

What leads to better health care innovation? Arguments for an integrated policy-oriented research agenda

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This essay is based on the recognition that the current ‘downstream’ health services research and policy approach to innovation misses the mark on one crucial point. It has not addressed how to promote the design of innovations that are likely to be more valuable than others. Re-visiting the ways in which health services research could inform innovation processes, this paper suggests that three attributes make innovations especially compelling from a health care system perspective: relevance; usability; and sustainability. These could be used as a starting point for outlining a policy-oriented research agenda that could bridge upstream design processes, and downstream needs and priorities. Given the pace at which innovations come about and the complexity of health care systems, we believe that both research and policy should be able to contribute significantly to the shaping of socially valuable technological change in health care. Recognizing that such a long-term goal cannot be reached through a linear, rationalistic process, our paper offers preliminary arguments to start to reconcile the health policy and innovation agendas.

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Reconciling the innovation and health care agendas?

Modern health care is eminently specialized and innovations are pushing the frontiers of what is knowable and doable a little further everyday. As vividly evoked by a patient association representative, new drugs emerge a bit like new rock stars:

‘There are thousands and thousands of good musicians, but only one or two we know about. How did they get to be so famous? ... We read in the [newspaper]: “New medication discovered for asthma”. There are probably hundreds of new medications, but the only one we hear about is this one. And then people start to pressure us: “How do I get that medication? ... I want it”. Then we, along with our medical advisors say, “Yeah, it’s good!” And then we start to pressure people and all of a sudden you have a rock star!’ (Patient Association 1)

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As with the work achieved ‘upstream’ by engineers, scientists, market analysts, biomedical equipment companies and shareholders, innovation processes remain largely opaque. This relative opacity is further reinforced by the focus of health services and policy research on ‘downstream’ factors, i.e. the effectiveness, cost and impact of technologies once they are introduced into the health care system. However, significant waste of resources (e.g. in terms of personnel, time, finances) and preventable problems (e.g. over- and underuse, safety or ethical issues) occur because innovation processes are not sufficiently informed by downstream concerns. Innovation designers rarely tap into the knowledge generated by health services researchers while health services researchers often fail to provide key insights about the *comparative value* of emerging innovations, such as their significance within the broader universe of desirable health care interventions.

As a result, after decades of research, there is an acute lack of knowledge about ways to promote the design of *more valuable* innovations.¹ Part of the solution, we suggest, is to develop a new collaborative policy-oriented research agenda that can bridge design processes, and health care needs and priorities. This idea is beginning to be recognized by academics and high-level policy-makers around the world.^{2,3} However, only a few concrete initiatives have been implemented in North America and Europe (see www.match.ac.uk), and

mostly because of the prominence of novel forms of technological developments that raise unique social, ethical and regulatory issues, such as biotechnology and nanotechnology. As we will argue, there are three generic valuable features of innovation that can be brought forward in the reconciliation of the innovation and health care agendas.

The disconnect between health care research and innovation policy

Since the 1980s, industrialized countries have relied, with some variation, on two broad public policy domains to deal with health care innovation. On the one hand, the *innovation* branch of government often supports national innovation and commercialization activities in order to generate economic prosperity for the country. On the other hand, the adoption of innovations is largely constrained by the *health policy* branch, which seeks to increase evidence-based decision-making and set priorities given available resources. These policy-making branches of government push in different directions.

The gap is further exacerbated by the complexity of the innovation and health policy branches' respective goals and responsibilities, and the point at which they intervene in the innovation process.² The innovation branch tends to intervene early, and mostly upstream, in order to promote or consolidate a country's innovation capacity, usually through a combination of fiscal, science and higher education policies. The health policy branch, by contrast, is concerned primarily with protecting the public, and so intervenes—through regulation and evaluation—just before innovations are ready to enter the market and once they are part of established clinical practices (downstream). The health policy branch usually focuses on one technology at a time, while the innovation branch supports a range of

public and private innovators operating in niches that are seen as commercially promising, but without an explicit and detailed assessment of health care priorities and needs. What often matters at this early stage is consolidating the financial and managerial capacity of companies (either spin-offs or more mature firms) so they can translate their ideas into marketable products.

