(4), 353-359.

Institute of Medicine (2010). *The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary. Synopsis and Overview.* Washington (DC): National Academies Press.

KNAW (2014). *Evaluation of New Technology in Health Care. In Need of Guidance for Relevant Evidence.* Amsterdam: Royal Netherlands Academy of Arts and Sciences (KNAW).

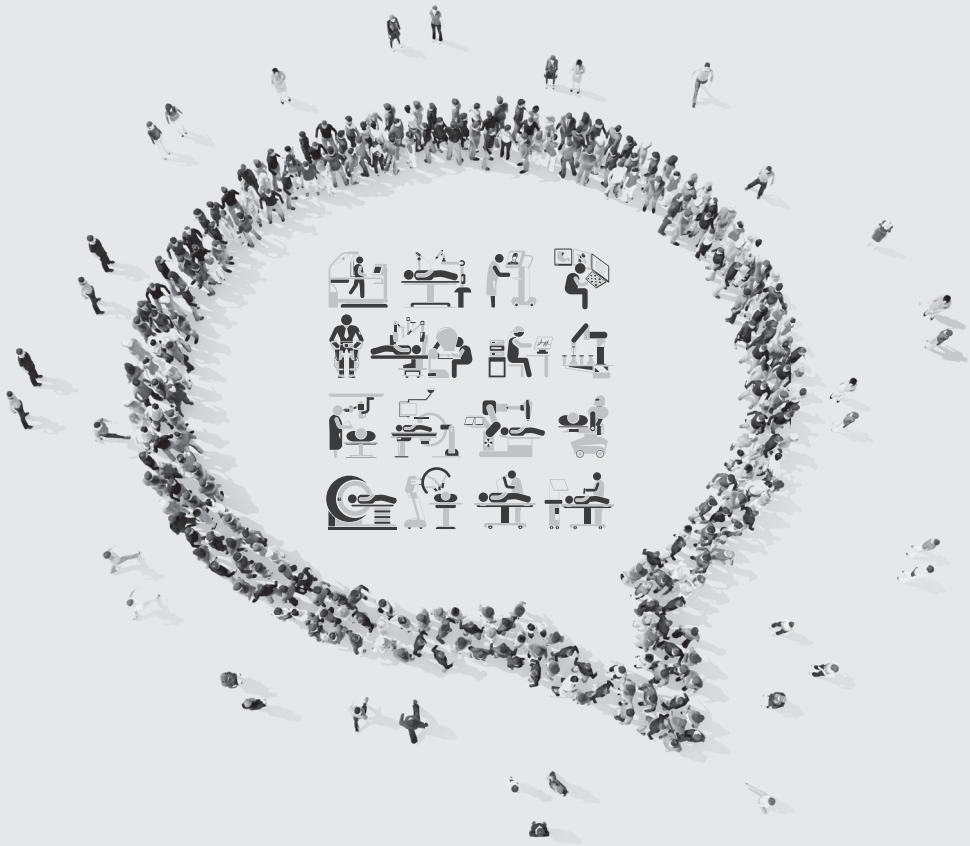
Lehoux, P. (2006). *The Problem of Health Technology: Policy Implications for Modern Health Care Systems.* New York: Routledge.

Mesthene,E. (2003). The social impact of technological change. In: R.C. Scharff, & V. Dusek (Eds.), *Philosophy of Technology: The Technological Condition*. Blackwell, Oxford, pp. 617-637.

Porter, M.E. (2010). What is value in health care? *New England Journal of Medicine*, 363(26), 2477-2481.

Ulucanlar, S., Faulkner, A., Peirce, S., Elwyn, G. (2013). Technology identity: the role of socio-technical representations in the adoption of medical devices. *Social Science & Medicine*, 98, 95-105.

Webster, A. (2004). Health technology assessment: a sociological commentary on reflexive innovation. *International Journal of Technology Assessment in Health Care*, 20(01), 61-66.



7 Embracing the public value of medical innovations

"All human beings are members of one frame,
Since all, at first, from the same essence came.
When time afflicts a limb with pain,
The other limbs at rest cannot remain.
If thou feel not for other's misery,
A human being is no name for thee."

(Adorning the wall of the United Nations building;
from Sa'adi, the 13th-century Persian poet)

The concept of innovation carries a strong connotation of novelty. Innovation is about the latest idea or object; one that is also supposed to be *better*. This dissertation has focused on this betterment – the value – of medical innovations. How do we know whether a medical innovation is better? Which visions of betterment drive the introduction of medical innovations in the health care system and which ones subside in real life? What does this mean in relation to the socially-responsible introduction of technology and its evaluation? In this final chapter, the main findings of this study are summarised, methodological considerations are addressed, and the contributions and implications of the study are discussed.

SYNOPSIS: EXPLORING THE REAL-LIFE VALUE OF MEDICAL INNOVATIONS

This dissertation has sought to address the betterment (value) of new medical technologies in publicly-funded health care systems with a focus on therapeutic in-hospital innovations. I have investigated diverse perspectives on an innovation's value in the real world and how the resulting insights can contribute to the socially responsible embedding and deployment of new medical technologies.

The **introductory chapter** of this dissertation explained that advanced medical innovations, even highly specialised therapeutic devices that seem at first glance just clinical or technical devices, do indeed have public significance, i.e., their (large-scale) introduction and use can pose challenges to the sustainability of health care systems, to social solidarity, and to the ethical suitability of medical services. I referred to these challenges as the 'public problem' of medical innovations. The study adopted the approach of techno-anthropology, developed at the interface of the fields of Science and Technology Studies (STS) and anthropology. This approach is composed of two steps: a qualitative, problem-oriented examination of human-technology relationships, and a subsequent interpretative analysis of how the resulting insights can inform those in charge of making actual decisions how to deal with the societal challenges of new medical technology. In congruence with these dual aims, the study took on a constructive investigative orientation: (*a*) to explore in-depth the social dynamics of introducing a new medical technology according to the ways it is perceived and constructed in practice and (*b*) to connect such insights with the knowledge base of health technology assessment (HTA). This study premised that

inquiring into an innovation's real-life value serves the purpose of addressing the public problem of new medical technology during its introduction phase.

Accordingly, in the **second chapter** of this dissertation, I explored the social dynamics of medical technology adoption by examining one specific case, the *da Vinci*® surgical robot in the Netherlands. This innovation assists surgeons to perform minimally invasive operations while seated at a console. It has been widely adopted worldwide and demand for it is still rising, despite its high costs and controversies about its superiority. Drawing on the conceptual-analytical notion of 'affordances', I examined why this new technology has been so well received in clinical practice and which value perspectives drove its early introduction. Affordances refer to the different meanings, promissory visions, and explicit or symbolic utilities that are recognised by actors within the social context of technology adoption and use. In a nutshell, affordances render *invitations for action*. The enthusiasm for demanding the da Vinci robot was driven by interrelated and mutually reinforcing affordances in order to achieve clinical, scientific (research), and entrepreneurial excellence. The innovation was adopted to pursue progress, precision, prestige, pioneering, performance, and profit. When shared within a network of interacting stakeholders, these affordances may make the take-up and use of the surgical robot sound perfectly rational and inevitable, hence a 'no-brainer'.

The subsequent study of the same innovation, presented in **chapter three**, highlighted that whether this innovation is actually better has been fiercely contested after its early introduction phase, despite 15 years of rising adoption and extensive (peer-reviewed) publications. The innovation's value was explored for the removal of cancerous prostate using the approach of 'mapping controversy from literature to actors'. Not only published studies (the formal research arena) but also the perspective of stakeholders involved in deployment of the innovation (the informal discursive arena) present a crowded platform of diverse, often polarised arguments on the value of robotic surgery. What was unclear a decade ago due to *lack* of evidence is still unclear because of *controversies* about evidence. Disputes involve respondents' disagreement with one another or their dissent from the current mainstream state of research and surgical practice. Controversy is all-pervading, ranging from inconclusive study results, to immense variation in designs, methods and purposes of studies, right down to what the very concept of 'value' constitutes. Mapping controversies on robotic surgery reveals the foundational roots of the dispute. Controversies rest on a multitude of value perspectives that are – in varying degrees – affiliated

with the innovation-based, market-based, or evidence-based considerations of technology introduction. They display diverse knowledge claims, reasonings, problem framings, social network alignments, vested interests, and symbolic (or cultural) values.

The case studies underscore the significance of an in-depth understanding of the processes of technology introduction. They indicate that introducing a medical innovation in clinical practice (hence into the health care system) is a social phenomenon: one that is characterised by the interconnectedness of diverse stakeholders and the heterogeneity of value perspectives; one that is rooted in different normative ideals of 'good care' or certain (personal) interests, while also being tightly intertwined with factual and technical aspects. This is the ground on which the public problem of medical technology emerges. The innovation's worthiness, i.e., 'why' introduce a certain technology and 'how' to achieve value in practice remains – sometimes considerably – contingent.

The rest of the dissertation involves conceptual analyses of the orientation of HTA and the direction of its development in light of the insights gained from the case studies. In **chapter four**, I expanded on the example of robotic surgery and described how we can address the public problem of complex in-hospital innovations when existing knowledge claims are incomplete, values contested, stakes high, and decisions urgent. In such situations, a central task of stakeholders is the management of uncertainties. Drawing on the literature, I argued that stakeholders' engagement in a collaborative discursive appraisal of technology is indispensable for a value-driven introduction of new technology, because many value issues are not easily amenable to a calculative, one-size-fits-all assessment. Stakeholders, including the receivers (patients), the operators (professionals), the researchers (evidence producers), the contractors (commissioners/insurers), the regulators (policy-makers) and the public (tax/premium payers) will learn from one another and take their understanding of value upstream, towards creating value for society at large. A collective debate can be part of the development and implementation of, for instance, an innovation's value-driven business models, centralization plan, conditional coverage/access, clinical practice guidelines, and benchmarks for appropriate use.

A critical societal appraisal of an innovation can take place, in which benefits and uncertainties (including measurable risks, foregone opportunities, and matters of concern to all stakeholders) are collectively explored, learnt from, and compromised upon. Guidance is provided comprising many potentially

challenging value issues concerning in-hospital innovations that need to be resolved. Robust deliberation can serve to equip workable (re)solutions under conditions of uncertainty and controversy. Such a discursive endeavour to *jointly* legitimise 'why' an innovation's outcomes are desirable and 'how' state of the evidence and practice of the innovation can be optimised to fulfil the right impacts, is what I referred to as 'value in co-creation'.

The fifth and sixth chapters examined the capacity of current HTA frameworks to deal with the public problem of complex medical technologies. This policy-oriented field of research has the burden of persuading a broad spectrum of stakeholders whether the adoption, continuing spread, and use of a new technology is valuable to society. Though the assessment of clinical effectiveness and cost-effectiveness on which existing HTA frameworks largely rely is necessary, it is not, in itself, sufficient for providing an uncontested insight into an innovation's society-wide value.

