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# Sincere thanks to...

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# The questions we had

# The problem with health innovation

• Significant disconnect between technology development and technology use despite a need for feedback between innovation upstream and downstream processes.



Figure 1: The feedback needed between upstream and downstream innovation processes<sup>1</sup>

<sup>1</sup> Lehoux P, Williams-Jones B, Miller FA, Urbach D, Tailliez S, 2008. What leads to better health care innovation? Arguments for an integrated policy-oriented research agenda. *Journal of Health Services Research and Policy*, 13(4), 251-254. DOI : 10.1258/jhsrp.2008.007173

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- Technology assessment is carried out too late to inform the development of technologies that are better adapted to the actual context of use.
- Although technology development bears significant issues for healthcare systems, it is barely addressed by health services and policy scholars.

# **Research questions**

- How are health technologies being developed in academic spin-offs?
   Who is involved, who is excluded? How are the challenges of healthcare systems addressed?
- What knowledge is sought, valued, used and ignored in technology design?
- What key decisions designers and various stakeholders make in health innovation?
- Why certain technologies, rather than others, are brought to the market?

# a The answers we found

# Health innovation is a collective action

The development of a new health technology involves a large number of actors:

- Engineers
- Scientists
- Industrial designers
- Entrepreneurs
- Potential users (clinicians, patients et their relatives)
- Stakeholders providing strategic or financial support (R&D policymakers, investors, shareholders)
- Stakeholders imposing various requirements (regulators, health policymakers, third party payers)

These actors intervene at different stages in the development pathway according to their expertise, values, objectives, professional and organizational roles, responsibilities and constraints, and according to the established norms and ways of doings things in their respective domains.

The commercialization of a given innovation is the outcome of transactions and knowledge-based exchanges between actors.





# Figure 2: Actors and key milestones in health innovation development<sup>2</sup>

#### This report focuses more specifically on:

- Designers
- Investors
- Regulators
- Innovation and health policymakers
- The media

<sup>&</sup>lt;sup>2</sup> Lehoux P, Miller FA, Daudelin G. How does venture capital operate in medical innovation? *BMJ Innovation*, forthcoming.

**The Designers** 



# Who are the design participants?

They include industrial designers, engineers, scientists, clinicians, healthcare managers, computer scientists and the managers of the spin-offs who were involved in the design collective (Bucciarelli, 2002<sup>3</sup>), playing a role in the development and commercialization of a new medical technology.

# What expertise do they have and what roles do they play?

Those who participate in the design collective possess distinct sets of expertise and have different responsibilities and motivations. Designers are influenced by the "world" with which they are familiar, and which shape their perception of the object to be design.

We observed design participants acting as a builder, an assembler or an adapter.

- The **builder** focused on a technical pursuit in an entrepreneurial setting. He contributed biomedical engineering and business management expertise. He drew up the initial business plan leading to the commercialization of the innovation.
- The **assembler** aimed at bringing about a paradigm shift in a clinical practice, which was considered inadequate. This person was a clinician and researcher and succeeded in bringing together the various types of expertise needed to carry out the innovative idea.
- The **adapter**'s objective was to help "real patients". He was a mathematician and computer expert. He set aside the most innovative aspect of his initial idea in order to develop a solution that would be better suited to the context of use.

Other design participants played complementary roles as:

- External contributors (industrial design consultants)
- "Multi-taskers" combining health and engineering expertise

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<sup>&</sup>lt;sup>3</sup> Bucciarelli LL, 2002. Between thought and object in engineering design. *Design Studies*, 23(3), 219-231.

• Translators and promoters of the innovation (health sector professionals and managers)

Design participants also contribute by recognizing the expertise they lack and by seeking additional contributors.

#### What confers value to a technology?

For technology developers, a technology has value if it brings about improvement in health and contributes to greater wealth. The simultaneous pursuit of these objectives is clearly seen in their appraisals, actions and decisions. It is this pursuit that shapes technological development.

"A good innovation? Is it something good that improves health, or is it something good that makes money? In healthcare? [laugh] Yeah, hum... Well a good invention is one that improves health and makes money and is commercially viable" (B1)

<u>Improving health</u> — Technology developers consider clinical care as a "good" that has value in itself. Given their close contact with clinical reality, they focused most of their design efforts **on improving the clinicians' impact**, i.e. by developing technologies that help clinicians to work better with and for patients. From this viewpoint, improved care can be brought about thanks to the **interactions made possible by the technology**.

"The idea was to create a system that was intelligent, which knew what the job of this person was, what he had to do, and which helped him do it." (C1)

"the overriding principle is what's best for the patient, because if it's not best for the patient, we're not interested in doing it." (B1)

<u>Contributing to greater wealth</u> — Technology developers also value **greater productivity** in health organizations. This perspective is based on their experience of the health sector. While improved productivity typically means achieving more with less, technology developers do not consider that this principle should be applied to all actors equally. Their decisions are guided by the idea that new technologies should **provide an economic advantage** to doctors.

