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RESEARCH ARTICLE

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

[Valeur en co-cr ation : Soumettre des technologies intra-hospitali res innovantes   une  valuation multipartite]

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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, deliberation, leadership, value.

R sum  : Cet article traite de la fa on de consid rer une proposition ax e sur la valeur d’innovations hospitali res lorsque cette valeur est susceptible d’incertitude – parfois consid rable. La contribution de la d lib ration multipartite (DM),  clair e par des  l ments probants, pour traiter des probl mes de valeur est examin e. Malgr  une reconnaissance g n ralis e de la participation multipartite dans l’ laboration des politiques de soins de sant , elle reste cependant rare dans le cadre du processus de d cision concernant les technologies intra-hospitali res. Une m thode de « synth se des connaissances interpr tatives » a  t  adopt e. Cette approche repose sur la construction d’une analyse conceptuelle interdisciplinaire s’appuyant sur diff rents volets de la litt rature en  valuation des technologies de la sant  (ETS), politiques publiques et  tudes en sciences et technologies. Les auteurs pr sentent l’introduction de technologies innovantes dans les h pitaux comme une mise en jeu de la valeur sociale de ces technologies et postulent que la base formelle de l’innovation est en soi insuffisante pour l gitimer leur introduction. Il est par la suite expliqu  comment la DM peut aider   maintenir la l gitimation publique envers ces nouvelles technologies. En soutenant un apprentissage mutuel, les parties prenantes augmentent leur compr hension de la valeur vers une compr hension

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de la valeur pour la société en général. La DM sert alors de plateforme pour de la « valeur en co-création » : en s'engageant dans une évaluation discursive de la valeur d'une innovation. Des conseils spécifiques sont proposés pour une évaluation multipartite de la valeur dans le cadre de la planification et de la mise en œuvre de ces nouvelles technologies afin de les introduire de manière responsable en milieu hospitalier. Un effort collaboratif de co-création de la valeur contribue au processus d'introduction décentralisée et orientée vers le marché des innovations dans les hôpitaux. L'objectif est de légitimer la diffusion, d'avoir un effet socialement souhaitable de l'utilisation de ressources limitées et d'agir collectivement pour atténuer les incertitudes au cours de la mise en œuvre.

Mots clés : diffusion de l'innovation, évaluation des technologies de la santé en milieu hospitalier, médecine basée sur les données probantes, participation multipartite, gouvernance clinique, délibération, leadership, valeur.

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 [1-2]. 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 taxpayers have been calling for a value-driven introduction (i.e., acquisition, use, dissemination, and insurance coverage) of medical innovations [3-6].

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 [7-8]. Although evidence of clinical utility (including safety and cost-effectiveness) is essential, the value-driven introduction of an innovation renders 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 semi-automatic) 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). 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 [9]. 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 help 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' [10].

Interpretative knowledge synthesis has its roots in qualitative research tradition and interdisciplinary knowledge production [11-12]. 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 [13-14]. 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) [11-12,15].

Approach

Interpretative knowledge synthesis is an endeavour distinct from 'evidence

synthesis' by means of (systematic) literature reviews [14]. Conventional systematic reviews are often conducted to quantitatively summarise the evidence from available studies with the aim of obtaining precise estimates of treatment effect [16]. 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 [14]. The HTA community is also less familiar with the methodology as it is debated predominantly in the fields of education and anthropology [17]. Although different terms have been used to label qualitative knowledge synthesis methods (e.g., 'meta-narrative' or 'narrative synthesis') [18], the overarching purpose is to substantiate the analysis being developed with adequate explanations [12]. 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) [19]. Argument formulation and data collection are, therefore, not seen as separate but iterative and double-fitting processes [20].

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 [14].

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 [17,21]. Our search and selection strategy were driven by the so-called ‘purposive sampling’ method [22]: by selecting articles that are considered relevant in contributing to the article’s core arguments. Relevant articles were retrieved up to June 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-June 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. This guidance 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 [19], 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). 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 [23]. Von Schomberg sketches a vision on RRI, in which realising the ‘right impacts’ takes centre stage in demonstrating the public value of innovation trajectories [23]. 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 [23]. 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 [24-26].

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 [27-33]. 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), public health interventions (e.g., breast cancer screening), and health system reforms [29,34-35]. 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 [36].

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.

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 [37-38]. 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' [7].

Box 1. The dynamics of configurational in-hospital 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 [17,39]
- 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 [40-41]
- 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 [4,7,39]
- 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) [42-43]
- The 'transformative potential' of the innovation may cause large-scale unexpected changes and disrupt existing practices and relations [44]
- The innovation's technical features are evolving, as are the regulations involving market access, finance, and provision of the innovation [17,45]
- The beneficiaries are diverse and the intended use is subject to ongoing change in practice [4,7].

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 [46]. 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 [47]. 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 [26,39]. Given the (extra) costs incurred, whether the innovation's budget 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 [48,49]. 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 [25,50]. 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 [26].

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 [43].

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 [51-52]. 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 [6,41,50]. 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 [38-39,53]. 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 [4,54]. 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 [54-55].

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 [36].