In **chapter five**, I joined the debate in the HTA literature about whether it is necessary to address wider societal values of health care interventions on top of a cost-effectiveness analysis. I argued that HTA needs to be fit for its purpose, i.e., informing legitimised decision-making on the introduction and use of health care interventions. This view holds that 'relevance' to the health (care) needs of the population must define the ingredients and methods of HTA. The relevance, in turn, needs to be justified with adequate reasoning. Inquiring into an innovation's public values then becomes inevitable. This encompasses budget, resource distributional, and fairness (equity) considerations on the one hand, and all the value judgments underlying calculative assessments on the other. It is this striving for a wider 'reasonableness' that brings HTA closer to its core societal mandate. Once reasonableness is the guiding principle for HTA frameworks, attention will be paid to eliciting and debating attributes of value in the real world because these attributes render the *de facto* reasons behind decisions on new technology.

This is the subject of **chapter six**. The enquiry into the value of medical innovations will then amount to a systematic exploration of an innovation's 'promises' and the 'practices' involving that innovation. Promises and practices represent diverse 'reasons' underlying technology introduction with reference to the *desirability* and *plausibility* of the benefits claimed (correspondingly, the 'why' and the 'how' of value). A Constructive approach in HTA, i.e. CTA, enables us to 'construct' the public problem of new medical technology by eliciting these

reasons and relating them to one another and to the wider societal values that health care systems want to achieve. In so doing, CTA can stimulate debate, collective learning, and reflexivity on the public value of medical innovations, thereby contributing to their socially-responsible introduction into the health care system.

METHODOLOGICAL REFLECTION

I. Strengths and limitations

This dissertation consisted of case studies (with a constructive investigative orientation) and interpretative knowledge syntheses. In chapter one, I explained the rationale of such an approach. It was designed pragmatically to provide an in-depth understanding and an integral appraisal of the introduction of medical innovations. The generic strengths and limitations of the chosen methodology could be said to be its defining characteristics. It provides us with a reconstruction of reality that is flexible, wide-angle (broad), and fit for the purpose of in-depth understanding and stimulating debate, while on the other hand, it is bulky and sophisticated. More specifically with respect to the core premise of this dissertation, i.e. addressing the public problem of medical technologies, the results of this study must be read in the light of a number of limitations in its design and conduct.

First, the focus of this study is on the entry of new technology into clinical care after market authorisation, i.e., when it is granted approval for becoming available on the market on a commercial scale. The pre-market or pre-launch stage of medical technologies is a crucial phase of innovation in constructing its value profile and its impact after market entry. It involves technology design, (venture) investment, regulatory approval, valorisation, and public relations. An exploration of these processes is fairly relevant for a comprehensive understanding of the value profile of medical innovations (Demers-Payette et al., 2016; Lehoux et al., 2017). This very early stage – when the technology is in a strict sense of the word 'emerging' – was not the focus of this study. It would have been an ideal addition to this dissertation, e.g., quasi-historical studies comparing a certain innovation in different stages of its development. However, this would have required a separate empirical and literature study, which went beyond the (time) scope of this dissertation.

Second, the case studies in this dissertation explored one form of medical innovation, i.e., a therapeutic medical device (the da Vinci robot), in one health care sector (hospital care), within one specific context (mostly in the Dutch health care system). The dissertation did not include comparisons across any of these domains. When designing the second case study on robotic surgery, I initially considered comparing it with another technology or comparing the Dutch case with another health care system, but I preferred an in-depth study. The choice of a case-of-one study was nevertheless made pragmatically, in accordance to the (time) scope of this project and with regard to the fact that I had already researched this innovation before.

Third, in chapter four I described the fruitfulness of participatory appraisal of in-hospital innovations. The arguments in favour of stakeholder participation in the case of in-hospital technologies as well as the guidance for deliberation developed in this chapter remain conceptual works. As emphasised in the chapter, the actual effect of such collaborative creation of value need to be examined in practice through real-world examples. Within the time frame of this dissertation, however, there was no room to organise deliberation sessions to examine how multi-stakeholder deliberation on an in-hospital innovation could work out in practice. The chapter has nevertheless paved the way for implementing participatory frameworks for in-hospital innovations, while also referring to several examples of public debates in other technology areas that we can learn from.

The limitations of this study point in the direction of future research to address the public problem of medical innovations. Comparative (case) studies can generate valuable insights regarding the social dynamics of introducing health care technologies. Such studies can complement single in-depth case studies. Comparisons can be made across several dimensions, depending on the exact focus of the study, for instance comparing the introduction of different technologies in one setting (hospital devices versus digital technologies or patient aids), in different types of care (therapeutic, primary care, preventive, long-term care), across health care systems/jurisdictions, or across technology sectors (health care versus education, defence, aviation, energy, agriculture sector, etc.). Exploring the social dynamics of medical innovations can be conducted through comparative empirical case studies such as that of Ulucanlar et al., in which they comparatively examined a number of innovative technologies in the English health care system (Ulucanlar et al., 2013). Comparisons can also be the subject of separate meta-syntheses. The findings of this dissertation can be

compared in a separate analysis with for instance, those of Compagni et al., in which they extensively examined the dynamics of robotic surgery introduction in Italy (Compagni et al., 2015; Mele et al., 2014); or they can be compared with the study of Agic, in which the social dynamics of mechanical help-heart implantation treatment was explored (Agic, 2012).

II. Representativeness

Related to limitations is the generalisability of the insights developed in this dissertation. Both the case studies and interpretative analyses are situated (context-specific) and problem-oriented. They were designed and conducted within a purposive framework pertaining to understanding and appraising the public problem of advanced medical technologies within publicly-funded health care systems. The findings of this study and the interpretations made could be recognisable in similar situations within this framework.

As an example of techno-anthropological research, this study provides a 'special kind' of representativeness. It involves neither the statistical representativeness of the case studies or study samples, nor how far individuals' perspectives are verbatim applicable in other (study) settings. Rather, certain *concepts* and ways of thinking about the case and its underlying problems can be transferable to other instances of socio-technical practice. This is referred to as a 'heuristic' and a 'conceptual' generalisation (Greenhalgh et al., 2011). The former involves achieving a clearer and comprehensive understanding of what is going on. The term heuristic refers to an approach to problem-solving that employs a practical method of finding a satisfactory solution based on learning and tacit knowledge (Wikipedia). The latter, conceptual generalisability, refers to theoretical abstraction, i.e., making sense of – and reasoning from – all the 'specificities' of the case to develop 'resemblances' and to produce analytic statements that can be transferable to other technologies/settings (Green & Thorogood, 2005; Greenhalgh et al., 2011). Such work can then be a source for sensitising stakeholders (raising their awareness), reflexive learning, and triggering a more productive collective debate (see below).

One aspect of the heuristic generalisability of this dissertation relates, in addition to a wide-angle exploration, to its *suggestiveness*. For instance, by exploring and understanding the adoption dynamics of robotic surgery and its *particular* nuances/details, we also enrich our *general* understanding of what it is to introduce a new technology, or even more generally, what new technology does, or

what the public problem of innovations *is* (Lehoux, 2006; Zuiderent-Jerak et al., 2011). This is because immersion in details enables us to heuristically understand complex cases and wicked problems (Greenhalgh et al., 2011). Chapter two, for example, reveals the performativity of da Vinci surgery in shaping the context in which it is used. This interdependence of means and ends is a recurrent 'concept' in many studies on emerging health care technologies and even policy instruments (Lucivero, 2016; Zuiderent-Jerak et al., 2011). Chapter three shows controversies about the value profile of one specific technology at this point of time. The interplay of facts and values in the innovation's social context, however, is again a concept explained when mapping controversies or organising public deliberations on many other health care technologies and in different countries (O'Doherty et al., 2013). In another instance, exploring the social dynamics of technology introduction can be suggestive of the social dynamics of innovation's non-adoption/rejection (and vice versa). Similarly it could suggest certain power relations among stakeholders that are likely to play out, to a greater or lesser extent, in the case of other health care innovations, notably complex therapeutic devices, health informatics innovations, or perhaps more generic emerging technologies such as genomics.

UNDERSTANDING AND CONNECTING: WHY BOTHER?

This study has examined two premises in dealing with the public problem of complex medical innovations: (*a*) to regard medical technology introduction as a social phenomenon, constitutive of innovations' actual value profile and (*b*) to connect innovations' social dynamics with technology assessment frameworks. As described in chapter one, the dissertation adopted the approach of 'techno-anthropology' (Børsen, 2013). Central to the work of techno-anthropology is *comprehension* and *connection*. These aims respectively amount to providing an in-depth, problem-oriented analysis and using the resulting insights to create 'critical proximity' between stakeholders/fields of expertise from particular professional cultures such as technology design, deployment, and regulation (Børsen, 2013; Lehoux et al., 2017). This work can also serve as an intermediary between techno-scientific projects and the perspectives of patients and the publics (Børsen, 2013; Botin et al., 2015). In congruence with this descriptive-connective purpose, the study's contribution to the public legitimacy of introducing medical technology is twofold: enhancing our understanding of the inherent complexities and value pluralities in innovation trajectories and feeding the knowledge infrastructure of health care with such insights to address the public

problem of medical technology. The findings of this dissertation – and more generally, techno-anthropological investigation of medical innovations – can provide, respectively, comprehension and connection.

I. Unblack-boxing an innovation's value profile

Unless ignorance is decisively chosen, understanding is a must when facing a complex situation. Innovation processes are complex. Our capacity to know needs to keep up with the novel scale of modern-day technological progress in medicine. As the complexity and interdependencies between different actors, structures, and networks of an innovation ecosystem increase, the dynamics and processes are subject to an ever-increasing sophistication. Moreover, innovation is an intensely future-oriented enterprise (Borup et al., 2006). Introducing a new technology usually involves self-promotion and persuasive efforts, which can effectively conceal from view that an innovation's value is here and now 'in the making'. An innovation's value is thus often 'black-boxed' with an array of promises, idealised imaginaries of an ultimate state, and tacit assumptions, whose desirability (the 'why') and plausibility (the 'how') are often deemed evident or whose fulfilment in the future is firmly believed, hence remaining largely taken-for-granted (Lehoux, 2006; Lucivero, 2016; Macnaghten et al., 2005; Moreira, 2012). Besides earlier statements made about robotic surgery, consider excerpts from a debate between two surgeons organised by the American College of Surgeons (ACS), which typically illustrates da Vinci surgery's black-boxed value:

> Dr. F.: Do we really need the robot?
>
> Dr. W.: Absolutely! It's going to take morbidity and mortality to another whole step dropping … We have to learn how to use it and how to use it well. And if we do so, we're going to see significant changes in clinical outcomes down the road (ACS, 2016).

As another example, though beyond the focus of this dissertation, consider CRISPR, a highly-promising emerging gene-editing technique. Currently in a preclinical phase, it is considered as medicine's breakthrough – and a topical issue in science journalism – with "the potential to change the lives of everyone and everything on the planet … Scientists envisage organ farms of the future

providing an endless supply of hearts, lungs, livers, and kidneys for transplant" (BBC Panorama 06.06.2016).[9]

Unblack-boxing medical innovations offers an in-depth analysis and simultaneously denotes the relevance of such a 'thick account' of medical innovations' real-world value (Ashcroft, 2012). Unblack-boxing involves investigating, mapping, and making sense of an innovation's value problems through a social constructive lens. It is a means to analytically examine scientific, technical, structural, socio-political, and ethical aspects underpinning an innovation's dynamics within an evolving social context of emergence and use – referred to in chapter one metaphorically as an ecosystem. This enables us to handle the challenges of studying 'the real' when making sense of a practice-based social phenomenon such as technology introduction: that reality is messy, evolving, situated, and interpretable. Opening up the black-box of medical innovations reveals three characteristics of the construction of innovations' real-world value and their public problem. These are as follows.

