



Responsible research and innovation: a productive model for the future of medical innovation

Olivier Demers-Payette, Pascale Lehoux & Geneviève Daudelin

To cite this article: Olivier Demers-Payette, Pascale Lehoux & Geneviève Daudelin (2016): Responsible research and innovation: a productive model for the future of medical innovation, Journal of Responsible Innovation, DOI: [10.1080/23299460.2016.1256659](https://doi.org/10.1080/23299460.2016.1256659)

To link to this article: <http://dx.doi.org/10.1080/23299460.2016.1256659>



Published online: 21 Nov 2016.



Submit your article to this journal [↗](#)



View related articles [↗](#)



View Crossmark data [↗](#)

RESEARCH ARTICLE

Responsible research and innovation: a productive model for the future of medical innovation

Olivier Demers-Payette ^a, Pascale Lehoux ^b and Geneviève Daudelin^a

^aInstitute of Public Health Research of the University of Montreal (IRSPUM), Montreal, Quebec, Canada;

^bDepartment of Health Administration, Institute of Public Health Research of the University of Montreal (IRSPUM), Montreal, Quebec, Canada

ABSTRACT

This article seeks to deepen our understanding of the responsible research and innovation (RRI) approach as it relates to health care systems, where the notion of responsibility is already deeply embedded. We empirically flesh out the RRI framework developed by Stilgoe et al. by drawing on the content of three mixed focus groups on health care system challenges that technological innovation could help address. These focus groups were held in Montreal (Quebec, Canada) and brought together users of medical technology (patients, clinicians), developers (engineers, designers), and innovation managers (at universities, in hospitals, and in biomedical firms). These empirical data offer contrasting views that are used to explore the four dimensions of the framework (anticipation, reflexivity, inclusion, and responsiveness) in order to derive a more specific understanding of what responsible medical innovation may entail.

ARTICLE HISTORY

Received 17 February 2016

Accepted 1 November 2016

KEYWORDS

Responsible innovation;
health innovation; healthcare
systems

1. Introduction

Technological innovations are a polarizing force in health care systems in that they exert pressure on available resources but also attract massive public investment. On the one hand, acquisition of medical innovations calls for substantial investments from the public authorities that regulate their diffusion. Mechanisms are in place to ensure the safety, efficacy, and quality of new medical technologies, before and after they enter the market: regulations applicable to medical devices and pharmaceutical products, guidelines on the use of biomedical products, health technology assessments (HTA) at the national, provincial or local level, etc. These State mechanisms are intended to preserve the fragile balance between growing public health spending and providing patients with access to promising medical innovations (Lehoux 2006). On the other hand, governments want to foster innovation in health by supporting research and development (R&D). Whether through direct or indirect funding (e.g. university research, academic technology transfer offices, training of highly qualified staff), the State is a key actor in supporting R&D in the health sector (Gelijns and Thier 2002; McMillan, Narin, and Deeds 2000). The hope is not only to build a competitive economy where knowledge and economic

dividends are intrinsically linked, but also to offer citizens access to innovative health solutions.

The enormous challenges and needs confronting health care systems today make the governance of innovation extremely complex. Governments are faced with tough choices since medical innovations hold both promises and perils. It is imperative that these technologies resolve and not create problems for health care systems. In recent years, there have been calls for better integration of organizational, clinical, societal, and ethical considerations into the research, design, and development of medical innovations (Faulkner 2009; Hyysalo 2010; Lehoux 2006; Lehoux and Blume 2000; Shah, Robinson, and AlShawi 2009; Sharples et al. 2012; Stilgoe, Owen, and Macnaghten 2013; Webster 2008). These calls advocate a new way of designing health technologies – a model for the design, development, and governance of medical innovation that carefully examines moral and social issues and encourages greater inclusion of the actors concerned by the innovation. Such integration would allow medical innovations to better respond to the multiple challenges and needs of health care systems and make it easier for the State to manage the delicate trade-off between investments and control in the governance of medical innovations.

This view echoes the responsible research and innovation (RRI) framework developed by Stilgoe, Owen, and Macnaghten (2013). This forward-looking approach calls for anticipating social risks, decentralizing technological choices, and sharing responsibilities in innovation. To reduce the unforeseen and undesirable consequences of innovations, Stilgoe et al. suggest implementing a responsible innovation process where (1) anticipation (the risks and opportunities of innovation), (2) reflexivity (paying close attention to value systems and social practices), (3) inclusion (sharing roles and responsibilities, democratization of technological choices), and (4) responsiveness (flexibility of the innovation trajectories) constitute essential and intertwined dimensions. This policy endeavour (van Oudheusden 2014) is growing in popularity, particularly in Europe and in relation to environmental concerns.

This article seeks to deepen our understanding of the RRI approach as it relates to health care systems, where the notion of responsibility is formalized within the legislative apparatus that govern health care and embedded, to varying extent, in health care providers' practices. More specifically, we believe that the approach developed by Stilgoe, Owen, and Macnaghten (2013) provides an opportunity to think productively about medical R&D but that its application to health care requires both conceptual and empirical development. To this end, we mobilize the content of three mixed focus groups on the needs and challenges of health care systems that technological innovations should address. These focus groups were held in Montreal (Quebec, Canada) during a one-day workshop that brought together users of medical technology (patients, clinicians), developers (engineers, designers), and innovation managers (at universities, in health organizations, and in biomedical firms). These empirical data offer contrasting views that are used to explore the key dimensions of the RRI framework in order to derive a more specific understanding of what responsible medical innovation may entail. Before proceeding, we clarify the different meanings of responsibility in health care systems.

1.1. Innovation and responsibility in health care

The RRI framework offers a new lens to consider and govern the innovation process. For Von Schomberg (2013, 63), RRI is a “transparent, interactive process by which societal

actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products.” While RRI represents an evolving concept (Rip 2014) with many dimensions (Stilgoe, Owen, and Macnaghten 2013), the concept of responsibility itself is a multilayered notion: it has both a “forward-pointing” meaning (care and responsiveness) and “backward-facing” (liability and accountability) meaning (Grinbaum and Groves 2013; Pellizzoni 2004). One may presume that such a multiplicity of meanings is also found when seeking to define responsible medical innovation.

In health care systems, responsibility may be first examined through the pre-existing set of rules and duties that govern the provision of medical services. In Canada for instance, various statutes and regulations on health services, social services, and public health require practitioners and public health authorities to deliver the necessary services to maintain and improve the health and wellbeing of the population.¹ As part of a social contract between the State and its citizens, these laws and policies represent the State’s responsibility towards the welfare of its population. Health professionals also have to fulfill moral and legal obligations and exercise professional judgement as part of professional bodies legislation, in particular statutes governing physicians (for example, in Quebec, the statute is the *Medical Act*, Chapter M-9). These laws grant physicians the exclusive right to practice their profession within strict arrangements, thereby making them liable for the acts they perform.

From a broad public health point of view, the notion of responsibility implies that individuals may have to behave in certain ways to remain healthy (e.g. quit smoking, perform physical activities, etc.). For Rose (2007, 134), “responsibility of the self implicates both *corporeal* and *genetic* responsibility” since individuals become responsible for the proper maintenance of their body but also for the proper management of their genomes (e.g. preventive mastectomy when one is genetically “at risk” of developing breast cancer). While holding individuals accountable for their lifestyle choice remains controversial, this understanding of individual responsibility is widespread (Cappelen and Norheim 2005). From a public health perspective, individual choices are known to be context-dependent since many socioeconomic factors affect health. Responsibility is therefore understood as a “collective political responsibility” (Grinbaum and Groves 2013, 132–133). Consequently, whether it involves the obligation to protect and improve the health and wellbeing of the population, accountability for the medical services rendered, or individual choices, the notion of responsibility in health is plural.