The *da Vinci*[®] surgical robot was adopted to achieve high-tech clinical practice excellence, research excellence, surgeon's comfort, and corporate advantages [43]. 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 [36].

Limited evidence

The third reason to argue for multi-stakeholder deliberation (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 [56]. 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.

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 [5,57]. 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 [5,58].

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 [4]. 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* [4,59-61]. 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 socio-technical processes representing the context of service delivery [5,26]. De Vries and Horstman's analogy with the automobile is illustrative here [53]. 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.

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 values [24,30,60]. Furthermore, an evidence basis by itself does not address how evidence is interpreted and actioned in practice [62]. 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) [26]? 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 [3-4,32]. 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 [9,63].

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, for example, 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 [58,64-65]. 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 (forthcoming article). And this is unlikely to occur in the near future as the technology and the practices involving it continue to evolve [5,57].

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 [66]. Deliberation is an ancient practice, dating back to the *agora* of Athens and is still commonly used [67]. MSD can be defined as a collective communicative process to examine an issue from different points of view [67]. MSD implies the consideration of different framings of risk and benefit to elicit ‘best reasoned’ choices [27-28,66]. 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) [61]. 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 [9].

Multi-stakeholder deliberation has been addressed in a number of fields of study, most notably, adaptive governance (a branch of public policy) [66], knowledge management (a branch of organisations studies) [68-69], change management (a branch of business leadership) [70], and the Responsible Research and Innovation framework (a branch of STS) [23,29,37]. In terms of theoretical foundation, MSD is linked to political theory of deliberative democracy and cognitive theory of judgment and decision-making [67].

The fruitfulness of MSD in legitimising choices rests on its two interrelated key characteristics: democratic and epistemic representativeness (see 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). 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 [25,37,61]. 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 [25,30,62,67]. Legitimising the ‘why’ and ‘how’ of introducing complex 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.

a. Systems thinking and anticipation

In as far as technology introduction can be conceived as 'system innovation' [40], MSD can serve as crucial *linkage* between different components of the health care system, and between 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' [71]. 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 [67].

b. 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 [53]. 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.

c. 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. 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* to one another as well as to oneself [72]. Through MSD, different assumptions and decisional trade-offs in technology (e)valuation can be made debatable that might otherwise remain implicit [30]. Moreover, new cumulative insights are generated as result of reflection on the past and exposure to diverse (value) perspectives [53,72-73]. Unlike, for example, lobbying, authentic deliberation is not about 'winning' arguments but about reasoned exchange and mutual learning [74]. MSD can, therefore, provide an interactive basis for knowledge co-creation under conditions of uncertainty and contention [29,73,75].

d. Coordinated (creative) action

By their very nature, deliberative processes involve 'value-based reasoning for collective problem solving' [34]. 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) [61]. 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 solutions to improve practices [29,53,69]. For instance, deliberation could help readjust strategies with respect to manufacturers' R&D, research funding, advertising, market access, procurement, etc.

may touch upon a variety of disciplines 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.

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 [32]. 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 [9,53]. 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 [9]. 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 [76]. 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 [40,77]. In parallel, MSD can also accommodate dialogue between the methodologies of generating evidence (i.e., knowledge exchange), typically between the formal HTA frameworks and the constructive technology assessment methods [25-26].

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:

- (a) developing business models and implementation plans,
- (b) developing plans for centralised (or collaborative) provision of advanced therapies,
- (c) managed entry and adaptive (or conditional) access,
- (d) developing clinical practice guidelines (CPGs) and benchmarks for appropriate use,
- (e) incremental improvements of new technology in clinical practice, and
- (f) 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, we provide topics for an actionable discursive appraisal of in-hospital technological innovations.

Developing business models and learning from successful implementation

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

<i>Spectrum of Value Appraisal</i>	<i>Aspects of Value</i>	<i>Matters of Concern*</i>
Desirability (the 'why')	Societal desirability & Ethical acceptability	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - What constitutes a substantive <i>added</i> 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?
	Research governance (<i>Evidence in co-creation</i>)	<ul style="list-style-type: none"> - To which ends are we generating evidence or funding research on a given innovation? - Identifying <i>a priori</i> 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)
Plausibility (the 'how')	Implementation	<ul style="list-style-type: none"> - 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.

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 [78]. 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 [79]. 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 [80]. 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) [81,82]. Another instance is 'adaptive' or 'conditional' access schemes for technology introduction such as Access with Evidence Development (AED) [83]. 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 [84-85]. Examples are the US Food and Drug Administration's call for deliberation on evidence requirement in a pre-market phase [86] and the European SEED project (Shaping European Early Dialogues for health technologies).

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 [4]. 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 (forthcoming article). 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 [52], while also being beyond the scope of individual local actors [54], 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 form of MSD, it would typically comprise foresight reports (e.g., horizon scanning, 'scenarios', or controversy mappings), iterative briefings, and panel discussions [25,35]. 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 [76,87-88].

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 [89]. 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 [28,74]. 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 conversations; 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 [90]. 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). We hope this article stimulates stakeholders' engagement in systematic deliberation on value of emerging medical innovations, notably prior to their widespread roll-out.

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