I.a. Fluidity

Unblack-boxing medical technology's value profile reveals and underscores the pivotal fluid nature of technology introduction and the construction of its actual value. Technology affordances and controversies about value all highlight this fluidity: that innovation, provision, evidence generation, and regulation are *hybrid* entities.[10] As case studies show, decisions to introduce an innovation into the health care system are made in the space between the built-in technical, factual and instrumental elements on the one hand, and promises, hopes and preferences on the other. This is in line with a broad array of empirical and theoretical insights generated by Science and Technology Studies (STS) on innovations in clinical care, life sciences, and beyond (Betten et al., 2013; Boer, 2014; Borup et al., 2006; Lehoux et al., 2010; Macnaghten et al., 2005; Moes et al., 2017; Sarewitz, 2004), not to make the reference list any longer. Values are all over the place in the real-life of medical innovations, in their development, deployment, and assessment (see also chapters two and five).

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9 CRISPR, an abbreviation of Clustered Regularly Interspaced Short Palindromic Repeats, is a family of DNA sequences that can act like a pair of 'scissors' to alter DNA. This techniques can make cross-species tissue growth and repairing defected genes possible.

10 According to sociologists Mol and Law, social phenomena exist in different spatial forms. What is considered as 'the social', they argue, can take place in 'fluid spatiality'. This is a kind of social space, in which entities are neither delineated by boundaries nor by linear relations. Instead, entities are evolving and may be similar and dissimilar at different locations within fluid space (Mol & Law, 1994).

Controversies about the evidence basis of da Vinci surgery showed how the different considerations in designing and conducting research are value-laden. Therefore, in order to understand the value of an innovation in the real world, one has to go beyond the artificial dichotomous analyses between society and technology, between facts and wants, subjective and objective, qualitative and calculative, and between universal standards and local specificities. Indeed, one has to immerse oneself in the fluidity and actuality of the 'technological culture', wandering about between different expert cultures across professional borders/fields of expertise in the innovation landscape (Bijker, 2001). To unblack-box an innovation in real-life is to subject technology introduction to a kind of cultural study, while also exposing the innovation's value profile to a cross-border (i.e., collective) scrutiny.

I.b. Discursivity

Deconstructing the dynamics of technology introduction exhibits the discursive nature of the public problem of medical technology (and as such, also the task of dealing with it). Case studies show how the many processes underlying the introduction of a new medical technology primarily belong to the realm of informal interpersonal relations rather than formal instrumental ones. Issues such as fear of missing out, prestige, being a forerunner, passion for progress, etc., that underlie the marketing and the spread of robotic surgery, are *real*. Discourses are constructed, shared, and used by stakeholders to shape 'frames' to make sense of and give sense to a particular issue of interest (Phillips et al., 2004). As chapter two showed, this discursive realm is, however, performative, drawn on certain dynamics of 'promise and requirement' (van Lente, 2012). Affordances become part of a shared agenda and entice isomorphic actions, i.e. in this case, adoption of da Vinci surgery (Compagni et al., 2015; van Lente, 2012). The point is that discourses – and the discursive dimension of technology introduction – are *not* trivial in shaping human decisions (unless one dismisses behavioural-economic research or claims that advertising does not work)! Acknowledging the discursive elements of technology introduction processes, then, brings the interpersonal arena into the spotlight during any attempt to understand and appraise the value of new medical technology. Attending to the discourses becomes indispensable on the part of all actors (thus including me, researching the discourses). According to Bijker, the Dutch pioneer of the mutual shaping of technology and society scholarship, all inhabitants of the technological culture – developers, users, assessors and the public – have a commitment to try to understand one another (Bijker, 2001). This clarifies what stakeholders must strive for when introducing a new technology: inquiring into one another's world and mutually learning about one another's concerns.

I.c. Normativity

In-depth insights from unblack-boxing a new medical technology reveals the normative nature of its introduction. The process of constructing an innovation's value is, in accordance with a large body of STS literature, not neutral but has normative significance and moral connotations. Various normative assumptions and prescriptive expectations are involved in technology introduction and evidence generation that are often hidden or presented as abstract or taken for granted (Lehoux, 2006; Lucivero, 2016; Moreira, 2012). Yet, they play a performative role that is *not* neutral. In his book on understanding the morality of technology, Verbeek describes the normative significance of a new technology in its role as 'mediator of human-world relationships' (Verbeek, 2011). Technologies constantly perform this mediating role by 'amplifying' certain perceptions/actions and 'inhibiting' others (*ibid.*). A new technology, therefore, amplifies particular conceptions of excellence and simultaneously inhibits others. Certain values and prescribing concepts then prevail. Examples are abundant, da Vinci surgery aside (chapters two and three): from how a particular understanding of 'deafness' dominates alongside the spread of cochlear implant technologies, to how women are made more responsible *and* more blameworthy for unwanted pregnancy in the case of contraceptive pills, to how a particular image of body and beauty is endorsed by cosmetic interventions, to redefining the concept of 'death' with the development of organ transplant interventions, to name a few. A social-constructive exploration of medical technology introduction sheds light on this normative reconfiguration. It provides us with a framework, capable of understanding and reflecting the normative implications of this technological mediation. This approach does so in two interrelated ways: (*a*) by making explicit the value perspectives (reasons) driving technology introduction, and (*b*) by explicating the normative standpoints underlying stakeholders' expressed values and confronting them with the higher societal objectives that health care systems want to achieve.[11]

The above-mentioned characteristics explain why excavating and understanding an innovation's dynamics is necessary. The 'inner core' of an innovation's social context is often hot, i.e., there are often a multitude of (justified) answers to one question, the question of an innovation's betterment. The nationwide implementation of the smoking secession program and electronic patients

11 The objectives of a health care system can in a nutshell be explained as sustainable improvement of the population's health with better, fewer, or less costly interventions (Goetghebeur & Wagner, 2017). See also chapters one and four.

record systems in the Netherlands are two heated examples.[12] Unblack-boxing medical innovations' social dynamics in the real world reveals some grass-root tensions in their introduction processes. This dissertation examined these tensions in the case of the introduction of da Vinci surgery. On the one hand, the decisions on introducing new technology – which at first sound merely local-individual and clinical-technical – are highly consequential on macro-level and non-technical (socio-economic and ethical) grounds. On the other hand, these decisions are driven by diverse goals, including the achievement of what is allowed by public health care systems in reality (see figure 1). These goals often collide (in theory and practice) to the extent that 'doing the best at all levels, for patients, populations, and healthcare systems' (Goetghebeur & Wagner, 2017) remains inevitably *frictional*.

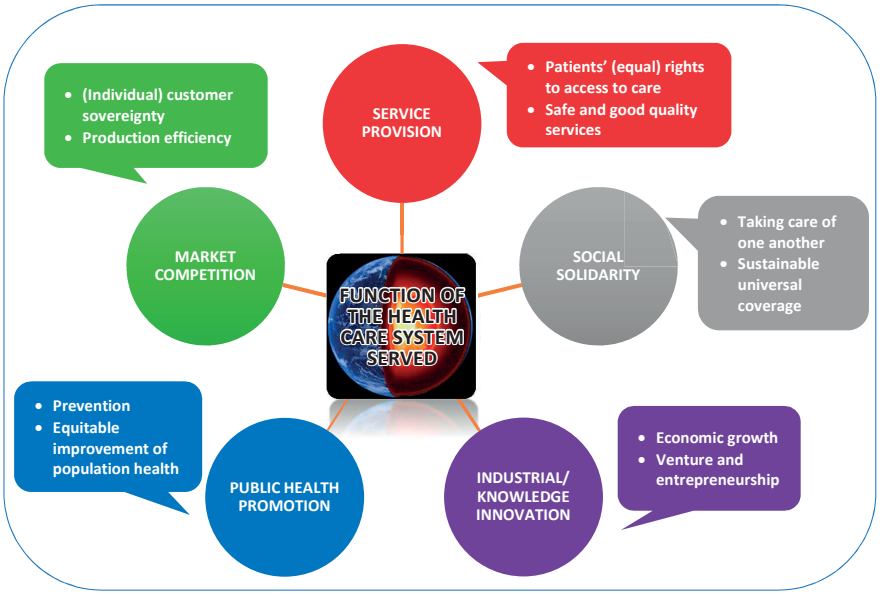

Figure 1. *The hot inner core of medical technology's public value.*

Where there is more than one framework for assessing worth, tension emerges. This tension can, however, be fairly productive. Rather than conceiving it as a 'barrier' to innovation, stakeholders can attend to it and make the articulation of

12 In the case of electronic patient records (EPR), Michel-Verkerke et al. described the six P's that need to be taken into account. The first three refer to users of the EPR: Patients, Professionals, and the Public. The latter three show the action types of a nation-wide EPR, namely: Purpose, Process, and Prerequisites (Michel-Verkerke et al., 2015).

a technology's public problem as part of their business process. This can serve as a reference point to inquire into an innovation's betterment based on proximity to serving societal problems. As a result, *value-driven* strategies can be devised for the design, deployment, assessment, and regulation of new technology. Resembling social psycho-analytics, unblack-boxing medical innovations, reveals this friction and, at the same time, endorses embracing it.

II. Connecting the dots within a medical innovation's ecosystem

With a wide-angle understanding of a technology's value comes a potential to connect knowledge domains and practices. Unblack-boxing an innovation's value profile provides fluid, problem-oriented insights that can directly feed the innovation's knowledge-base, namely the HTA. They can also act as 'linkage' to circulate knowledge among different elements in the innovation's ecosystem (Lomas, 2007; Ward et al., 2009). Such *knowledge brokering* can identify new research foci and horizons, while also enhancing alignment between decisions on evidence generation, technology acquisition, patient education, service provision, and regulations (Fournier, 2012; Lomas, 2007).

II.a. Integrating 'constructive' evaluation logic into HTA

In-depth insights into innovations' dynamics involve a reconstructive, 'social mapping' investigation. Chapter three provided an empirical case in point. It can be positioned at the interface between the worlds of technology evaluation, namely, STS and HTA. Such insights can contribute to the role, methodology, and future direction of HTA by enriching its empirical and theoretical contents (i.e., building capacity) or it can facilitate cross-fertilisation of these investigative approaches by extending concepts from one to the other (i.e., integrating knowledge).