For medical innovation, institutional rules assign specific obligations to the actors concerned in the development of new health technologies (i.e. developers, manufacturers, public authorities, researchers, and others). Accountability is in fact embedded in the policies and regulations that frame R&D, manufacturing and distribution of medical devices² and pharmaceutical products (Faulkner 2009).³ These policies, statutes, and regulations seek to ensure the quality, effectiveness, and safety of medical devices and drugs sold in a given country. It is up to the manufacturers to show that their products respect the requirements in terms of clinical evaluations, are manufactured according to established standards such as ISO,⁴ and marketed according to prescribed norms (e.g. medical equipment labelling). Such responsibility is “future-oriented” (Grinbaum and Groves 2013) and reflects the evolving nature of innovation itself. Producers of medical technologies have an obligation to periodically confirm to the regulatory authorities the accuracy of the

information provided in their license applications, as well as declare any side effects (known or discovered once on the market) associated with their therapeutic product. The special attention paid to medical technology firms to ensure they follow the established rules and anticipate risks is all the more important given that the medical innovation process is characterized by tremendous uncertainty (Gelijns, Zivin, and Nelson 2001): the complexity of the human body, the diversity of the human population, the limited application of clinical trial results to real-life situations, and unforeseen technical aspects. Because of these uncertainties, accountability rests with the producers of medical innovations, and the associated risks are tightly controlled. Furthermore, medical technologies and pharmaceutical products are frequently assessed by government agencies that rely on systematic reviews of clinical trials and cost-effectiveness analyses (Banta 2003).

If the medical innovation process – from concept to market – already entails many forms of responsibility, what is the benefit of defining the concept of responsible innovation specifically for the health sector? In our view, the RRI approach developed by Stilgoe, Owen, and Macnaghten (2013) focuses on dimensions overlooked in the current governance of health care innovations. As an example, producers of new health technologies rarely consider users in their innovation process and by not doing so, are missing important information (Martin and Barnett 2012; Money et al. 2011). Nor is enough attention paid to the social and ethical dimensions when assessing health technologies (Lehoux and Blume 2000; Lehoux et al. 2004). Even when licensed by public authorities, new medical technologies can have disastrous consequences if their producers fail to sufficiently consider and anticipate their uses and the context in which they are implemented (Dain 2002; Høyer, Christensen, and Eika 2008). Moreover, health laws and policies idealize values that are rarely if ever fully implemented in practice (Giacomini, Kenny, and DeJean 2009). The RRI framework developed by Stilgoe et al. distances itself from the consequentialist model of responsibility, which focuses mostly on assessing products and monitoring their social or environmental consequences once they are fully developed. Grinbaum and Groves (2013, 132) argue that the emphasis on accountability should be replaced by “care for the vulnerability” of technology (future) users. Because the RRI framework is more concerned with the dynamics that drive the innovation process, it can contribute, we believe, to a better understanding of how responsible medical innovation could better address the needs and challenges of health care systems.

1.2. Focus groups on the needs and challenges of health care systems

During a one-day workshop on the design of medical innovations, we fostered a dialogue on the way new technology could help address the needs and challenges of health care systems with participants who had direct experience in the development and use of health technology and held different types of expertise. Three focus groups were organized since there are particularly effective in exploring a topic of mutual interest and gathering information on personal and collective views and experiences (Kitzinger 1994, 1995; Lehoux, Poland, and Daudelin 2006). Our participants broached several aspects to consider in order to better align the design of medical innovations with the health care system and its users.

More specifically, the mixed focus groups consisted of participants ($n = 19$ in total, $n = 6-8$ per group) recruited for their different, cross-sectional views on medical innovations:

clinician-researchers, hospital managers, representatives from patient associations (in particular, users of technical aids), biomedical engineers, industrial designers, medical device manufacturers, and technology transfer experts. These mixed focus groups, each facilitated by a moderator, engaged in lively discussions that were recorded, transcribed, and coded with the open-source qualitative analysis software *TAMS Analyzer*. The framework by Stilgoe, Owen, and Macnaghten (2013) was used as a heuristic tool to code the empirical material, identify points of divergence and convergence and recurring themes across groups. We used a deductive approach to analyse the content of the transcripts (Hsieh and Shannon 2005) and to compare and contrast what health care system needs and challenges the framework's four dimensions (anticipation, reflexivity, inclusion, and responsiveness) helped to articulate. We generated concept-ordered matrices to visually arrange the data (Miles, Huberman, and Saldaña 2014). These matrices were used during debriefing sessions with members of the research team to examine in greater depth how the issues raised by participants shed light on what responsible medical innovation may entail. Special attention was also paid to participant interaction (e.g. tension, disagreement, agreement) in order to rigorously analyse the verbatim transcripts (Lehoux, Poland, and Daudelin 2006). Our study was approved by the Health Research Ethics Board of the University of Montreal.

2. The challenges of responsible medical innovation

Table 1 provides a summary of our analyses of the three mixed focus groups, which are organized around the four dimensions of the framework of Stilgoe, Owen, and Macnaghten (2013) (see Table 1). According to these authors, the four dimensions are interconnected and need to be part of an integrated framework. Still, to increase clarity, we successively address each dimension, underscoring when relevant the relationships they entertain with one another.

2.1. Anticipation, or the challenge of clearly understanding the uses of a medical innovation and its context

Anticipation, the first dimension of the framework, calls for a systemic and prospective analysis of the social, ethical, and political consequences of innovations in a context of rapid technological change. The idea is to anticipate the effect of an innovation before its dissemination and incorporate the assessment into regular R&D activities instead of reacting after the fact. For Stilgoe et al., anticipation means considering the expected and unforeseen risks of the impending innovation as well as the associated opportunities. It therefore requires examining the future desirable and undesirable effects of the innovation process.

The analysis of the focus groups reveals that one key challenge raised by anticipation in medical innovation is to clearly understand the immediate and future context of use. Participants stressed the importance of a strong adequacy between the actual and anticipated clinical needs and the proposed technological solutions. Many lamented the fact that important user needs are overlooked in favour of less relevant technologies. For example, in the discussion below, participants wonder about the alignment between the needs of Alzheimer patients – for whom social isolation is an issue – and technological solutions such as wearable sensors that monitor their behaviour:

Table 1. A summary of our analyses of three mixed focus groups with users and developers of health technology.