Thus despite the seemingly common purpose of improving population health, the two policy domains of health care and innovation rarely interact; and to complicate matters further, they emphasize goals that may diverge starkly, e.g. promoting commercial success versus fulfilling health care needs. Although these tensions are intrinsic to innovation, two challenges are caused by the gulf between innovation and downstream processes, especially in the case of technological innovations (Figure 1). First, patients, clinicians and decision-makers often struggle with the local adoption of innovations that are in one way or another problematic (because of ethical, clinical, economic or organizational shortcomings). For instance, the use of cochlear implants with children who are born deaf has been strongly rejected by deaf communities worldwide; computerized medical records are still insufficiently user-friendly, have proven unpopular with clinicians and thus have been unevenly implemented;⁴ non-interoperable telemedicine applications remain at the pilot stage;⁵ non-standardized IV delivery programmable pumps have led to increased medication errors;⁶ and the cost, complexity and pace of renewal of imaging devices creates acute challenges for hospital administrations.⁷

The second challenge is to increase the efficiency of the innovation process, and avoid investment of time and resources in technologies that lack clinical relevance or are likely to be misused. Although very few scholars would dare to provide robust estimates of the rate of success of medical device innovation (only the

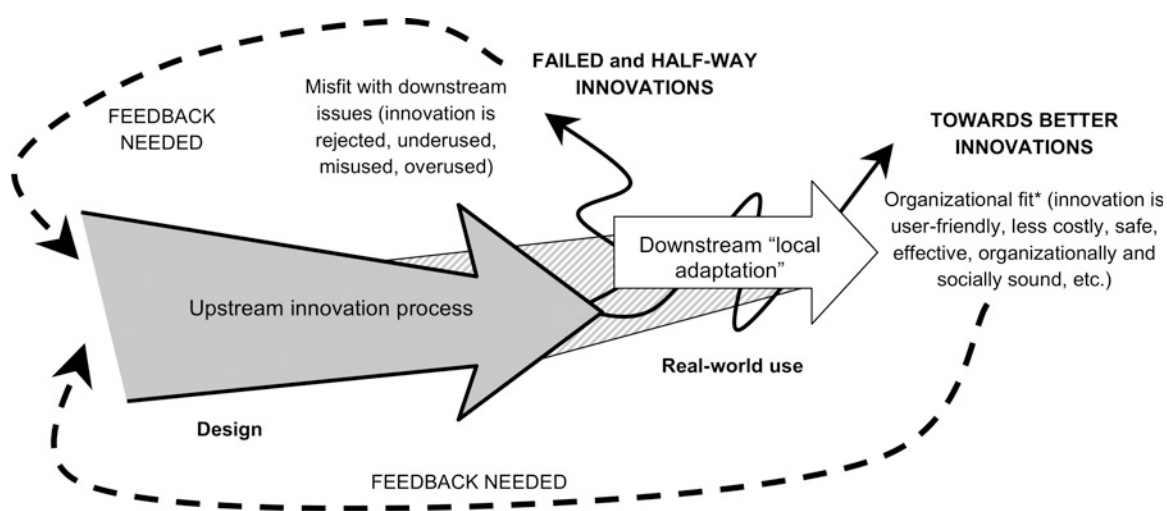


Figure 1 The feedback needed between upstream and downstream innovation processes *Note: From a health care system perspective, a desirable innovation is a technology that: (1) is equally or more effective and costs less than its current alternative; (2) can be used safely and effectively by less skilled and less costly personnel; (3) can be used safely and effectively in any kind of setting and in all geographical areas; (4) solves a health problem permanently or produces diagnostic certainty; (5) does not trigger side effects or reduce a patient's mobility or autonomy; and (6) does not raise ethical dilemmas or give rise to equivocal social transformations¹

pharmaceutical industry process has been extensively studied), a reasonable estimate would be that between 50% and 90% of innovations never get off the ground. There are also signs that the complexity and uncertainty of innovation processes are increasing. The patent allowance (the percentage of applications reviewed by examiners that are actually approved) in the US in 2006 was 54%, the lowest on record in over 20 years.⁸

How could health services research inform innovation processes?

To date, the main downstream response to the problems observed has been to produce more evaluative research and to seek to enforce its use in health care policy. However, as Figure 2 illustrates, there is a significant quandary in the prevailing downstream approach, which emphasizes Health Technology Assessment (HTA). An innovation is ‘wrongfully’ adopted when costs are too high given the observed benefits (i.e. resources are wasted), and patients and/or health care providers are exposed to unjustified risks. Alternatively, when an innovation is not adopted and there is solid HTA evidence to do so, then the savings appear unwise and some legitimate health needs may not be met.