Mainstream HTA can learn from the field of STS to be more responsive to the social construction of technology and its actual impact. This opens up new foci in assessing medical technologies, characterised by attentiveness to real-world practices in the early stages of innovations, particularly by incorporating a systematic exploration of an innovation's promises and practices into HTA (see chapter six). This can also respond to the call for a more flexible, 'non-one-size-fits-all' approach to evaluating new medical technology, one that is informed by the contextual knowledge and a 'linked' perspective on evidence (KNAW, 2014; RVS, 2017). HTA can broaden its scope by taking into account the normative practices stakeholders regard as more desirable. It can *integrate* the

'value drivers' that underlie stakeholders' decisions into assessments and make them explicit for cross-stakeholder and public examinations; it can elicit values and focus on the relational character of the norms mediated through technology use. This can complement recent attempts to quantitatively incorporate more aspects of a technology's value into economic assessments when calculating an innovation's value for money, known as 'extended cost-effectiveness analysis' (Garrison et al., 2017).[13]

In addition, inclusive and nuanced insights into the real world of medical innovations can help HTA become more reflexive to its *purpose* and social mandate, i.e., to 'potentiate the capacity of public health care systems to reach their goal'. HTA development has so far focused mainly on its methodology rather than its purpose and knowledge basis (Lehoux, 2006; Moreira, 2012). Integrating perspectives from STS adds a reflexive character to HTA that invites stakeholders to reconsider the meaning of technological progress and to reflect on the tendency to subordinate ends to means that comes from an emphasis on technological progress in the modern era (Lehoux, 2006; Moreira, 2012). Such reflections are not a 'replacement' for conventional HTA studies, but a crucial addition to them, and a 'companion' in innovation trajectories (Schot & Rip, 1997). Of course, mainstream STS research may also learn from HTA, though elaborating on this goes beyond the scope of this dissertation. For instance, STS studies can take the urgency of making decisions into account and integrate the resource scarcity considerations of technology utilisation into assessments (Lehoux, 2006; Moreira, 2012).

II.b. Linking HTA and practice improvement

Focusing on an innovation's social dynamics in studying medical technologies involves transcending the object of study from technology in solo to socio-technical *practices*. This provides more inclusive insights into an innovation's actual value profile. Building such 'thick' descriptions into mainstream HTA can help us overcome the criticism levelled at mainstream HTA of commonly targeting technology in a stand-alone setting, detached from its real-life circumstances.

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13 Economic evaluations commonly employ methods such as conjoint analysis (e.g., discrete choice experiment or contingent valuation) to elicit willingness to pay for the intervention in question, as a representative of a technology's value for money (Bridges et al., 2011).

Once socio-technical practices are placed centre stage in technology studies, medical technology introduction can be regarded as real-world 'societal experimentation' rather than a theory-testing experiment (de Vries & Horstman, 2008; Gross & Krohn, 2005). As described in chapter four, in such societal experiments, the state of knowledge on an innovation's value is fledgling and evolving, hence it is incomplete at any given moment (RVS, 2017). Our knowledge of medical innovation's value is thus shaped by a combined real-world assessment and practice improvement. This implies integrating the retrospective approach of an assessment with the prospective approach of reducing uncertainties in practice (Ciani et al., 2016; Frønsdal et al., 2010). As the case of robotic surgery showed, this amounts to the interrelationship between evidence generation and training, business arrangements, team coordination, implementation issues, etc. In a societal experiment, the centrepiece of evaluation-improvement practices is clearly *trade-offs* and it is a compromise of the merit of one option relative to other options in the process of technology introduction.

To that end, studies of innovations' social dynamics provide insights for analysing and identifying possibilities to 'modulate' technology developments at an early stage. Modulation here refers to the attribution of responsibility to different stakeholders during the process of technological introduction, when a new technology's impact is in the making (Lucivero, 2016). The modulation of ongoing socio-technical practices is a concept introduced by STS scholar Arie Rip as an alternative to top-down policy directives in the governance of technological innovations. Modulation involves the alteration of technology introduction practices in accordance both with existing constraints and with broader societal objectives in order to achieve socially-desirable ends from technological developments (Schot & Rip, 1997). Central to modulation is reducing technological uncertainties through enhancing stakeholders' awareness and attentiveness to the consequences of decisions and nested interdependencies – both immediate and more distant ones – within the innovation ecosystem.

II.c. Linking HTA and innovation policy

Techno-anthropological analyses of innovations' real world dynamics and their value problems strengthen the link between HTA and the innovation agenda. The distinctive comprehensive-connective orientation of techno-anthropological research makes these scholarly works capable of engaging with policy debates in real-time, thereby linking academic and policy-oriented developments regarding medical innovations (Macnaghten et al., 2005; van Est & Brom, 2012).

Techno-anthropological studies can also respond to the need for knowledge domains within the innovation ecosystem that are adaptive, reflexive, and anticipatory (Macnaghten et al., 2005; Rip, 2001; Rip, 2010). Such knowledge is expected to (*a*) aid identification of the impact of technological changes, (*b*) render stakeholders more self-aware of their own taken-for-granted expectations and decisional motives, (*c*) help anticipate a technology's potential impact and further embedding in the health care system (e.g., impact on resource redistribution with reference to its recurrent patterns of adoption/utilisation), and (*d*) guide public authorities to mobilise the most appropriate financial resources and modes of governance to regulate them. This is in congruence with a philosophy of Technology Assessment that highlights its societal purpose: 'to reduce the costs of learning by error – which characterises much of our handling of technology in society – and to do so by anticipating potential impacts and future developments of new technology and by accommodating such insights in decision-making and its implementation' (Rip, 2001; van Est & Brom, 2012). In the example of da Vinci surgery, the case studies anticipated a potential service overuse and the unlikelihood of resolving contested value issues for the time being with more published clinical studies. The former has in the meantime been demonstrated in the form of supply-induced 'substitutions' between the treatment alternatives (Shen & Shih, 2016).

Studies that elicit diverse value perspectives and subject them to wider cross-stakeholder scrutiny (with respect to societal objectives such as solidarity and fairness) provide a distinctive orientation for knowledge production in technology assessment; one in which the starting point for conducing assessments is a 'wicked' policy problem rather than a technological object (Giacomini et al., 2013). This has particular implications for hospital-based HTA as it is expected to connect local and national decision-makers on innovative therapeutic devices (Martelli et al., 2017) (see also chapter four).

II.d. Connecting technocratic and democratic practices in technology introduction

Case studies and subsequent conceptual analyses in this dissertation recurrently highlight that demonstrating the value of new (complex) medical technology is a collective responsibility. Both words, 'collective' and 'responsibility' indicate that the stakeholders involved in medical technology introduction, notably those in charge of making actual decisions, must engage in mutual discourse and learning as to how to justify decisions and how to deal with the public problem of new technologies in situations of controversy, diversity of value perspectives, and contingency of value. Stakeholder participation and 'evidence-

informed deliberative decision-making' have in recent years received remarkable emphasis from scholars who have examined the role and developments of HTA (Abelson et al., 2013; Baltussen et al., 2017; Blume, 2013; Daniels & van der Wilt, 2016; Garrison et al., 2017; Giacomini et al., 2013; Husereau et al., 2016; Lehoux et al., 2009; Migliore, 2016; Moreira, 2012; RVS, 2017; Towse & Barnsley, 2013; van Est & Brom, 2012) (and I could go on with citing).

This dissertation has expanded the application of stakeholder participation from macro-level policies into the distinctive decision-making setting of adoption and implementation of an in-hospital innovation. Subjecting medical technology introduction to a multi-stakeholder discursive appraisal helps strengthen a (more) democratic governance of these innovations, in Bijker's words, 'democratising technological culture' (Bijker, 2001). This is well-attuned to the current decentralised, market-oriented processes of introducing medical innovations. It involves an *interactive* mode of governance, rather than a linear, first-innovate-then-evaluate approach. Both public authorities and private parties can thus be collaboratively involved in the whole innovation process. Done well, it can reduce the need for top-down policies (e.g., actuarial restrictions) by linking perspectives on regulatory control with technology appropriation. The aim is that expert actors involved in technology introduction elicit the preferences of patients and citizens (as taxpayers and as voting publics), but also equally important is that they engage in continual knowledge exchange and cumulative learning aimed at a combined technology assessment and practice improvement. Though not touched on in this dissertation, deliberation on innovations' value ideally includes 'upstream engagement', i.e., the participation of stakeholders involved in the very early stages of innovations such as technology designers, investors, and the industry's R&D planners (Lehoux et al., 2017).

A vast amount of STS literature is available within and beyond the health care sector on stakeholder and public participation in debating the societal desirability and ethical acceptability of techno-scientific innovations. For instance, public debate has taken place over several years about the merits and potential consequence of these innovations: environmental and human health impacts of nano-particles, about the right to know (or not to know) in cases of genetic and screening tests, or 'normal' performing of the human body and psyche in the case of human enhancement technologies (Abelson et al., 2013; Betten et al., 2013; Boenink, 2012; Lemke & Harris-Wai, 2015; Pidgeon & Rogers-Hayden, 2007). In these areas, there is recognition of the need for participation with the

aim of mutual learning and working out pragmatic solutions without necessarily reaching consensus.

By means of what is referred to in chapter four as co-creating value, the technical verification of published evidence can be intertwined with a collective interrogation of an innovation's betterment with reference to its proximity to serving societal priority problems. By connecting the dots within a medical innovation ecosystem, we can visualise 'the invisible elephant'. Defining 'betterment' forms part of this process. Stakeholders can learn from one another in a pluralistic social context, in which they have justifiably different motivations, obligations, and visions. We can respond to the problems that new technologies might throw up and limit their undesirable effects. But there is more to creating value than just mitigating risks. We can collectively establish optimal and appropriate patterns of innovation use and we can also shape the overall direction of technological developments.

ALL THINGS CONSIDERED

Delving into value plurality in a medical innovation ecosystem is gratifying and enabling, particularly in the era of 'value-based health care'. It moves us upstream in our conception of and commitment to the introduction of new technologies in health care. It is the appreciation of value plurality that prompts us to inquire into one another's worlds in search of commonalities, shared purposes: what it is that we *all* care about and how to incorporate such public value thinking into technological decisions. This is indeed a quest for us all, and a quest for all seasons. As Bruno Latour, a pioneer of STS, states in his call for ratifying techno-scientific issues in public, "it is up to us to change our ways of changing" (Latour, 1993). Embracing the public problem of medical innovations solidifies the atmosphere of democracy in our constant endeavour to reflect on and (re)define the 'value' that we create together. We can collectively work out solutions that are 'in part true and in part fair' (McMullin, 1987). We can integrate the analytic quest of 'what works' with the democratic inquiry of 'what matters' and 'what is right'. Again, a quest for us all and for all seasons. We, the inhabitants of our technological culture, are all MPs in 'the Parliament of Innovation'.[14] Let's convene.

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14 This was inspired by the metaphor of 'the Parliament of Things' (Latour, 1993).

REFERENCES

Abelson, J., Blacksher, E.A., Li, K.K., Boesveld, S.E., Goold, S.D. (2013). Public deliberation in health policy and bioethics: mapping an emerging, interdisciplinary field. *Journal of Public Deliberation*, 9(1), 5.

ACS, (2016). Two surgeons debate the robot. American College of Surgeons. http://www.generalsurgerynews.com/ Accessed 1 August 2017.

Agic, H. (2012). *Hope Rites: An Ethnographic Study of Mechanical Help-Heart Implantation Treatment.* Dissertation: Linköping University, Sweden.

Ashcroft,R.E. (2012). Health technology assessment. In: R. Chadwick (Ed.), *Encyclopaedia of Applied Ethics*. Elsevier, Oxford, pp. 556-565.

Baltussen, R., Jansen, M.P.M., Bijlmakers, L., Grutters, J., Kluytmans, A., Reuzel, R.P. et al. (2017). Value assessment frameworks for HTA agencies: the organization of evidence-informed deliberative processes. *Value in Health*, 20(2), 256-260.