<i>Dimension of the framework (Stilgoe, Owen, and Macnaghten 2013)</i>	<i>Health care system needs and challenges that responsible medical innovation should address</i>
Anticipation Identification of new opportunities for innovation, as well as their social, ethical, and political risks	Preclinical analysis of needs and of clinical, economic, organization, social, and ethical impacts of medical innovations <ul style="list-style-type: none"> • Align needs and solutions • Identify and adapt to evolving needs • Understand future impact on health care system (clinical and human, technological and financial resources)
Reflexivity Examination of the value system and societal practices governing R&D	Sociopolitical analysis of the context in which medical innovations are produced and used <ul style="list-style-type: none"> • Dignity, autonomy and empowerment • Consider continuum of care, lifecycle, clinical ethos • Tension between lucrative clinical niches, rare diseases, and population needs • Coordination, power relationships, and multidisciplinary • Regulatory and financial context of innovation • Different cultures: business and health
Inclusion Consideration of a wider public in R&D	Public deliberation on systemic health issues and/or user engagement in the medical innovation process <ul style="list-style-type: none"> • Sound integration of user knowledge and know-how • Accessibility to users and contexts of use • Need for shared language
Responsiveness Mobilization of emerging views, norms, and knowledge in the R&D process	Funding, regulations, and audits allowing for an adaptive medical innovation process <ul style="list-style-type: none"> • Health organizations that can adapt to emerging practices • Emergence of user preferences and behaviours • Institutional contingencies and framework of technological development • Adaptation to diverse contexts of use • Tension between technological obsolescence, fashion effects, and legitimate resistance to innovation

W2 (user):⁵ “But people with Alzheimer’s can’t express their needs. Their caregivers do it for them. So it ends up being the caregiver’s needs, not the patient’s. It gets complicated. For example, I recently attended a conference where they showed technology for people who have Alzheimer’s and who are living alone – door sensors and all kinds of other stuff.”

M2 (user): “But how is that useful?”

W2 (user): “I said to myself, ‘I could’ve used this when my kids were teens ...’ [laughter] But for someone with Alzheimer’s ...”

M4 (developer): “Useless, these are horrible theoretical projects.”

M5 (developer): “They’re technologies looking for an application.”

This lack of alignment between needs and technological solutions is the result of an innovation strategy that pushes the innovation into the health care system instead of trying to better anticipate and understand actual user needs.⁶ In this regard, a participant criticized the “push strategy”:

which is not necessarily suitable, not only because there's little chance that your product will make it to market, but what's more, it risks creating a new need and bogging down the system. You therefore need to really make sure that there's a need right from the start. (M10, developer)

The participants thus highlighted the need for a more in-depth analysis of how the technology in question will be used and how it will affect the system.

As one participant pointed out:

It makes no sense to develop a technology without first asking whether it will be useful. In our engineering lab, this is the first question we ask. You can have the best idea in the world, but if it has no application, then why would you work on it? It's a waste of time; you're better off spending your time on something useful. (M5, developer)

This means the developer must clearly identify the need upstream of the innovation process, be able to adjust to the changing needs in time and space, and that these needs are shared by most of the users. Another participant pointed out the difficulty of aligning a controlled laboratory environment with a clinical environment:

W1 (developer): "The research team starts with a challenge but loses sight of what really goes on in the broader system. In the end, we find ourselves with a technology that meets the initial need but that may have strayed from the actual situation. So we end up with added value that's difficult to measure. It's also very hard to identify who will be interested in this added value."

As well, downstream of the innovation process, the new technology "creates needs" (M8, user), which impacts human, material, and financial resources in the system. Indeed, therapeutic advances converge with scientific discoveries, technological progress, and changes in clinical practices (Mina et al. 2007; Morlacchi and Nelson 2011). The outcome of this interplay is often unpredictable, and the design or dissemination of a new medical technology leads to changes in the delivery and context of care. Once deployed in the clinical setting, a medical innovation can be found to have applications other than those originally intended, the therapeutic targets can change, or procedures can become more complex (Gelijns, Zivin, and Nelson 2001). A participant pointed out the consequences of these transformations on the finances and human resources of a health care centre:

M8 (user): "For example, the pharmaceutical industry creates pulmonary artery pressure medication. All of a sudden, there's a need for ultrasounds, to monitor patients annually. That innovation creates demand on the system, which obviously costs money. So there's that idea as well. Yes, innovation can reduce costs, but it can also lead to things that require more human resources."

Another participant echoed this view:

If you look at it from the point of view of the health system, there are costs, it's inevitable. Health care costs are rising, so technology has to allow us to control them, not increase them. But since there's no integration right now, it seems like they're increasing. (M7, user)

Aside from a better understanding of the possible uses of a medical innovation, participants would like to see these innovations better integrated into the environment in which they are used. Evaluating the financial impact on hospitals is not enough to understand the context of use; the medical innovation must also be evaluated in terms of its

impact on human resources (e.g. the need for training, redefinition of clinical acts, changes in the relationships between professionals), and on patients (e.g. management of the illness, diagnosis of incurable diseases). The assessment of medical technologies must go beyond the traditional cost-effectiveness analysis to consider, anticipate, and address rigorously the social, ethical, organizational, and political issues (Hofmann 2005; Lehoux and Williams-Jones 2007; Leys 2003).

In sum, in the search for responsible medical innovation, the purpose of anticipation cannot just be to gain a better understanding of the innovation's risks and opportunities; it has to accurately pinpoint evolving needs in a complex system and anticipate a range of possibilities the innovation may open up or close down at short and long term. The participants' concerns emphasize that anticipation needs to pay attention to the varying contexts of use (health organizations and home). As we elaborate next, to develop responsible innovation that better manage social, organizational, and ethical issues, developers (and users) need to remain open to the views of others, to be responsive to new knowledge and values and to question their professional ethos.

2.2. Reflexivity, or the challenge of aligning health and innovation value systems and social practices

Reflexivity, the second dimension of Stilgoe et al.s' framework (2013), essentially refers to institutional reflexive capacity.⁷ This dimension is concerned with institutional mechanisms (codes of conduct, advisory committees, moratoriums, etc.) that scrutinize and reveal the activities, obligations, and assumptions of the actors (e.g. researchers, developers, funders, regulators) in the innovation process. At the individual level, reflexivity requires that the actors involved in technological development be able to recognize and articulate their own knowledge, values, and beliefs as well as those of others. Reflexivity therefore seeks to uncover value systems and theories that guide social practices in the health system and R&D practices.

Although our mixed focus groups constitute, *prima facie*, a place where participants can distance themselves from their practices and understanding of their respective worlds (i.e. design, clinic, R&D in industry), we are less interested in their reflexive capacity than in their thoughts on the value systems and principles that underpin the health care system and medical innovations.

In the focus group discussions, the participants dwelled on the complexity of the health care system, complexity that stems as much from the myriad values and social practices as from its organizational or relational mechanisms. These values and practices result in a unique view of responsibility in medical innovation. For example, the participants raised the issue of dignity and autonomy of health care system users:

What does personal choice mean? It's as though as soon as you talk about health care, the patient's wishes become secondary. I spent a lot of time in the system and I can tell you that treating the patient like a child is common practice. It's just not right. [Health care providers] know what you need better than you. (M13, user)

Others cited specific innovations related to shared decision-making between the patient and the treatment team and technological tools to support these principles: "More and more, patients want to have a say in their treatment, and there's a need to help them

make decisions and therefore to have technology that allows people to make decisions about their health” (M8, user). The participants would like to see medical innovations that will place users at the centre of the health care system and equip them to assume an active role in decisions about their health.

As new health technologies transform our view of the human body, illness, and life (Brown and Webster 2004), it is essential to be reflexive about the consequences of technological choices:

M12 (developer): “We spoke about a holistic approach earlier. We need to consider the value of the technology and how to implement it into the system, what it’s going to bring not just in terms of savings but in terms of value for the patient. [...] Last week I attended a presentation on genetic screening. We develop and spend a lot of money on genetic tests for illnesses that we can’t treat. What’s the point of screening and then telling new parents that their child has an illness that they can’t treat? You’re better off not knowing.”

This example of genetic screening shows that the effects of newly implemented medical innovations require an in-depth analysis. These innovations are rooted in a continuum of care that involves an entire chain of interventions and service delivery. Diagnosis is just the first step in a long, complex process of preventive care or treatment that durably affects patients and their relatives.