Downstream research and policy are of course necessary and useful. The problem is that their potential to inform innovation processes is limited. Furthermore, relying solely on a downstream approach is a mistake because it misses the mark on one crucial point: in attempting to provide timely, post hoc and piecemeal evidence (that may or may not be used in decision-making), it cannot differentiate innovations that are clearly more valuable than others and enlighten the design process accordingly.¹ Yet, the policy challenge is neither to increase the adoption of innovations nor to slow it down. Instead, the fundamental policy question bridging the two agendas of innovation and health care should be: what makes *superior* innovations come about and how can innovation policies lead to the development of brilliant innovations while avoiding troublesome failures? Part of the solution, we argue, will rely on: clear and strong incentives for innovators to design more desirable innovations; and appropriate feedback from health services and policy research

about the level of fit (or misfit) between potential innovations and their likely real-world use.

Tackling the blind spot in the downstream approach: understanding what produces superior innovations

At least three features make certain innovations more compelling than others. First, one crucial issue is the *respective relevance* of innovations, e.g. the appropriateness of their purpose when compared to other existing or feasible interventions, given the population health needs and the health care delivery problems to be addressed. For instance, a systematic review of telemedicine concluded that among the most promising applications was teleneurosurgery.⁵ This is a puzzling observation considering the number of other legitimate applications that could meet significant health needs. Although it may be true that evidence has been produced about this particular application, one cannot determine whether it is more or less relevant compared to other technologies. The strength of systematic reviews is to summarize available evidence, not to determine which innovations are socially and clinically appropriate. Comparing technologies that pursue different purposes implies asking not just how effective the technology is, but also how significant it is within the broader universe of health care services. We thus need comparative research *across* different types of innovation.

Second, a key feature is *usability*, a term understood broadly as encompassing not only the practical functionality of a device, but also the multiple ways that humans interact with it in the context of their daily lives.⁶ Although some manufacturers may consult users at some point in the innovation process, the level of involvement varies greatly and is often unstructured. Nevertheless, direct and active cooperation between users and designers arguably enhances quality, functionality, usability, effectiveness and adoption of innovations.⁹ In fact, shortcomings observed downstream can, to a certain extent, be prevented by upstream decisions that consider the costs of technologies, the settings where they will be used (primary care centres, hospitals, the patient’s home) and the level of skills required to use them appropriately.

Third, understanding the *sustainability* of innovation requires a thorough analysis of the various ways in which manufacturers’ commercial viability (not necessarily ‘growth’) can be established. Examining the way commercial strategies generate unexpected consequences, Kent and Faulkner¹⁰ showed how marginal improvements to prosthetic devices (e.g. the Trilucent breast implant and the 3M Capital hip prosthesis) induced safety problems. The industry, feeling a need to maintain competitive distinctiveness, introduced new implants that produced superficial improvements, but which altered their composition and led to premature failure. Hence, comparative studies of business models and their implications for design may help strengthen sustainable innovation.

	Innovation is adopted	Innovation is not adopted
‘Good’ reasons to adopt	Fit between evidence and action	Unwise savings Unmet needs
‘Bad’ reasons to adopt	Waste of resources Unjustified risks	Fit between evidence and action

Figure 2 The quandary of issues linked to the downstream adoption or non-adoption of health innovations

Taking up the challenge

According to Crowley and colleagues,¹¹ a unique public–private partnership ‘enterprise’ is required to succeed in transferring basic research into practice to improve population health. Although these authors offer compelling arguments, we believe it is impossible to define a single agenda that could drive innovation in medicine. Moreover, because of the structure of the biomedical industry and the variety of country-specific regulatory processes, many key decisions take place both *within* and *beyond* national borders. Accordingly, we would argue against moves to create mega-structures with mandates to reconcile the innovation research and policy agendas in each country.

Instead, we believe that a new kind of policy-oriented research should be initiated, based on a core set of valuable features (i.e. relevance, usability and sustainability) that some innovations possess and that others do not. Our premise is that the resulting knowledge could help reconcile the health care policy and innovation agendas, particularly if it can be made available in a format that is accessible to designers and other stakeholders. This is why a collaborative, policy-oriented research agenda that includes adequate Knowledge Transfer and Exchange (KT&E) strategies is vital. Only truly translational and interdisciplinary research can take up the challenge and carry out related KT&E activities that could actively engage members of the public (as taxpayers who contribute to innovation research).

Our central argument of course leaves several questions unanswered. A central question is why would the medical equipment industry, which is already operating in a complex commercial and regulatory environment, feel it has a stake in our proposal. As explained earlier, a more systematic approach to product development, including user involvement, could greatly improve the innovation process. Hence, we argue that the industry’s efficiency and vitality is closely linked to our proposal, something that is gradually being recognized by industry itself.¹² Overall, we need research that can identify what better health innovations are before they reach the market, and thus help improve design processes by identifying knowable and often preventable downstream problems.

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