Betten, A.W., Roelofsen, A., Broerse, J.E.W. (2013). Interactive learning and action: realizing the promise of synthetic biology for global health. *Systems and Synthetic Biology*, 7(3), 127-138.

Bijker,W.E. (2001). Understanding technological culture through a constructivist view of science, technology, and society. In: S.H. Cutcliffe, & C. Mitcham (Eds.), *Visions of STS: Counterpoints in science, technology and society studies*. State University of New York, Albany, pp. 19-34.

Blume, S.S. (2013). Medical innovations: Their diffusion, adoption, and critical interrogation. *Sociology Compass*, 7(9), 726-737.

Boenink, M. (2012). Debating the desirability of new biomedical technologies: lessons from the introduction of breast cancer screening in the Netherlands. *Health Care Analysis*, 20(1), 84-102.

Boer, A. (2014). *Choices in Health Care: Truth and Values*. Inaugural lecture, Erasmus University Rotterdam.

Børsen,T. (2013). Identifying interdisciplinary core competences in Techno-Anthropology: interactional expertise, social responsibility competences, and skills in anthropology-driven design. In: T. Børsen, & L. Botin (Eds.), *What Is Techno-Anthropology?* Aalborg University Press, Aalborg, pp. 35-66.

Borup, M., Brown, N., Konrad, K., van Lente, H. (2006). The Sociology of expectations in science and technology. *Technology Analysis & Strategic Management*, 18(3/4), 285-298.

Botin,L., Bertelsen,P., & Nøhr,C. (2015). Challenges in improving health care by use of health informatics technology. In: L. Botin, P. Bertelsen, & C. Nøhr (Eds.), *Techno-Anthropology in Health Informatics: Methodologies for Improving Human-technology Relations*. IOS Press, Amsterdam, pp. 3-13.

Bridges, J.F., Hauber, A.B., Marshall, D., Lloyd, A., Prosser, L.A., Regier, D.A. et al. (2011). Conjoint analysis applications in health - a checklist: a report of the ISPOR Good Research Practices for Conjoint Analysis Task Force. *Value in Health*, 14(4), 403-413.

Ciani, O., Armeni, P., Boscolo, P.R., Cavazza, M., Jommi, C., Tarricone, R. (2016). De innovatione: The concept of innovation for medical technologies and its implications for healthcare policy-making. *Health Policy and Technology*, 5(1), 47-64.

Compagni, A., Mele, V., Ravasi, D. (2015). How early implementations influence later adoptions of innovation: social positioning and skill reproduction in the diffusion of robotic surgery. *Academy of Management Journal*, 58(1), 242-278.

Daniels, N., van der Wilt, G.J. (2016). Health technology assessment, deliberative process, and ethically contested issues. *International Journal of Technology Assessment in Health Care*, 32(1-2), 10-15.

de Vries,G., & Horstman,K. (2008). Learning from the work that links laboratory to society. In: G. de Vries, & K. Horstman (Eds.), *Genetics from Laboratory to Society. Societal Learning as an Alternative to Regulation*. Palgrave Macmillan, Basingstoke, pp. 171-190.

Demers-Payette, O., Lehoux, P., Daudelin, G.v. (2016). Responsible research and innovation: a productive model for the future of medical innovation. *Journal of Responsible Innovation*, 3(3), 188-208.

Fournier, M.F. (2012). Knowledge mobilization in the context of health technology assessment: an exploratory case study. *Health Research Policy and Systems*, 10(1), 10.

Frønsdal, K.B., Facey, K., Klemp, M., Norderhaug, I.N., Morland, B., Rottingen, J.A. (2010). Health technology assessment to optimize health technology utilization: using implementation initiatives and monitoring processes. *International Journal of Technology Assessment in Health Care*, 26(3), 309-316.

Garrison, L.P., Kamal-Bahl, S., Towse, A. (2017). Toward a broader concept of value: identifying and defining elements for an expanded cost-effectiveness analysis. *Value in Health*, 20(2), 213-216.

Giacomini, M., Winsor, S., Abelson, J. (2013). Ethics in health technology assessment: understanding health technologies as policies. *Healthcare Management Forum*, 26(2), 72-76.

Goetghebeur,M., & Wagner,M. (2017). Identifying value(s): a reflection on the ethical aspects of MCDA in healthcare decisionmaking. In: K. Marsh, M. Goetghebeur, P. Thokala, & R. Baltussen (Eds.), *Multi-Criteria Decision Analysis to Support Healthcare Decisions*. Springer, Cham, pp. 29-46.

Green, J., Thorogood, N. (2005). *Qualitative Methods for Health Research*. London: Sage publication.

Greenhalgh, T., Russell, J., Ashcroft, R.E., Parsons, W. (2011). Why national eHealth programs need dead philosophers: Wittgensteinian reflections on policymakers' reluctance to learn from history. *Milbank Quarterly*, 89(4), 533-563.

Gross, M., Krohn, W. (2005). Society as experiment: sociological foundations for a self-experimental society. *History of the Human Sciences*, 18(2), 63-86.

Husereau, D., Henshall, C., Sampietro-Colom, L., Thomas, S. (2016). Changing health technology assessment paradigms? *International Journal of Technology Assessment in Health Care*, 32(4), 191-199.

KNAW (2014). *Evaluation of New Technology in Health Care. In Need of Guidance for Relevant Evidence.* Amsterdam: Royal Netherlands Academy of Arts and Sciences (KNAW).

Latour, B. (1993). *We Have Never Been Modern.* Harvard University Press.

Lehoux, P. (2006). *The Problem of Health Technology: Policy Implications for Modern Health Care Systems.* New York: Routledge.

Lehoux, P., Daudelin, G., Demers-Payette, O., Boivin, A. (2009). Fostering deliberations about health innovation: what do we want to know from publics? *Social Science & Medicine*, 68(11), 2002-2009.

Lehoux, P., Denis, J., Rock, M., Hivon, M., Tailliez, S. (2010). How medical specialists appraise three controversial health innovations: scientific, clinical and social arguments. *Sociology of Health & Illness*, 32(1), 123-139.

Lehoux, P., Miller, F.A., Daudelin, G.v., Denis, J.L. (2017). Providing value to new health technology: the early contribution of entrepreneurs, investors, and regulatory agencies. *International Journal of Health Policy and Management*, 6(9), 509-518.

Lemke, A.A., Harris-Wai, J.N. (2015). Stakeholder engagement in policy development: challenges and opportunities for human genomics. *Genetics in Medicine*, 17(12), 949-957.

Lomas, J. (2007). The in-between world of knowledge brokering. *British Medical Journal*, 334(7585), 129-132.

Lucivero, F. (2016). *Ethical Assessments of Emerging Technologies: Appraising the Moral Plausibility of Technological Visions.* Cham: Springer International Publishing.

Macnaghten, P., Kearnes, M.B., Wynne, B. (2005). Nanotechnology, governance, and public deliberation: what role for the social sciences? *Science Communication*, 27(2), 268-291.

Martelli, N., Puc, C., Szwarcensztein, K. (2017). Hospital-based health technology assessment in France: a focus on medical devices. *Thérapie*, 72(1), 115-123.

McMullin,E. (1987). Scientific controversy and its termination. In: H.T. Engelhardt, & A.L. Caplan (Eds.), *Scientific Controversies: Case Studies in the Resolution and Closure of Disputes in Science and Technology*. Cambridge University Press, Cambridge, pp. 49-92.

Mele, V., Compagni, A., Cavazza, M. (2014). Governing through evidence: a study of technological innovation in health care. *Journal of Public Administration Research and Theory*, 24(4), 843-877.

Michel-Verkerke, M.B., Stegwee, R.A., Spil, T.A. (2015). The six P's of the next step in electronic patient records in the Netherlands. *Health Policy and Technology*, 4(2), 137-143.

Migliore, A. (2016). Technology assessment of innovative medical devices in Europe. *Expert Review of Medical Devices*, 13(3), 217-219.

Moes, F., Houwaart, E., Delnoij, D., Horstman, K. (2017). Contested evidence: a Dutch reimbursement decision taken to court. *Health Economics, Policy and Law*, 12(3), 325-344.

Mol, A., Law, J. (1994). Regions, networks and fluids: anaemia and social topology. *Social Studies of Science*, 24(4), 641-671.

Moreira, T. (2012). *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum.* London: Routledge.

O'Doherty, K.C., MacKenzie, M.K., Badulescu, D., Burgess, M.M. (2013). Explosives, genomics, and the environment: conducting public deliberation on topics of complex science and social controversy. *Sage Open*, 3(1), 1-17.

Phillips, N., Lawrence, T.B., Hardy, C. (2004). Discourse and institutions. *Academy of Management Review*, 29(4), 635-652.

Pidgeon, N., Rogers-Hayden, T. (2007). Opening up nanotechnology dialogue with the publics: risk communication or upstream engagement? *Health, Risk & Society*, 9(2), 191-210.

Rip,A. (2001). Technology assessment. In: N.J. Smelser, & P.B. Baltes (Eds.), *International Encyclopaedia of the Social & Behavioural Sciences*. Elsevier, Oxford, pp. 15512-15515.

Rip,A. (2010). Processes of Technological Innovation in Context and their Modulation.*Relational Practices, Participative Organizing*. Emerald, pp. 199-217.

RVS (2017). *Zonder Context geen Bewijs (No Evidence without Context: On the Illusion of Evidence-based Practice in Health Care)*. The Hague: RVS (The Dutch Council for Health and Society).

Sarewitz, D. (2004). How science makes environmental controversies worse. *Environmental Science & Policy*, 7(5), 385-403.

Schot, J., Rip, A. (1997). The past and future of constructive technology assessment. *Technological Forecasting and Social Change*, 54(2-3), 251-268.

Shen, C., Shih, Y.C.T. (2016). Therapeutic substitutions in the midst of new technology diffusion: the case of treatment for localized prostate cancer. *Social Science & Medicine*, 151, 110-120.

Towse, A., Barnsley, P. (2013). Approaches to identifying, measuring, and aggregating elements of value. *International Journal of Technology Assessment in Health Care*, 29(4), 360-364.

Ulucanlar, S., Faulkner, A., Peirce, S., Elwyn, G. (2013). Technology identity: the role of sociotechnical representations in the adoption of medical devices. *Social Science & Medicine*, 98, 95-105.

van Est,R., & Brom,F. (2012). Technology assessment, analytic and democratic practice. In: R. Chadwick (Ed.), *Encyclopedia of Applied Ethics*. Elsevier, Oxford, pp. 306-320.

van Lente, H. (2012). Navigating foresight in a sea of expectations: lessons from the sociology of expectations. *Technology Analysis & Strategic Management*, 24(8), 769-782.

Verbeek, P.P. (2011). *Moralizing Technology: Understanding and Designing the Morality of Things*. Chicago: University of Chicago Press.

Ward, V., House, A., Hamer, S. (2009). Knowledge brokering: the missing link in the evidence to action chain? *Evidence and Policy*, 5(3), 267-279.

Zuiderent-Jerak, T., Grit, K., van der Grinten, T. (2011). *Markets and Public Values in Healthcare*. The Netherlands Scientific Council for Government Policy, Webpublication 57.

Afterword: Valorisation

The research has been done and the applicability of the knowledge basis of medical innovations for addressing public value discussed. A question, however, remains about the societal impact of this research project in a more concrete sense. In this final piece, I touch upon this issue in the form of self-administered Q&A.