The need for broad reflection on medical innovations also applies to situations where technological developments are constantly increasing life expectancy. In health care, technologies are generally viewed as an opportunity to enrich our possibilities of action, as an effective and reactive model, or as a way to increase medical interventions (Hofmann 2002). Citing examples of technological advances in neonatology, one participant raised certain concerns about these technological capacities.

W2 (user): “It’s amazing that they were able to save him because he was so premature. Technology has allowed us to overcome extraordinary challenges. We really succeeded in saving someone. But, in the end, who will take care of this child? Once he leaves the hospital, what kind of quality of life will he have? And what kind of quality of life will his parents have? Were the parents really told what kind of life they could expect to have with this child?”

This example demonstrates the tough balancing act the health care system faces – in this case, intervening to save the life of an extremely premature infant while ensuring the quality of life of the child and his family. And as technology advances, this balance is constantly being called into question. Many participants wondered how the notion of balance applies to the treatment of rare diseases. Some raised questions about how to respond to these limited but costly clinical niches while at the same time meet the health needs of the population. At a time when health care systems need to control costs, striking a balance means making difficult choices. Citing amyotrophic lateral sclerosis as an example of a rare disease, one participant stressed that the quest for balance must factor in the notion of equity:

W6 (user): “Does this mean that the money needed for research or to cure a disease is based on how many people are sick? [...] Is everybody important? And I’m not talking about equality, I’m talking about equity. How do we make sure that people with rare, fatal diseases [are taken into consideration]? Can the concept of fairness, not just equality, be factored into the allocation of public funds to research and development?”

What these comments reveal is that the design of responsible medical innovation must factor in diverse societal values and practices. Not isolated objects, health technologies are embedded in a heterogeneous network of tools, practices, values, and principles that make action possible in health care (Timmermans and Berg 2003). As the participants often repeated, there are also organizational (e.g. funding of health establishments) and relational considerations. In a discussion on organizational innovations that could be used to improve coordination among health professionals as well as patient follow-ups, a participant raised an issue specific to the health care system, i.e. the power dynamics between health professionals. In her view, the creation of multidisciplinary teams is a delicate process that must contend with clearly delineated responsibilities and inter-professional relations that can, at times, be difficult:

W5 (user): “In the field of rehabilitation, we say that we take a holistic view of the patient, but the fact is that the health care system doesn’t necessarily make this possible. Practitioners are trained to view the patient as a whole but then they’re not given the right to take the necessary action or to think about these things. When I worked in a research and rehabilitation centre, I worked with clinicians on chronic pain and they certainly knew that psychosocial and psychological factors have to be considered but they also knew it wasn’t part of their mandate. So they can’t consider these factors or they can’t treat these patients because they’re not allowed to.”

These reflections on values, social practices, organizational mechanisms, and relationships between professionals clearly show that for the focus group participants, all responsible medical innovation projects should revolve around the patient. They invite us to question this medical and organizational ethos regarding changes brought about by innovation and to exhibit more reflexivity in designing medical innovations for the health care system.

The way the health care system interfaces with the innovation system was also addressed; some participants expressed values and principles specific to the financing and commercialization of innovation. For its part, the biomedical industry focuses on lucrative markets to offset the major financial risks incurred. As one participant said, producers of medical innovations look for lucrative clinical niches instead of focusing on meeting the population’s health needs:

M14 (developer): “As a general rule, the industry will only address problems that are profitable, [...] There’s no question that Viagra is great. Maybe if I’m impotent someday, I’ll be happy to have it, but there’s more important research that needs to be done first and that’s not being done because it won’t be for people who will pay, because the drug won’t be worth enough. At the moment, medicine is being driven by financial considerations. When you go to the medical device trade shows, what you see is that they’re not selling care, they’re selling the most expensive medical devices while keeping up with the competition in order to make profits. They’re all private companies.”

Furthermore, this opportunistic research takes place within a restrictive regulatory context as one participant explains: “There are so many obstacles before you get to market. You have to go through the [Food and Drug Administration] and Health Canada, prove the product’s effectiveness and safety, and then there are other agencies, like the [Quebec Health technology Assessment Agency]” (M9, developer). Funding is also difficult to obtain in this sector. One participant mentioned that the culture of innovation in industry could not be more different than in the health care system:

M7 (user): “The industry will say: ‘Okay, that’s enough, we’re dropping this, let’s get organized and move in this direction.’ Hospitals, by their very nature, are resistant to change. Their thinking is, ‘At least I know where I’m headed.’ Before they decide to change directions, they want to be sure it’s going to work. [...] Electronic records are a case in point – we’ve been talking about them ever since I started my medical career. I’m about to retire and we still don’t have them [laughter].”

For Stilgoe, Owen, and Macnaghten (2013), reflexivity is closely tied to the three other dimensions. For example, anticipating the risks of an innovation implies a strong reflexive capacity for actors to understand the likely consequences of the interplay between technical and social changes (Beck 2001). In sum, reflexive issues that arose within the focus groups made it clear that harmonizing the value systems and social practices governing the health care and innovation systems is a necessary, albeit difficult task. Nonetheless, the concerns shared by our participants suggest that a responsible medical innovation should focus on the user experience (patients in particular), integrate their specific requirements into the context of use and empower them. Also, as further developed below, to nurture a reflexive capacity and reactively modulate innovation trajectories, social actors other than engineers and researchers must be included in the process.

2.3. Inclusion, or the challenge of including the wider public in the medical innovation process

Inclusion, the third dimension of the framework, calls for the broad engagement of various interest groups in the innovation process itself with a view to bringing together different points of view in order to allow the actors to learn from each other. This learning also revolves around a quest for social legitimacy for innovation projects.

Inclusion is part of a political context that is increasingly attentive to the involvement of a wider public in scientific and technological decisions. In the past, society’s contribution to research and innovation projects was based on the “deficit model,” whereby researchers transferred knowledge to an ignorant public (Bauer, Allum, and Miller 2007). While this “deficit model” still exists, other approaches have emerged that recognize the usefulness of involving the public in scientific and technology decisions (Bauer, Allum, and Miller 2007). This recognition has led to a proliferation of approaches for involving the public in scientific and technology decisions (Rowe and Frewer 2005). The health sector, more specifically, has been particularly proactive in patient and public participation. Many have sought to involve patients in HTAs (McGregor and Brophy 2005). Others have attempted to include citizens in community health priority-setting processes (Abelson et al. 2003; Boivin et al. 2014) or in the drafting of clinical practice guidelines (Boivin et al. 2010). Public and user engagement is also recommended in order to improve the relevance of new technologies, their implementation, and use (Bridgelal Ram, Grocott, and Weir 2008; Grocott, Weir, and Bridgelal Ram 2007; Martin et al. 2012; Shah, Robinson, and AlShawi 2009; Sharples et al. 2012).

Our participants were well aware of the strengths and limitations of inclusive processes. As one participant pointed out, including the actors concerned in the medical innovation process is an ideal to aspire to: “Ideally, each actor would be able to express an opinion when a technology is being developed” (W1, developer). However,

many challenges make this ideal difficult to attain. As mentioned earlier, producers of medical innovations must demonstrate an interest in the knowledge and know-how of the users, be they health professionals or patients. These producers must also have the knowledge and ability to understand the needs of health care environments and develop innovation projects accordingly. Integrating users in the process also implies access to health care centres, staff and patients. While a clear understanding of needs based on clear objectives is essential in any technological development, the reality is that producers and users live in different worlds that are difficult to bring together, as one participant pointed out:

M5 (developer): “One of the challenges of technological development is that there are many potential users who have needs. Spend a day in a hospital and you’d be blown away by how many needs there are. The problem is that patients, and doctors too for that matter, don’t know what technologies are available. They’re not tech people. Engineers, computer experts, developers, etc. are the ones who understand technology, but they’re not in the hospitals. They have no clue what the needs are. The challenge is to put these people in touch with users. Then, maybe you’d have more relevant technological innovations because they’d be meeting a need. As it stands, engineers and developers are working in a vacuum; they have ideas and they think that’s what people need.”