"You have to show to the nurses how that's in the patients' best interest and it's efficient for them. For the physicians, how it's either efficient or not financially detrimental. So there's no way around it. You have to address that conflict." (B1)



By pursuing in parallel the two objectives of health improvement and greater wealth, technology developers are forced to make different types of compromise.

"We made a lot of bad decisions, or... not necessarily bad but... we've made compromises... We knew that from a scientific standpoint we could obtain better results by doing things differently. But (the investors) told us to stay on the same track because they needed to see sales coming, so they could start to get money back." (A1)

They must satisfy the expectations of numerous stakeholders. The "value proposition" of the technology must include elements that increase its value for users and potential buyers (the market), while respecting medical technology regulatory requirements and, for investors to obtain returns on their investment, being as profitable as possible as quickly as possible.



The Investors

# Who are the investors?

Venture capital investors working for private and public funds that invest in new health-technology based ventures.

# What expertise do they have and what roles do they play?

Investors pursue a specific goal: to obtain optimal return on investment. Therefore, they seek to increase the financial value of the firm, in anticipation of a liquidity event allowing them to recover their investment and make a profit. Their actions proceed in three successive steps.

1. Assessing the value of a deal

In order to select the projects to be financed, investors rely on:

- Due diligence, i.e. assessment of risks and of the likelihood of success of a project, based on legal, accounting, scientific and managerial expertise
- Assessment of the management team
- Gut feeling



"When we consider investing, we evaluate the product first, then the market — and the competition involved —, the team that will manage the project, and how I can sell it and make money. In terms of venture capital, the faster I sell the project, the better it is." (Inv5)

"It's a very subjective process, even if we consider all kinds of facts (...)." (Inv3)

The technology to be developed is evaluated from different viewpoints:

- Potential market outside Canada, since the national market is considered insufficient
- Investment portfolio (to reduce risk, investment sectors are diversified)
- Specific criteria regarding funds (for example, investing in breakthrough innovation only)
- 2. <u>Constructing and protecting value</u>

"investment decisions are relatively simple to make: we love, or we don't; we agree, or we disagree. It's what happens next. It's what follows that matters. [...] I'm not paid to invest. I get paid to generate a return. So it's not the \$ 1 that I put, but the \$ 10 I'll be able to get in a few years from now." (Inv4)

Once a decision to invest has been made, the investors work at increasing the value of the investment:

• By using their personal resources (network of contacts, business experience) to support the management team

"As an investor with deep pockets, I should be able to provide access to resources. I call this macro management; providing resources, providing help, opening doors." (Inv1)

• By making sure that the milestones established in the financing agreement (clinical trials, regulatory approval, etc.) are completed on schedule, otherwise the investors may withdraw

"Smaller the company is, the more investors want to be involved. (...) if there's a decision to make, like 'a study should be done again.' (...) a study should be repeated? Why? It wasn't part of our plan. And how much it will cost to redo this study? That's \$200,000? No, we can't. If we put 200,000, we will have to refinance sooner than expected, and if we refinance faster than expected, we won't have the value we want." (Inv3)

• By influencing technology development, for example, the choice of clinical indications and key positions in the firm through the Board of Directors.

"Let me give you an example: I'm developing a new computer program, I have an indication for imaging, well, I have breast cancer, prostate cancer, brain cancer. Good. But I have limited budgets, I must prioritise over time. The investors will get involved because sometimes we'll ask for external reports and say 'well I'd rather like you to go in the brain because there's less competition' (...)." (Inv1)

The investors' commitment structures the company; the overall goal is to make it grow so it can later be acquired by a larger manufacturer or be listed on the stock market.

3. <u>Monetizing value</u>

When the firm reaches maximum value — for example, after FDA approval which opens the American market— or when it falls short of being the expected "home run", investors try to recover their investment or to limit their losses by provoking a liquidity event. In such cases, the shares of the firm are traded on a public (stock exchange) or private market (sold to another firm). Often, restructuring takes place in order to make the firm more easily "sellable." This can involve disposing of a portion of the firm, selling patents for a technology whose development is abandoned, focusing on a specific medical indication, etc.

"I've been asked, as a member of the Board if I would leave [investment firm] to take care of this venture full-time as interim President —which quickly turned into President— with the task of trying to find a honourable exit for shareholders, investors. So we raised a little more cash, (...) we limited our activities around two technologies that were more promising, and it's on that basis that we sold the assets to an American company." (Inv3)

# What confers value to a technology?

From the investor's viewpoint, a technology must:

- Respond to a medical need
- Provide a benefit to the health system in medico-economic or productivity terms (Inv6).