In the dissertation you discussed the real-world value of medical innovations. Now tell me about the real-world value and relevance of your research?

I need to describe the context in which this research project arose and developed. The main preoccupation behind this project was a health policy question at the intersection of social health insurance and technological developments in health care: how can the system of public provision of health care services develop alongside and in response to technological innovations in medicine? This question has been on the agenda of the National Health Care Institute (*Zorginstituut Nederland*, ZIN) since 2008. In that same year, I joined the Institute's department of Research and Development and became involved in research on this topic. In particular, I explored the context in which decisions to adopt and use complex medical technologies are made.

ZIN is the Dutch government's independent advisory organisation on the content and quality of public health care services. It is a key actor in the Dutch health care system and ensures that good quality health care services remaining affordable and accessible to all citizens. The Institute recognised a need for insight into the dynamics of introducing new medical technologies in practice and kindly allowed me to continue research on this topic in the form of a PhD research in collaboration with Maastricht University. The reason was that the regulatory framework of the Dutch health care system allows a great majority of innovative therapies to be used in clinical practice, hence also publicly financed, without having to undergo any assessment on the part of the Institute. On the other hand, in relation to particular innovative therapies that are indeed subject to explicit national assessments – such as expensive medicines, ZIN faced another challenge. Some assessments, though conducted with evidence-based methodologies and robust scientific instruments, nevertheless met with often intensive public discussions on the merit of these therapies. A climax of controversy and public debate ensued, for example, in the case of the assessment of new therapies for the Pompe and Fabry diseases (respectively Myozyme and Fabryzyme) in 2012 (Schinkelshoek & Martini, 2012).

The research that led to this dissertation was, therefore, conducted to meet a *practical* knowledge need, namely to generate insights into introducing new medical technologies and informing a national public organisation. The same insight was also intended to serve a *societal* purpose, namely exploring the public legitimacy of actual decisions made when introducing advanced treatments. Moreover, the results of my research have convinced me of the significance of the underlying policy question, now and in the future: how the system of public provision of health care services and that of technological innovation in medicine can remain relevant to each other.

Would you say that this research project has impact?

I refer to the work presented in chapter two of the dissertation and the background empirical study on da Vinci surgery (Abrishami, 2011), conducted at ZIN and which resulted in this chapter. In terms of scientific impact, the results were published in Social Science & Medicine, which is, according to Schimago Scientific Journal Ranking (SJR), a top-5 journal in health and social sciences. The project was presented in international scientific congresses on a range of topics such as the governance of emerging science and technology, responsible research and innovation, medical device's market access, outcomes research, and HTA. The project has also been used for educational purposes. For example, the background report was translated into the Czech language and used by a training institute as material for a health policy course. In addition, the project has had impact on research policy. In March 2015, the European Network of Health Technology Assessment (EUnetHTA) referred to this study in a letter about priorities on HTA methodology that they sent to the Directorate-General for Research and Innovation of the European Commission. In this letter, the EUnetHTA's executive committee stated that research on the spread of advanced innovative medical devices, as the case study of da Vinci surgery exemplified, is "highly relevant" in the development of the upcoming Horizon2020 work plans and calls for proposals (EUnetHTA, 2015).[1]

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1 Other research priorities mentioned in the letter were: Alignment of HTA use at local, national, and international levels; The importance of additional patient data collection for HTA; Synergy between HTA and clinical guideline development as incentives for appropriate use of health care; Research into the organisation of care and health systems; Anthropological research to better capture patient perceptions and preferences; and Transferability of cost-effectiveness data.

The research has also had an impact in terms of attracting public attention. The journal article was covered by 'The New Prostate Cancer InfoLink' – a top-rated patient information website of the Prostate Cancer International, in which the view was expressed that such assessments of why and how new technologies are rapidly adopted into medical practice may be of great interest to sophisticated marketers of such devices as well as to the medical and scientific community (The New Prostate Cancer InfoLink, 29.07.2014). The background work also attracted attention, particularly in the Netherlands. It stimulated discussion on the topic of introducing advanced, expensive technologies. This project provided a ground for the decision of the biggest Dutch health insurance company to influence the dissemination of robotic surgery by not providing investment support for the purchase of extra units of the da Vinci robot as of 2012. The project also received media attention in the Netherlands including relatively lengthy coverage in *Nieuwsuur*, a Dutch television news programme about current affairs that is broadcast by the public broadcaster NOS (*Nieuwsuur* 12.12.2011).

Soon afterwards and as a result of this public awareness, the Dutch Minister of Health was asked by the Second Chamber of Parliament to react to the dissemination status of robotic surgery in the country. In her reply, the Minister concluded: "I therefore see the case as a signal to hospitals to be critical when presenting 'business cases' for [introducing] innovation" (letter to Parliament CZ-U-3098018, 20.12.2011). Referring to this research report, the introduction of da Vinci surgery was also used as a case study in a number of reports from government agencies including the Health Council of the Netherlands

(*Gezondheidsraad*, 2014), the Netherlands Court of Audit (*Algemene Rekenkamer*, 2015), and the Netherlands Bureau for Economic Policy Analysis (CPB, 2017).

So, yes, I think this project has had some societal impact. In particular, it has served a communicative purpose and contributed to making the da Vinci robot *public*, i.e., stimulating public debate on the merits of this innovation as one example of advanced therapies.

What might be the implications of this dissertation?

I would refer to the main themes of the dissertation, namely 'understanding' and 'connecting' for the sake of public value. This can lead to new, value-driven ways of innovating that are more in keeping with 'the era of affordable care: the end of sexy' (Mattke et al., 2016), and 'Era 3 for medicine and health care' (Berwick, 2016). A focus on understanding and connecting also renders a generic implication of dealing with such complex social issues as introducing advanced medical innovations. This is a recognition of the distinctive *kind of work* that will follow at both an individual and an institutional level, namely prioritising listening and mutual learning. For example, this could imply a shift in work culture from 'silo working' towards a more integrated approach; a shift in corporate strategy towards social entrepreneurship, or a shift in human resource policy towards recruiting those with *hybrid* competence such as knowledge interpreters, generalist content coordinators, and science practitioners (i.e., those involved in academic research while affiliated with organisations and companies). It might also imply an educational priority for medical curricula, health policy training, and business schools.

Another implication could relate to the direction of evaluation research at the science-policy interface. This, again, calls for a hybrid form of research, one that is problem-oriented and interdisciplinary (Schmidt, 2011). In the book, I referred to this as 'evidence in co-creation' or 'fit-for-purpose HTA'. My involvement with the actual work of ZIN has convinced me of the practical relevance of such a research approach to dealing with public policy issues. This also inspired the design of the dissertation. In my conversations with diverse stakeholders about da Vinci surgery, I was impressed by the amount of experiential expertise that can be harnessed to deal with the 'public problem' of medical innovations. What I learnt is this: in-depth research into the definition and analysis of a policy problem is crucial to the job of solving it (Hoppe, 2010). The problem

with problem-oriented interdisciplinary research is, however, that its ownership is unclear and it is under-represented (Schmidt, 2011). Compared with theory-oriented research, it might sometimes be regarded as contributing less to the advancement of one single theoretical perspective, thereby – being less favourable with journal editors – making it difficult to publish. On the other hand, compared with 'discoveries' and bibliographic rewards, problem-oriented knowledge creation is often under-rewarded, particularly in contributing to a spectacular career/CV for researchers.

Finally, prioritising listening and learning will imply a clarification of the role of public (HTA) agencies in fulfilling their mandates.[2] Once understanding and connecting is prioritised, facilitating participatory decision-making then becomes an important task for public (HTA) agencies (Goetghebeur et al., 2017). To fulfil this task, public agencies will accordingly need to adjust their *modus operandi* and play a distinctive *moderator* role. At the National Health Care Institute this has come to be recognised. Enhancing interactive decision-making is an emerging topic on the agenda and I hope this book stimulates further reflection on this issue. At times, I hear my colleagues using such metaphors as 'film director', 'catalysator', 'ambassador', and 'tea/coffee pourer' to describe the new role of the Institute as facilitator of participatory approaches.

2 New priorities for public (HTA) agencies may imply a subsequent adjustment in their mode of governance.

Mode of governance	Role of public agencies	Central management element	Operationalisation
By authority	Regulator	Rules	Enforcement (management via input)
By transaction	Inspector	Contract	Performance (management via output)
By facilitation and connection	Moderator	Network communication	Co-creation (management via outcomes as shared results)

Adapted from (Hill & Hupe, 2009)

Paraphrasing Albert Einstein, you understand what you say if you can explain it to your grandmother. How would you explain what you argued in this book to your grandmother?

I would frame it as the story of a collective commitment to solidarity and trust (Prainsack & Buyx, 2011). We all want other members of society to be trustworthy. A patient wants his/her doctor to be trustworthy, and similarly, the doctor wants the same in his/her child's teacher, and so on. Therefore, we all need to demonstrate *our* trustworthiness, and we can do so by demonstrating that we care about one another's concerns. Far from being an idealised sermon, I believe this is a must in our contemporary world, in which perspectives are often diverse and are sometimes developed in 'echo chambers', where tasks are fragmented and becoming increasingly more specialised. We need to reflect on the consequence of our actions and take into account the reasoning of others when making a decision that has consequences on others. This is the morale of the story that I would construct. I'm sure my grandmother would understand this, as years ago she herself used to remind me of the 'golden rule', "try to treat others as you would want them to treat you".

REFERENCES

Abrishami, P., (2011). Da Vinci Surgery: Is It a No-brainer? Robot-assisted Prostate Surgery in the Mirror of Social Health Insurance. https://www.zorginstituutnederland.nl/ Accessed 27 October 2017.

Algemene Rekenkamer (2015). *Basispakket Zorgverzekering [Benefits Package of Care Insurance]*. The Hague: Algemene Rekenkamer.

Berwick, D.M. (2016). Era 3 for medicine and health care. *Journal of American Medical Association*, 315(13), 1329-1330.

CPB (2017). *De Introductie van Dure Technologie in de Zorg [The Introduction of Expensive Technology in Care]*. The Hague: CPB.

EUnetHTA, (2015). EUnetHTA letter to the European Commission's DG Research and Innovation on methodological issues of high importance. http://www.eunethta.eu/outputs/eunethta-letter-european-commission-s-dg-research-and-innovation-methodological-issues-hig-1 Accessed 27 October 2017.

Gezondheidsraad (2014). *De Kunst van het Nee Zeggen. Factoren Die Bijdragen aan Onnodige Zorg [The Art of Saying No. Factors Contributing to Unnecessary Care]*. The Hague: Gezondheidsraad.

Goetghebeur, M.M., Wagner, M., Samaha, D., O'Neil, W., Badgley, D., Castro-Jaramillo, H. et al. (2017). Exploring values of health technology assessment agencies using reflective multicriteria and rare disease case. *International Journal of Technology Assessment in Health Care*, 33(3), 1-17.

Hill, M., Hupe, P. (2009). *Implementing Public Policy: An Introduction to the Study of Operational Governance*. Wiltshire: Sage Publication.

Hoppe, R. (2010). *The Governance of Problems: Puzzling, Powering and Participation*. Bristol: Policy Press.