This interest for user engagement upstream of the innovation process in the health sector is meeting with resistance from industry (Martin and Barnett 2012; Money et al. 2011). The participants echoed this resistance and did not support all-out participation:

Based on my experience in product development, there’s some added value to user engagement, but there are also big risks. It becomes very hard to find consensus. What I do agree with is that it’s important to start with a good summary of the project and sound objectives. (M4, developer)

For our participants, inclusion is more about finding a way for different worlds to work together and develop a common language so both producers and users can learn from each other:

M3 (user): “As you say, the different worlds – industry, academia, scientists, engineers and users – all have to co-exist. And I don’t think the eyeglasses imagery works. You need more than glasses; you need a different language, a different communication. These people don’t speak the same language, they come from different worlds, different cultures. Even engineers and doctors come from different ...”

M5 (developer): “They come from completely different worlds.”

M3 (user): “They don’t speak the same language, they don’t understand each other.”

In essence, the analysis of the focus groups reveals that although the inclusion of actors such as users (health professionals, patients, and caregivers), purchasers (health care organizations, third-party payers), and citizens in the medical innovation process is advantageous, it is also fraught with problems. Participants shared concerns about access to users and health care organizations, interest and sensibility of the developers of medical innovations, and lack of a common language. These issues need to be considered to move towards responsible innovation in health, acknowledging at the same time that inclusion is not a miracle solution to avoid the emergence of *irresponsible* innovation (Hyysalo 2010).

2.4. Responsiveness, or the challenge of modulating medical innovation trajectories in a highly regulated environment

Responsiveness, the last dimension of the framework, involves the capacity of the innovation process to change in response to emerging views, knowledge, values, and changes in the innovation environment. Responsiveness is therefore about making the inevitable adjustments to innovation trajectories as they progress and mobilizing the expectations of everyone involved. It also places emphasis on the capacity of producers to factor in emerging values, norms, knowledge, and perspectives in medical innovation R&D.

Current literature suggests that the processes of technological change and development are highly dynamic and may offer many learning opportunities to those involved. Technological options, user preferences and the necessary institutional changes may not necessarily be imposed but may rather be created and adjusted during the technology development process (Bijker and Law 1992; Mackenzie and Wacman 1999; Williams and Edge 1996). The innovation trajectories in health care are not linear but evolving across time and distributed across space (Consoli and Mina 2009; Ramlogan et al. 2007). Medical innovation amounts to a learning process between clinical practice, scientific knowledge, and technical developments (Morlacchi and Nelson 2011). Yet, this process remains highly structured by institutional rules and policies (i.e. licensing, assessment, funding, national and international standards, etc.) that regulate innovation trajectories (Webster 2008). Innovation governance tools may even sometimes follow a “logic of unresponsiveness” (Pellizzoni 2004, 558), which impedes the innovators’ desired capacity to absorb relevant knowledge, values, and judgements. Therefore, one key challenge is to steer the medical innovation trajectories within a highly regulated context towards more desirable pathways.

When analysing the focus group discussions, we realized that responsiveness is not limited just to the R&D phase but also encompasses the utilization phase. Our participants pointed out that technologies must adjust to the diverse contexts in which they are used:

M7 (user): “Care can differ depending on where it is delivered. If we bring a given technology to one place, there’s no guarantee that it will be useful in another, which is where our attempt at standardization of health care comes in. But how can you standardize when the methods of operation differ from one place to the other?”

In addition, the participants’ comments prompt us to consider another form of responsiveness, that of the health care system in relation to various organizational or technological innovations. For instance, as one participant stated, medical advances lead to the rapid obsolescence of existing technologies:

I’m interested in telemedicine and tele-rehabilitation, an area in which few cost analyses exist, especially regarding the cost-effectiveness of the technologies. And here too, the technology is changing quickly. In this case, if you look at the cost of the technology and equipment, you’d find that it used to cost \$80,000, but today you can do the same thing with an iPad. (W5, user)

The replacement of expensive equipment in a context of rapid technological development and cost control is placing tremendous pressure on health care centres, which must continually adapt. Striking a balance in this regard is made all the more difficult by pressure from health professionals and especially specialists, who insist on having the latest medical devices:

W3 (developer): “There’s also pressure for cutting-edge technologies. Another example is MRIs. Radiologists no longer want 1.5 Tesla MRI images because 3 Tesla images are now available. In five years, the 1.5 Tesla at [name of hospital] will be tossed out and replaced with a 3 Tesla, except that instead of costing \$1.5 million, it will cost \$3 million. And all because the images are crisper and better quality so that we’ll be able to see and detect more things. We create clinical needs.”

Still, the fact that the health care system is not very responsive is not an entirely bad thing. As emphasized in the following discussion, the health care system’s relative inertia lamented by some can actually be seen as positive in some respects:

W3 (developer): “There’s tremendous resistance.”

M7 (user): “There’s resistance. But it’s legitimate because we know that our treatment methods are safe. If we change them, we don’t know what the outcome will be.”

To summarize, not only should innovation trajectories be reactive, but responsible innovations should also respond to the specificities of diverse clinical environments. Interestingly, for our participants, responsiveness in the medical innovation process is not circumscribed to the knowledge, values, and judgements pertaining to the design, development, production, and diffusion stages. The utilization stage matters as well.

3. Moving towards responsible medical innovation

We began this article by emphasizing the fact that the notion of responsibility was already highly formalized through legislation and embedded, to varying extent, in health care practices. Such responsibility has been institutionalized according to a consequentialist model that largely ignores the dynamics driving innovation processes as much as the needs and challenges of health care systems. For this reason, we used the RRI framework developed by Stilgoe, Owen, and Macnaghten (2013) as a heuristic tool to explore, through the views, expertise and experience of participants engaged in the development, management, and use of medical innovations what responsible medical innovation may entail.

Our paper contributes to current knowledge in two ways. First, our analyses empirically fleshed out key issues responsible medical innovation should seek to address (summarized in Table 1). Deploying a responsible innovation approach in health care requires that developers carefully anticipate the consequences and opportunities associated with medical innovations, including their organizational, social, economic, and ethical issues. Responsible medical innovation also calls for users and developers to align potential innovations with clinical and health care system challenges and needs. To this end, there must be harmonization between the value systems and social practices governing the health care system and the medical innovation system. Actors belonging to these two systems should thus engage in reflexive, interactive, and learning processes to develop a common understanding of the issues at play. While patients and health care providers must play a significant role in medical innovation processes, technology developers should also involve a wider public through formal deliberative mechanisms. Such structured interaction between actors would bring to light each party’s assumptions and knowledge so as to swiftly influence the medical innovation trajectory. To this end, regulations and monitoring mechanisms must allow for some flexibility in the medical innovation process without,

however, compromising the safety of new products. Attention must therefore be paid both upstream (R&D) and downstream (dissemination and use) of the innovation cycle.

