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

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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.

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 and lowering 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 [1,2].

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 decentralized 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 [3–6]. 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 [5]. Surgeons and hospitals wanted to pioneer the provision of this high-tech, high-precision surgical platform as a symbol of

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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 parameters 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 [6,7]. 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 [5,8]. They shape preference and choice, attract interest, justify behavior, guide activities, foster investment and mobilize resources [6,7]. Promises and affordances depict a desired impact with reference to the nature, size and plausibility of the benefits claimed [9]. They are 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 [5,10–12]. 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 [13]. 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 behavior 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)specializations 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 [1,14,15].

### Promises & practices of complex innovations

As the complexity of innovations increases, an inquiry into value becomes more pressing. “Value should always be defined around the customer,” emphasizes Porter [2], 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 (semi-autonomous 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 [3].
- 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’ [15], namely, economic (entrepreneurial) and knowledge (research) yields, are as yet unfulfilled or being difficult to measure, they are rarely assessed [5,14].

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 the attributes of value that play a role within the setting of use.

### Assessing promises & practices: constructive technology assessment

The enquiry of value of medical innovations amounts to a systematic exploration of the setting of use. The sociology of technology provides a methodological orientation for assessing the value of emerging medical technologies, namely, under the Constructivist Technology Assessment (CTA) paradigm [16,17]. However, such an approach is not well integrated into Health Technology Assessment (HTA) yet.

A constructivist approach enables us to simultaneously capture the socio-organizational 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 insights 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 [5].

CTA can be very informative in the early stage of complex emerging technologies [5,16,17]. 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 [4,10,11,17–19]. 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.

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