Mattke, S., Liu, H., Orr, P. (2016). Medical Device Innovation in the Era of the Affordable Care Act: The End of Sexy. *Rand Health Quarterly*, 6(1), 1-12.

Prainsack, B., Buyx, A. (2011). *Solidarity: Reflections on an Emerging Concept in Bioethics*. London: Nuffield Council on Bioethics.

Schinkelshoek, J., Martini, T. (2012). *Meer dan een Incident: CVZ, Pompe & Fabry [More than an Incident: CVZ, Pompe & Fabry]*. The Hague: Schinkelshoek & Verhoog.

Schmidt, J.C. (2011). What is a problem? On problem-oriented interdisciplinarity. *Poiesis & Praxis*, 7(4), 249-274.

The dissertation at a glance

Public Value of Medical Innovations: A quest for all and for all seasons

SUMMARY

This dissertation addresses the societal value of new medical technologies in publicly-funded health care systems with a focus on in-hospital therapeutic innovations. Hospitals are an important entry point for new technologies. Many in-hospital innovations – sometimes even big-ticket items – are introduced and put into use in the absence of an established evidence basis and in the face of considerable uncertainty regarding their societal desirability and value for money. Using the introduction of the *da Vinci*® surgical robot as an example, I explored in this study how decisions to purchase and use this innovation are made in practice and how the innovation's real-life value is legitimised in such situations of uncertainty. I also explored the value profile of the same innovation after the early introduction phase and mapped what I observed: a crowded platform of controversial arguments about the merits of this technology both in published studies and in the perspectives of stakeholders involved in its introduction, i.e. providers, payers, policy-makers, and patients. The idea was to gain a broad understanding of the social dynamics of medical technology introduction and to examine the capacity of the resulting insights to deal with the societal challenges of new technologies, namely, as part of the knowledge base of technology assessment. This is an under-examined area of study within existing scholarship on technological innovations in medical care. In particular, the socio-cognitive underpinnings of technology use and evidence generation have been inadequately addressed both in the field of diffusion of innovation studies in medicine and in Health Technology Assessment (HTA).

The study was conducted within the theoretical framework of the social construction of technology, which entails that technological developments and societal values interact and co-shape one another. Qualitative research methods from the field of anthropology were used, i.e., a comprehensive document analysis, in-depth interviews with a wide range of stakeholders involved, and interpretative syntheses of literature. This study reconstructed and analysed diverse value perspectives underlying the introduction of medical innovations. Grounded on different motivations and obligations, these visions interfere with one another and interact with the as yet fledgling evidence basis of new technology. The dissertation highlights the importance of addressing this 'public problem' by attending to the value plurality within the context of care delivery and the knowledge basis of technology assessment. A synopsis is provided in chapter seven. Delving into value plurality in a medical innovation ecosystem is gratifying and enabling. It moves us upstream in our conception of and commitment

to the socially-responsible introduction and deployment of new technologies. This is indeed a quest for us all and a continuous quest, for all seasons. By means of what I refer to as 'co-creating value', stakeholders can engage in collective debates (*a*) to compromise on workable solutions for the appropriate introduction and use of an innovation and (*b*) to learn from one another how to integrate public value thinking into the processes of evidence generation and the deployment of new technology. Particularly in the era of 'value-based health care', this contributes to enhancing public legitimisation of medical innovations and help realise value for society at large.

SUMMARY FOR THE PUBLIC

Advanced new treatments are being used, for instance, in hospitals to improve patient care. However, in the early stages of introducing these new therapies, their merits to society are not always straightforward because they are new, sometimes too expensive for the public purse, and often not supported with unambiguous research evidence showing that they work well and are worth their costs. In this dissertation, it is argued that although these therapies involve highly-specialised clinical devices, they also have a *public* facet. Whether they benefit society at large remains a question that is relevant to all actors in the health care system and that is in need of collective debate. It is therefore important that, among others, representatives of doctors, health care insurers/commissioners, technology developers, patients, and indeed members of the public engage in such debates to learn from one another how to identify the most appropriate ways of introducing and using new technologies.

De publieke waarde van medische innovaties: een zoektocht voor ons allen

SAMENVATTING

Het begrip innovatie impliceert nieuwigheid. Innovatie gaat over de (aller) nieuwste ideeën of objecten, die ten opzichte van al het bestaande beter beogen te zijn. Dit proefschrift concentreert zich op deze kwestie van het 'beter zijn', specifiek wat betreft de *waarde* van medische innovaties. Vaak worden zorginnovaties in de praktijk toegepast vóórdat hun (meer)waarde voor de samenleving voldoende aangetoond is. Hoe weten we of een medische innovatie beter is? Welke perspectieven op dit 'beter zijn', zijn leidend bij de introductie van medische technologieën en welke zijn in de praktijk buiten beschouwing gelaten? Wat betekent dit voor een maatschappelijk verantwoorde invoering en voor een gepast gebruik van nieuwe technologieën en de evaluatie daarvan?

Dit proefschrift heeft de waarde van nieuwe therapeutische ziekenhuistechnologieën binnen het publieke gezondheidszorgstelsel bestudeerd. De diverse perspectieven op de waarde van een zorginnovatie in de praktijk zijn in kaart gebracht en vervolgens is er onderzocht hoe de resulterende inzichten kunnen bijdragen aan een maatschappelijk verantwoorde inbedding en implementatie van nieuwe medische technologieën.

In het **inleidende hoofdstuk** van dit proefschrift leg ik uit dat de invoering van geavanceerde medische apparaten die in eerste instantie uitsluitend een reeks van klinische of technische beslissingen lijkt te betreffen, ook een *publieke* betekenis heeft. Dat wil zeggen dat grootschalige aanschaf, toepassing en gebruik van deze zorginnovaties uitdagingen creëert voor de duurzaamheid van het zorgstelsel, de sociale solidariteit en de ethische geschiktheid van zorgverlening om bij te dragen aan de oplossingen van maatschappelijke gezondheidszorgproblemen. Dit heb ik het 'publieke probleem' van zorginnovaties genoemd en dit staat centraal in dit proefschrift. De studie is met behulp van techno-antropologie uitgevoerd. Deze aanpak is op het snijvlak van het vakgebied antropologie en de Wetenschaps- en Technologiestudies (*Science and Technology Studies*, STS) ontwikkeld. Techno-antropologische studies bestaan uit twee stappen: een kwalitatief, probleemgericht verkenningsonderzoek en een daaropvolgende interpretatieve analyse met als hoofdvraag hoe het opgeleverde verkennende inzicht ons kan helpen om te gaan met het publieke probleem van nieuwe technologieën. In samenhang met deze twee stappen heeft dit project een constructieve opzet om (*a*) de sociale dynamiek van de introductie van een nieuwe medische technologie diepgaand te beschrijven en (*b*) de opgeleverde inzichten te integreren in de kennisbasis van de beoordel-

ing van zorgtechnologieën, namelijk in *Health Technology Assessment* (HTA). Onderzoek naar de *real-life* waarde van een zorginnovatie, zoals toegepast in dit proefschrift, kan ons helpen om het publieke probleem van nieuwe medische technologie tijdens de introductiefase aan te pakken.

Vervolgens heb ik in het **tweede hoofdstuk** de sociale dynamiek van de invoering van medische technologie bestudeerd aan de hand van een specifieke casus, namelijk de chirurgische *da Vinci*®-robot in Nederland. Deze innovatie is wereldwijd toegepast en is goed ontvangen binnen de chirurgische gemeenschap. De vraag naar robotchirurgie blijft toenemen, ondanks haar hoge kosten en het feit dat de beoogde superioriteit ervan ter discussie staat. Op basis van het conceptueel-analytische begrip van '*affordances*' heb ik onderzocht waarom deze nieuwe technologie zo goed ontvangen is in de klinische praktijk en welke drijfveren bij haar intrede een rol spelen. *Affordances* verwijzen naar de verschillende betekenissen, beleefde visies en het expliciete of symbolische nut dat door de actoren in de sociale context van aanschaf en gebruik worden herkend en aangenomen. Het enthousiasme om de da Vinci-robot toe te passen, werd gedreven door onderling verbonden en wederzijds versterkende *affordances* om klinisch, onderzoeksmatig (wetenschappelijk) en bedrijfsmatig te excelleren. De innovatie is omarmd om vooruitgang, nauwkeurigheid, prestige, een koploperpositie, prestaties en winst te realiseren. Wanneer deze verwachte voordelen in een netwerk van interacterende partijen gedeeld worden, versterken ze het idee dat de toepassing en het gebruik van deze techniek vanzelfsprekend is.

In de daaropvolgende studie van dezelfde innovatie, die in **hoofdstuk drie** is gepresenteerd, kwam naar voren dat nog steeds ter discussie staat of deze innovatie eigenlijk wel beter is. Dit ondanks de vijftien jaar groeiende toepassing en uitgebreide (*peer-reviewed*) publicaties. Er is vooral gekeken naar de waarde van deze innovatie bij het toepassingsgebied prostaatverwijdering. Ik heb zowel de formele arena onderzocht namelijk de gepubliceerde studies, als de zogenaamde informele discursieve arena, het perspectief van stakeholders die bij de introductie van deze innovatie betrokken zijn. In beide arena's is er sprake van veel uiteenlopende en vaak strijdige argumenten over de waarde van robotchirurgie. Wat een decennium geleden onduidelijk was door *gebrek* aan bewijs, is nu onduidelijk door *controverse* over bewijs. De gepubliceerde studies tonen verschillende, soms tegenstrijdige conclusies. Daarnaast is de relevantie van de gehanteerde klinische en economische uitkomst(mat)en omstreden. Ook zijn er diverse meningen over de geschikte onderzoeksmethoden om waarde te beoordelen. En ten slotte is er controverse over wat de toegevoegde

waarde van robotchirurgie impliceert en wat het begrip 'waarde' betekent. Het in kaart brengen van controverses over robotchirurgie laat zien dat er in de praktijk diverse waardenperspectieven bestaan om de voordelen en de nadelen van robotchirurgie te rechtvaardigen. Deze waardenperspectieven berusten op verschillende opvattingen over bewijsvoering, bedrijfsvoering en wat relevante voordelen zijn van vernieuwing in de zorg.

Deze twee studies onderstrepen het belang van een diepgaand inzicht in het proces van de introductie van zorginnovaties. Zij wijzen erop dat de introductie van een medische innovatie in de klinische praktijk een sociaal fenomeen is, dat wordt gekenmerkt door interacties tussen diverse belanghebbenden en door heterogeniteit van waardenperspectieven in de praktijk, *ook* bij het genereren van bewijs. Deze waardenperspectieven zijn gebaseerd op verschillende normatieve idealen van 'goede' zorg en op specifieke (persoonlijke) belangen in de praktijk. Dit is waar het publieke probleem van nieuwe medische technologie zich voordoet. De daadwerkelijke waarde van een zorginnovatie, namelijk 'waarom' een bepaalde technologie geïntroduceerd zou moeten worden en 'hoe' waarde in de praktijk te realiseren, blijft vaak onduidelijk.