A second contribution of our paper pertains to its application of the RRI framework, which productively led to a more specific understanding of what responsible medical innovation may entail, but which also brings forward the relevance of establishing further linkages between the framework and existing bodies of knowledge. Scholarly works in the areas of Science and Technology Studies, sociology of health and illness, user and/or public involvement, philosophy of technology and bioethics do share affinities in their overall aim of shedding light on the ethical and social underpinnings of technological innovation in health. [Table 2](#) provides examples of approaches that are relevant to the further development of responsible medical innovation.

For example, the development of a new diagnostic test could incorporate social, ethical, and organizational considerations throughout the innovation trajectory (e.g. social acceptability, environmental impact, accessibility and fairness, psychosocial effects, patient-focused perspectives, implementation in organizational routines, training, and professional skills). Value-based decision frameworks ([Duthie, Bond, and Juzwishin 2014](#); [Jiwani 2015](#)) could assist to identify the values, ethical justifications, and social practices relevant to health innovation decisions, to develop a shared understanding among stakeholders and to work out an acceptable innovation solution. In addition co-design methods ([Sanders and Stappers 2008](#)) or value-driven innovation ([de Ana et al. 2013](#)) could be implemented to encourage cooperation between producers and users. On another level, public deliberation mechanisms could be implemented for decision-making purposes and for prioritizing such “responsible” tests in the health care system ([Abelson et al. 2003](#); [Boivin et al. 2014](#); [Martin and Barnett 2012](#); [Rowe and Frewer 2005](#); [Sharples et al. 2012](#)).

While the RRI framework helped us to organize and interpret rich empirical observations, it is not without limitations. While it may be useful as an innovation governance instrument, it appears less readily usable to steer current ways of designing and producing medical innovations. [Stilgoe, Owen, and Macnaghten \(2013\)](#) applied their framework through a stage-gate governance process of a geoengineering project where research councils were closely involved (i.e. funds were allocated following a stage-gate process). Such an approach would be difficult to apply in the current medical device industry, which is highly heterogeneous (large, dominant multinationals, and many small and medium-sized enterprises), has not integrated user involvement strategies to a large extent, and often operates under strict confidentiality requirements. Within this perspective,

Table 2. Bodies of knowledge that are relevant to the further development of responsible medical innovation.

Anticipation	Constructive assessments of health care technologies (Douma et al. 2007)
Reflexivity	Social assessment of medical technologies (Lehoux and Blume 2000 ; van Oudheusden 2014) Value-based decision frameworks (Duthie, Bond, and Juzwishin 2014 ; Jiwani 2015)
Inclusion	Public deliberation and/or user engagement mechanisms (Abelson et al. 2007 ; Bridgelal Ram, Grocott, and Weir 2008) Co-design methods (Sanders and Stappers 2008) Value-driven innovation (de Ana et al. 2013)
Responsiveness	Open innovation in health care (Bullinger et al. 2012)

Table 3. Policy tools that are relevant to the further development of responsible medical innovation.

Anticipation – The challenge of clearly understanding the uses of a medical innovation and its context

- Proactive and iterative HTA in early stages of the innovation process with emphasis on clinical, economic, patient-related, and organizational aspects (Douma et al. 2007)
- Use of prospective scenarios to anticipate effects of medical innovations and foster R&D planning (Vollmar, Ostermann, and Redaelli 2015)
- Diffusion to the medical industry of existing guidelines on ways to integrate social, organizational, and ethical issues in medical innovation (Hofmann 2005; Lehoux and Williams-Jones 2007)

Reflexivity – The challenge of aligning health and innovation value systems and social practices

- Revision of engineering and industrial design training curriculum to better integrate ethics and social concerns (Martin, Rayne, and Kemp 2005)
- Addressing ethical and social issues responsibly during the development of new technology through value sensitive design approach (Timmermans, Zhao, and van den Hoven 2011)
- Use of value-based decision frameworks to identify values, develop a shared understanding among actors and work out an acceptable innovation solution (Duthie, Bond, and Juzwishin 2014; Jiwani 2015)
- Social and political assessment of medical innovation projects and the (future) context of use (Lehoux and Blume 2000; van Oudheusden 2014)

Inclusion – The challenge of including users/publics in the medical innovation process

- Diffusion to the medical industry of existing toolboxes on the involvement users and the public in medical innovation process (Aldersey-Williams, Bound, and Coleman 1999; Sanders and Stappers 2008)
- Bridging initiatives between developers, providers, and researchers (initiated and supported by national research councils)
- Dedicated public funding to promote user engagement in medical innovation process (e.g. tax credit), while considering the complexity of such engagement

Responsiveness – The challenge of modulating medical innovation trajectories in highly regulated environments

- Creation of innovation loci inside health organizations (e.g. living lab) (Hyysalo and Hakkarainen 2014)
- Fostering disruptive social or technological innovation approaches (e.g. “hackathons” in health, open innovation initiatives) (Bullinger et al. 2012; Chowdhury 2012)
- Adaptation of risk regulatory tools and systems (Lee and Petts 2013)
- International policy dialogue on the globalization of medical innovation process and products (e.g. multi-sites clinical trials, direct-to-consumer marketing, medical device trade balance, etc.)

Table 3 provides a series of policy tools that should be more specifically examined since they may contribute to the further development of responsible medical innovation.

Another aspect of the framework that merits further examination is the interaction between the four analytic dimensions. Our observations show that the actors involved in developing innovations and those who make use of them operate in different worlds. The distance between them is largely reinforced by the linear vision and organization of technological development. Can the application of the four dimensions bridge the gap between these worlds and lead to the creation of an enduring shared world for responsible innovation? What theoretical lens should be mobilized to make sense of these shared and non-linear practices?

4. Conclusion

Since their creation in the 1970s, the notion of responsibility has been embedded in health care systems through legal and professional statutes and obligations. The purpose of this article was to deepen our understanding of the RRI approach in the context of technological innovation in health care. As suggested by our empirical observations and the scholarly literature on health innovation, the approach developed by Stilgoe, Owen, and Macnaghten

(2013) offers us an opportunity to think productively about the design and use of new medical technologies. In this article, we achieved an important first step in making the model much more specific to health innovation. The four dimensions that we empirically consolidated form a whole that we acknowledge is incomplete. However, our analyses brought to the fore key challenges that responsible medical innovation could address by articulating: (1) a clearer understanding of the uses of a medical innovation and of its context; (2) a better alignment between health and innovation value systems and social practices; (3) a sustained engagement of users and the public in the innovation process; and (4) a flexible steering of innovation trajectories within a highly regulated environment.

Notes

1. In Canada, *Canada Health Act* (R.S.C., 1985, c. C-6). In Quebec, *An Act Respecting Health Services and Social Services* (Chapter S-4.2) and the *Public Health Act* (Chapter S-2.2).
2. In Canada, the *Medical Devices Regulations* (SOR/98-282).
3. In Canada, the *Food and Drugs Act* (R.S.C., 1985, Chapter F-27). A policy also guides the manufacture of drug products by pharmacists: the *Policy on Manufacturing and Compounding Drug Products in Canada* (POL-0051).
4. In Canada, the production of medical devices must comply with the requirements of national standard *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* (CAN/CSA-ISO 13485:03).
5. Considering the variety of disciplines and professional roles of our participants, we designate for each quote whether the participant is a woman (W) or man (M) and either a user (e.g. physician, nurse, occupational therapist, representative from patient associations, caregiver) or a developer (e.g. biomedical engineer, industrial designer, medical device developer, technology transfer expert). Although this classification over-simplifies the richness of the standpoint from which participants shared their views, it does consolidate anonymity and it remains analytically consistent with the framework.
6. Participants also question the importance placed on the technological product as a solution to a clinical problem.
7. Stilgoe, Owen, and Macnaghten (2013) also refer to the reflexive capacity of individuals (mostly researchers). They emphasize, however, the need for greater *institutional reflexivity* in R&D governance.

Acknowledgements

We would like to thank the participants of this study who graciously accepted to share their views and insights. Myriam Hivon, Jean-Louis Denis, Fiona Miller, Bryn Williams-Jones and David Urbach – colleagues who are involved in the broader study from which this paper draws its data – shared insightful comments throughout the research process.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This research was funded by an operating grant from the Canadian Institutes of Health Research (CIHR; #KTB-114384). P. Lehoux held a Canada Research Chair on Health Innovations (2005–

2015). Our research group infrastructure is supported by the Fonds de la recherche du Québec-Santé (FRQS).

Notes on contributors

Olivier Demers-Payette holds a B.A. in Science and Technology Studies, a M.Sc. in Healthcare Administration, and a Ph.D. in Public Health. During his studies, he worked on citizen and users involvement in medical innovation process and technological choices. He is now a research assistant.

Pascale Lehoux holds a degree in Industrial Design and a Ph.D. in Public Health. She is a professor in the Department of Health Administration at the School of Public Health of University of Montreal. In the last years, she examined the design process of health innovation. Her new research programme aims to elucidate new ways to design, finance, and manufacture innovations.

Geneviève Daudelin holds a B.A. in Social Work and a Ph.D. in Sociology. Over the years, she worked on human reproduction, health technologies, knowledge of healthcare services users, and public participation. Currently, she works as a research assistant on health innovation at the Institute of Public Health Research of the University of Montreal.

ORCID

Olivier Demers-Payette  <http://orcid.org/0000-0002-6711-6716>

Pascale Lehoux  <http://orcid.org/0000-0001-9482-1800>

References

- Abelson, J., J. Eyles, C. B. McLeod, P. Collins, C. McMullan, and P.-G. Forest. 2003. "Does Deliberation Make a Difference? Results from a Citizens Panel Study of Health Goals Priority Setting." *Health Policy* 66: 95–106.
- Abelson, J., P.-G. Forest, J. Eyles, A. Casebeer, E. Martin, and G. Mackean. 2007. "Examining the Role of Context in the Implementation of a Deliberative Public Participation Experiment: Results from a Canadian Comparative Study." *Social Science & Medicine* 64: 2115–2128.
- Aldersey-Williams, H., J. Bound, and R. Coleman. 1999. *Methods Lab: User Research for Design*. London: Helen Hamlyn Research Centre.
- Banta, D. 2003. "The Development of Health Technology Assessment." *Health Policy* 63: 121–132.
- Bauer, M. W., N. Allum, and S. Miller. 2007. "What Can We Learn from 25 Years of PUS Survey Research? Liberating and Expanding the Agenda." *Public Understanding of Science* 16 (1): 79–95.
- Beck, U. 2001. *La société du risque. Sur la voie d'une autre modernité*. Paris: Éditions Flammarion.
- Bijker, W. E., and J. Law. 1992. *Shaping Technology/Building Society. Studies in Sociotechnical Change*. Cambridge: MIT Press.
- Boivin, A., K. Currie, B. Fervers, J. Gracia, M. James, C. Marshall, ... J. Burgers. 2010. "Patient and Public Involvement in Clinical Guidelines: International Experiences and Future Perspectives." *Quality & Safety in Health Care* 19 (5): 1–4.
- Boivin, A., P. Lehoux, R. Lacombe, J. Burgers, and R. Grol. 2014. "Involving Patients in Setting Priorities for Healthcare Improvement: A Cluster Randomized Trial." *Implementation Science* 9 (1): 24–34.
- Bridgelal Ram, M., P. R. Grocott, and H. C. M. Weir. 2008. "Issues and Challenges of Involving Users in Medical Device Development." *Health Expectations* 11: 63–71.
- Brown, A., and A. Webster. 2004. *New Medical Technologies and Society: Reordering Life*. Cambridge: Polity Press.
- Bullinger, A. C., M. Rass, S. Adamczyk, K. M. Moeslein, and S. Sohn. 2012. "Open Innovation in Health Care: Analysis of an Open Health Platform." *Health Policy* 105 (2–3): 165–175. doi:10.1016/j.healthpol.2012.02.009.

- Cappelen, A. W., and O. F. Norheim. 2005. "Responsibility in Health Care: A Liberal Egalitarian Approach." *Journal of Medical Ethics* 31: 476–480.
- Chowdhury, J. 2012. "Hacking Health: Bottom-up Innovation for Healthcare." *Technology Innovation Management Review* 2 (7): 31–35.
- Consoli, D., and A. Mina. 2009. "An Evolutionary Perspective on Health Innovation Systems." *Journal of Evolutionary Economics* 19: 297–319.
- Dain, S. 2002. "Normal Accidents: Human Error and Medical Equipment Design." *Heart Surgery Forum* 5 (3): 254–257.
- De Ana, F. J., K. A. Umstead, G. J. Phillips, and C. P. Conner. 2013. "Value Driven Innovation in Medical Device Design: A Process for Balancing Stakeholder Voices." *Annals of Biomedical Engineering* 41 (9): 1811–1821. doi:10.1007/s10439-013-0779-5.
- Douma, K. F. L., K. Karsenberg, M. J. M. Hummel, J. M. Bueno-de-Mesquita, and W. H. Van Harten. 2007. "Methodology of Constructive Technology Assessment in Health Care." *International Journal of Technology Assessment in Health Care* 23 (2): 162–168.
- Duthie, K., K. Bond, and D. Juzwishin. 2014. "Improving Leadership Through Values-based Decisions." *Healthcare Management Forum* 27 (4): 168–170.
- Faulkner, A. 2009. *Medical Technology into Healthcare and Society. A Sociology of Devices, Innovation and Governance*. New York: Palgrave Macmillan.
- Gelijns, A. C., and S. O. Thier. 2002. "Medical Innovation and Institutional Interdependence. Rethinking University–Industry Connections." *Journal of the American Medical Association* 287 (1): 72–77.
- Gelijns, A. C., J. G. Zivin, and R. R. Nelson. 2001. "Uncertainty and Technological Change in Medicine." *Journal of Health Politics, Policy and Law* 26 (5): 913–924.
- Giacomini, M., N. Kenny, and D. DeJean. 2009. "Ethics Frameworks in Canadian Health Policies: Foundation, Scaffolding, or Window Dressing?" *Health Policy* 89 (1): 58–71.
- Grinbaum, A., and C. Groves. 2013. "What Is 'Responsible' about Responsible Innovation? Understanding the Ethical Issues." In *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, edited by R. Owen, J. Bessant, & M. Heinzl, 119–142. London: Wiley.
- Grocott, P. R., H. C. M. Weir, and M. Bridgelal Ram. 2007. "A Model of User Engagement in Medical Device Development." *International Journal of Health Care Quality Assurance* 20 (6): 484–493.
- Hofmann, B. 2002. "The Myth of Technology in Health Care." *Science and Engineering Ethics* 8: 17–29.
- Hofmann, B. 2005. "Toward a Procedure for Integrating Moral Issues in Health Technology Assessment." *International Journal of Technology Assessment in Health Care* 21 (3): 312–318.
- Høyer, C. S., E. F. Christensen, and B. Eika. 2008. "Adverse Design of Defibrillators: Turning Off the Machine When Trying to Shock." *Annals of Emergency Medicine* 52 (5): 512–514.
- Hsieh, H.-F., and S. E. Shannon. 2005. "Three Approaches to Qualitative Content Analysis." *Qualitative Health Research* 15 (9): 1277–1288.
- Hyysalo, S. 2010. *Health Technology Development and Use: From Practice-bound Imagination to Evolving Impacts*. New York: Routledge.
- Hyysalo, S., and L. Hakkarainen. 2014. "What Difference Does a Living Lab Make? Comparing Two Health Technology Innovation Projects." *CoDesign* 10 (3–4): 191–208.
- Jiwani, B. 2015. "Ethically Justified Decisions." *Healthcare Management Forum* 28 (2): 86–89.
- Kitzinger, J. 1994. "The Methodology of Focus Groups: The Importance of Interaction Between Research Participants." *Sociology of Health and Illness* 16 (1): 103–121.
- Kitzinger, J. 1995. "Qualitative Research: Introducing Focus Groups." *British Medical Journal* 311: 299–302.
- Lee, R. G., and J. Petts. 2013. "Adaptive Governance for Responsible Innovation." In *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, edited by R. Owen, J. Bessant, and M. Heinzl, 143–164. London: Wiley.
- Lehoux, P. 2006. *The Problem of Health Technology: Policy Implications for Modern Health Care Systems*. New York: Routledge.