De rest van het proefschrift betreft een conceptuele analyse van de richting en de ontwikkelingen van HTA. In **hoofdstuk vier** heb ik aan de hand van het voorbeeld van robotchirurgie beschreven hoe we het publieke probleem van complexe ziekenhuisinnovaties in de praktijk kunnen aanpakken terwijl de bestaande kennis onvolledig is, de waarden betwist worden en een keuze snel gemaakt moet worden. In een dergelijke situatie is een belangrijke taak van partijen het omgaan met onzekerheden. Ik heb uitgelegd dat de betrokkenheid van belanghebbenden in een gezamenlijke discursieve beoordeling van technologie onmisbaar is, omdat een technocratische *one-size-fits-all* beoordeling onvoldoende in staat is om rekening te houden met diverse waardenvraagstukken. De belanghebbenden, namelijk de zorgontvangers (patiënten), de toepassers (zorgprofessionals), de onderzoekers (bewijsproducenten), de betalers (verzekeraars), de regelgevers (beleidsmakers) en de burgers (premiebetalers) zouden in gesprek moeten gaan om van elkaar te leren hoe zorginnovaties waardegericht te introduceren. Een gezamenlijk debat kan deel uitmaken van de ontwikkeling en uitvoering van bijvoorbeeld verantwoorde business modellen, het centralisatie- of verspreidingsplan, voorwaardelijke vergoeding en ontwikkeling van praktijkrichtlijnen en (volume)normen. In dit hoofdstuk heb ik een leidraad ontwikkeld waarin diverse waardenvraagstukken rond de introductie van curatieve ziekenhuisinnovaties op een rij zijn gezet. Eigenlijk gaat het over

twee essentiële vragen: waarom een bepaalde zorginnovatie wenselijk is en hoe de stand van het bewijs en de praktijk van deze innovatie kunnen worden geoptimaliseerd om maatschappelijk verantwoorde resultaten te behalen. Zo'n discursieve poging om gezamenlijk de waaromvraag en de hoe-vraag van medische technologie te legitimeren, is wat ik noem 'waarde in co-creatie'.

De twee vervolghoofdstukken bespreken het vermogen van de huidige beoordelingen (HTA) om het publieke probleem van complexe medische technologieën te adresseren. Het beleidsgeoriënteerde onderzoekskader van HTA heeft de verantwoordelijkheid om een breed spectrum van belanghebbenden te overtuigen dat de adoptie, verspreiding en het gebruik van een nieuwe technologie voor de samenleving al dan niet waardevol is. De bestaande HTA-kaders betreffen vooral de beoordeling van klinische effectiviteit en de kosteneffectiviteit. Deze zijn noodzakelijk maar op zichzelf onvoldoende om een onbetwistbaar beeld van de waarde van een innovatie aan de samenleving te tonen.

In **hoofdstuk vijf** heb ik deelgenomen aan een lopende discussie in de literatuur over de reikwijde van HTA. De vraag was of een kosteneffectiviteitsanalyse wel of niet voldoende is om de maatschappelijke en ethische aspecten van zorginnovaties binnen HTA te kunnen adresseren. Ik heb beargumenteerd dat de HTA geschikt zou moeten blijven voor zijn maatschappelijke doel, namelijk het legitimeren van de besluitvorming over de introductie en het gebruik van gezondheidszorginterventies. Zodra de geschiktheid voor doel (*fitness for purpose*) het leidende principe wordt voor het bepalen van de scope van de beoordelingen, wordt er aandacht besteed aan de publieke waarden van een zorginnovatie in de praktijk. Deze publiek waarden bestaan uit budget-, resourcedistributie- en billijkheidsoverwegingen. Bovendien zijn de berekeningen binnen het HTA-kader niet waardevrij. Het uitzoeken van en debatteren over diverse waardenperspectieven worden hierdoor onvermijdelijk omdat deze de *daadwerkelijke* redenen van beslissingen behelzen.

Dit is het onderwerp van **hoofdstuk zes**. De zoektocht naar de waarde van zorginnovaties zal leiden tot een systematisch verkenningsonderzoek naar de 'beloften' van een innovatie en de 'praktijken' betreffende die innovatie. De beloften en praktijken vertegenwoordigen de redenen van de invoering van een nieuwe technologie. Ze vertegenwoordigen respectievelijk de maatschappelijke wenselijkheid en de praktische uitvoerbaarheid van een zorginnovatie (overeenkomend met het 'waarom' en de 'hoe' van de geclaimde waarden). Een 'constructieve' benadering binnen HTA (dus constructieve technologie-

assessment, CTA) stelt ons in staat om het publieke probleem van nieuwe medische technologie te reconstrueren door de bovengenoemde aspecten van de waarde expliciet te maken en te weerspiegelen in het licht van bredere maatschappelijke waarden die de samenleving wil bereiken. Daarbij biedt een CTA de mogelijkheid aan partijen om reflexiviteit toe te passen en wederzijds te leren. Zo kan CTA bijdragen aan de maatschappelijk verantwoorde introductie van medische technologie in het zorgstelsel.

Het **slothoofdstuk** reflecteert op de analyse van voorafgaande hoofdstukken en in het bijzonder op de bijdragen en implicaties van de specifieke verkenningsbenadering van het project. Onderzoek naar de sociale dynamiek van een nieuwe technologie kan twee doeleinden dienen: *begrijpen* en *integreren*. Het eerste gaat over een uitgebreid begrip van wat er gaande is bij de invoering en het gebruik van zorginnovaties in de praktijk. Dit inzicht maakt de diverse discoursen rondom waarde en de daarbij onderliggende spanningen expliciet. Het onthult het publieke probleem van zorginnovaties. Het tweede gaat over het verbinden van diverse elementen van het innovatieproces, vooral de bewijsvoering, de bedrijfsvoering en de beleidsvoering. Het proefschrift onderstreept het belang om in het huidige tijdperk van waarde-gedreven zorg (*value-based health care*), het publieke probleem van complexe zorginnovaties aan te pakken. Dit betekent dat er rekening gehouden moet worden met de waardenpluraliteit binnen de sociale omgeving van zorgverlening en technologieontwikkeling.

Vanzelfsprekend doet dit een beroep op ons allen. De publieke waarde is het waard om ons dag in dag uit gezamenlijk voor in te zetten. Door middel van het co-creëren van waarde kunnen verschillende partijen debatteren en van elkaar leren om de publieke waarde van zorginnovaties gezamenlijk te bepalen en te verweven in de kennisinfrastructuur van technologiebeoordeling. Dit zal uiteindelijk bijdragen aan de publieke legitimiteit van medische innovaties en het realiseren van waarde voor de samenleving als geheel.

PUBLIEKSSAMENVATTING

Geavanceerde nieuwe behandelingen worden bijvoorbeeld in ziekenhuizen toegepast om patiëntenzorg te verbeteren. In de vroege stadia van de introductie van nieuwe therapieën zijn hun merites voor de samenleving echter niet altijd eenvoudig te bepalen. In deze periode zijn deze zorginnovaties nog onvoldoende onderzocht. Ze zijn soms erg duur en vaak is er nog geen eenduidig bewijs dat ze goed werken en dat ze hun kosten waard zijn. Dit proefschrift laat zien dat, hoewel deze therapieën zeer specialistische medische apparaten bevatten, ze ook een publieke betekenis hebben. Ziekenhuizen beslissen meestal individueel om nieuwe therapieën aan te schaffen en te gebruiken. De vraag is echter in hoeverre deze innovaties ten goede komen aan de samenleving als geheel, gezien hun kosten voor de burgers (premiebetalers) en de maatschappelijke veranderingen die deze innovaties met zich meebrengen. Deze vraag is relevant voor alle partijen namelijk artsen, zorgverzekeraars, beleidsmakers, patiënten en uiteraard het publiek. Het is daarom van belang dat de vertegenwoordigers van deze partijen een gezamenlijk debat met elkaar voeren om van elkaar te leren of en zo ja, hoe de nieuwe technologieën het beste ingevoerd en gebruikt kunnen worden.

PUBLICATIONS COMPOSING THIS BOOK

Article	Corresponding chapter
Understanding the adoption dynamics of medical innovations: Affordances of the da Vinci robot in the Netherlands Abrishami, P., Boer, A., Horstman, K. (2014) *Social Science & Medicine* 117: 125–33.	Two
When the evidence basis breeds controversies: Exploring the value profile of robotic surgery beyond the early introduction phase. Abrishami, P., Boer, A., Horstman, K. *Health Economics, Policy, and Law* (provisionally accepted)	Three
Value in co-creation: Subjecting in-hospital technologies to multi-stakeholder appraisal Abrishami, P., Boer, A., Horstman, K. (2017) *International Journal of Hospital Based Health Technology Assessment* 2017(1): 12–30	Four
Ethics in HTA: Examining 'the need for expansion' Abrishami, P., Oortwijn, W., Hofmann, B. (2017) *International Journal of Health Policy and Management*, 6(10): 551–553.	Five
How can we assess the value of complex medical innovations in practice? Abrishami, P., Boer, A., Horstman, K. (2015) *Expert Review Pharmacoeconomics & Outcomes Research* 15(3): 369–71.	Six

BACKSTAGE

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It is about the business of promoting collective health, I mean, when you talk about 'useful' innovations".

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My mom and dad, my sister Parisa and her husband Mohsen and her son Mehrad, my brother Alireza and his wife Elahe, I have written this book some 6000 kilometres away from you, but distance loses its meaning when it comes to

hearts and minds. You are always close to me, in my heart and mind, always! Mohsen and Parisa, I have written my dissertation. Now it's your turn: good luck. Alireza and Elahe, I truly wish you the best of luck in your work! Mehrad, my uncle once made some microscopic lamellas and invited me to observe. I did and that's how I became interested in biological science, when I was as young as you are now. Hopefully this book, your uncle's dissertation, will encourage you in your studies. My dear parents Fereshte and Mehdi, you cultivated the seeds of curiosity and perseverance in me. These characteristics have been vital to my life, my career, and indeed this book. How can I thank you in words? … I am now reminded of Hans Christian Andersen's 'when words fail, music speaks'. Instead of writing words, may I invite you to sing together with me the beautiful old Persian song, '*To ey Pari, kojaee*' ['Where are you, my Fairy']?

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Payam Abrishami,
Amsterdam, November 2017

ABOUT THE AUTHOR

I am a researcher and policy advisor on medical innovations at the National Health Care Institute (*Zorginstituut Nederland*), the Dutch government's advisory organisation on the content and quality of public health care services. I was trained as a medical doctor and medical anthropologist and have a background in health technology assessment. I am a curious explorer, a learner, and a fan of music and social documentary films. Bridging science, policy, and practice has always appealed to me and shaped my professional journey. The ambition to understand how clinical decisions and health policies work in practice inspired my switch from being a family physician (2000-2004, Iran) to becoming a quality inspector of curative care (2003-2006, Iran) and subsequently a researcher examining the introduction of complex therapeutic technologies into the health care system (2008-present, The Netherlands). This dissertation is part of the same journey.

Payam Abrishami

Advanced medical technologies are being used, for instance, in hospitals to improve patient care. However, in the early stages of introducing these new therapies, their merits to society are not always straightforward because they are new, sometimes too expensive for the public purse, and often not supported with unambiguous research evidence showing that they work well and are worth their costs. In this book, it is argued that although these therapies involve highly-specialised clinical devices, they also have a public facet. Whether they benefit society at large and how to introduce them appropriately remains an inquiry that is relevant to all actors in the health care system and that is in need of collective debate.