- Lehoux, P., and S. S. Blume. 2000. "Technology Assessment and the Sociopolitics of Health Technologies." *Journal of Health Politics, Policy and Law* 25 (6): 1083–1120.
- Lehoux, P., B. Poland, and G. Daudelin. 2006. "Focus Group Research and 'the Patient's View.'" *Social Science & Medicine* 63: 2091–2104.
- Lehoux, P., S. Tailliez, J.-L. Denis, and M. Hivon. 2004. "Redefining Health Technology Assessment in Canada: Diversification of Products and Contextualization of Findings." *International Journal of Technology Assessment in Health Care* 20 (3): 325–336.
- Lehoux, P., and B. Williams-Jones. 2007. "Mapping the Integration of Social and Ethical Issues in Health Technology Assessment." *International Journal of Technology Assessment in Health Care* 23 (1): 9–16.
- Leys, M. 2003. "Health Care Policy: Qualitative Evidence and Health Technology Assessment." *Health Policy* 65: 217–226.
- Mackenzie, D. A., and J. Wacman. 1999. *The Social Shaping of Technology* (2nd ed.). Philadelphia, PA: Open University Press.
- Martin, J. L., and J. Barnett. 2012. "Integrating the Results of User Research into Medical Device Development: Insights from a Case Study." *BMC Medical Informatics and Decision Making* 12: doi:10.1186/1472-6947-12-74.
- Martin, J. L., D. J. Clark, S. P. Morgan, J. A. Crowe, and E. Murphy. 2012. "A User-centred Approach to Requirements Elicitation in Medical Device Development: A Case Study from an Industry Perspective." *Applied Ergonomics* 43 (1): 184–190.
- Martin, T., K. Rayne, and N. J. Kemp. 2005. "Teaching for Adaptive Expertise in Biomedical Engineering Ethics." *Science and Engineering Ethics* 11 (2): 257–276.
- McGregor, M., and J. M. Brophy. 2005. "End-user Involvement in Health Technology Assessment (HTA) Development: A Way to Increase Impact." *International Journal of Technology Assessment in Health Care* 21 (2): 263–267.
- McMillan, G. S., F. Narin, and D. L. Deeds. 2000. "An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology." *Research Policy* 29: 1–8.
- Miles, M. B., A. M. Huberman, and J. Saldaña. 2014. "Designing Matrix and Network Displays." In *Qualitative Data Analysis. A Methods Sourcebook*, edited by M. B. Miles, M. Huberman, and J. Saldaña, 107–119. London: SAGE Publications.
- Mina, A., R. Ramlogan, G. Tampubolon, and J. S. Metcalfe. 2007. "Mapping Evolutionary Trajectories: Applications to the Growth and Transformation of Medical Knowledge." *Research Policy* 36: 789–806.
- Money, A. G., J. Barnett, J. Kuljs, M. P. Craven, J. L. Martin, and T. Young. 2011. "The Role of the User Within the Medical Device Design and Development Process: Medical Device Manufacturers' Perspectives." *BMC Medical Informatics and Decision Making* 11: 15–27.
- Morlacchi, P., and R. R. Nelson. 2011. "How Medical Practice Evolves: Learning to Treat Failing Hearts with an Implantable Device." *Research Policy* 40: 511–525.
- Pellizzoni, L. 2004. "Responsibility and Environmental Governance." *Environmental Politics* 13 (3): 541–565.
- Ramlogan, R., A. Mina, G. Tampubolon, and J. S. Metcalfe. 2007. "Networks of Knowledge: The Distributed Nature of Medical Innovation." *Scientometrics* 70 (2): 459–489.
- Rip, A. 2014. "The Past and Future of RRI." *Life Sciences, Society and Policy* 10 (1): 17–31.
- Rose, N. 2007. *The Politics of Life Itself. Biomedicine, Power, and Subjectivity in the Twenty-first Century*. Princeton, NJ: Princeton University Press.
- Rowe, G., and L. J. Frewer. 2005. "A Typology of Public Engagement Mechanisms." *Science, Technology and Human Values* 30 (2): 251–290.
- Sanders, E. B.-N., and P. J. Stappers. 2008. "Co-creation and the New Landscapes of Design." *CoDesign* 4 (1): 5–18.
- Shah, S. G. S., I. Robinson, and S. AlShawi. 2009. "Developing Medical Device Technologies from Users' Perspectives: A Theoretical Framework for Involving Users in the Development Process." *International Journal of Technology Assessment in Health Care* 25 (4): 514–521.
- Sharples, S., J. L. Martin, A. Lang, M. P. Craven, S. O'Neill, and J. Barnett. 2012. "Medical Device Design in Context: A Model of User-device Interaction and Consequences." *Displays* 33 (4–5): 221–232.

- Stilgoe, J., R. Owen, and P. Macnaghten. 2013. "Developing a Framework for Responsible Innovation." *Research Policy* 42: 1568–1580.
- Timmermans, S., and M. Berg. 2003. "The Practice of Medical Technology." *Sociology of Health & Illness* 25: 97–114.
- Timmermans, J., Y. Zhao, and J. van den Hoven. 2011. "Ethics and Nanopharmacy: Value Sensitive Design of New Drugs." *Nanoethics* 5 (3): 269–283.
- Van Oudheusden, M. 2014. "Where Are the Politics in Responsible Innovation? European Governance Technology Assessments, and Beyond." *Journal of Responsible Innovation* 1 (1): 67–86.
- Vollmar, H. C., T. Ostermann, and M. Redaelli. 2015. "Using the Scenario Method in the Context of Health and Health Care – A Scoping Review." *BMC Medical Research Methodology* 15 (1): 89–99.
- Von Schomberg, R. 2013. "A Vision of Responsible Innovation." In *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, edited by R. Owen, J. Bessant, and M. Heinzl, 51–74. London: Wiley.
- Webster, A. 2008. *Health, Technology & Society: A Sociological Critique*. New York: Palgrave Macmillan.
- Williams, R., and D. Edge. 1996. "The Social Shaping of Technology." *Research Policy* 25: 865–899.