The challenges faced by healthcare systems, such as population ageing, may represent "superb opportunities for investment" (Inv4), provided that they translate into significant potential markets. Given the complexity of the task and

the (considerable) time required, developing a health technology "is not like developing a toaster" (Inv4), but

"the best technology in the world, if it does not interest a potential client, is worthless. That's why we will (...) spend more time on marketing aspects than on the technology." (Inv4)

In other words, the intrinsic quality of a technology and its commercial value are two different things.



# Who are the regulators?

They are employees of the agencies that regulate whether new health technologies can enter specific healthcare markets.

# What expertise do they have and what roles do they play?

The regulators' role is to ensure that new technologies conform to safety, efficacy and quality standards before manufacturers are granted the right to market them. Regulatory agencies are also responsible for post-market surveillance. Certain standards apply to the technology itself and others to the firm, i.e., its management and production procedures (such as ISO norms).

Regulators operate on the bases of a "regulatory science" (Jasanoff, 2005<sup>4</sup>):

- The scientific basis requires that certain types of evidence be produced by the firm (animal testing, clinical trials, etc.) and a formal evaluation by regulators of the relevance and robustness of the evidence submitted;
- **The legal** basis requires conformity to standards and auditability.

Given that their goal is to prevent the marketing of technologies that do not meet safety and efficacy standards, regulators actively share with technology

<sup>&</sup>lt;sup>4</sup> Jasanoff S, 2005. Designs on Nature. Science and Democracy in Europe and the United States, Princeton University Press.

developers information regarding regulatory requirements and possible commercialization trajectories. By doing so, they contribute to the overall quality of new technologies.

"I've always tried to do knowledge transfer. So all I can provide them with as added value, which will enable them to improve their product, that's what I try to provide." (R1)

"Manufacturers are in general addressing the new demands much more competently than they did before. I think since our mandatory licensing came into effect, and it's been in effect now for about twelve years, manufacturers of, certainly of class 3 and 4 devices are much more knowledgeable about what is required to obtain a license. Therefore the reliability of technology is now much better than it used to be before we had licensing provisions." (R3)

Regulatory requirements bring about an important transformation since the firm must engage in the production of evidence and data on both its technology and managerial structure and processes.

Regulators also exert a major effect on the firm's stock options: their value automatically increases when approval is granted by a regulatory agency.

Thus, regulators play a double role:

- A concrete role that affects the development of a new health technology as well as that of the firm bringing it to market;
- A symbolic role that increases the confidence of potential users and investors. By reducing risks, regulatory approval has a protective and reassuring effect for the public as well as for firms and their shareholders.

#### What confers value to a technology?

From the regulators' perspective, the value of a technology is based on its conformity to quality, safety and efficacy standards. The evaluation process does not take into account the challenges of healthcare systems in terms of costs of the technology, its relevance or ability to fulfil important needs, or the degree to which it can be considered innovative.

"(...) like the cost benefits, we don't look at that and it's not part of, under our regulations, we just look at whether the device is safe and effective. What they do look at is usability (...) human factors (...) to ensure that the buttons are correct, you know, ergonomically correct so that they don't push the wrong button. Or ... that the screen and the display, you can see it at different angles of say, the technician got to bend

over to do something, you know. So we look at that but we don't look at the cost or you know staff shortages or the needs." (R2)

"But unless there is something actually deficient about the device, we would not take that into consideration either at licensing time or post market. It's sort of... do you want to buy the cheapest car on the market or do you want to buy a fancy car. The cheap one isn't as nice as the fancy one, but they're both legal." (R3)

"We sometimes see applications which we call 'me too' applications. It's no different from twenty other ones out there, but the manufacturer wants to get in this business and we say fine. You know the world doesn't need yet another of these things, but fine if you want to sell one, you get one. So we don't judge whether this is really beneficial or new." (R3)



#### Who are innovation policymakers?

They are civil servants in the ministry divisions responsible for economic and innovation policy.

#### What expertise do they have and what roles do they play?

For innovation policymakers, technology-based innovation is the surest road to growth and prosperity. Academic research is an important source of innovation and considered able to provide solutions to major social problems, particularly that of achieving economic growth.

"Research has to have an ultimate objective. Discovery is great but, but we're pouring an awful lot of money into research and developments, so we need to make sure that we're getting outputs from that. And, in fact, (...) the driving force behind the S&T Strategy was the recognition that Canada really needs to do more to turn ideas into innovations that actually provide concrete solutions to whether it's improving our economic competitiveness or addressing important environmental..., health or other social challenges." (POL4)



Government programs intended for small technological firms are created with this goal in mind.

These programs offer financial support — grants, loans or tax credits — and managerial support to emerging firms. The requirement for obtaining this support is to respect the rules of the programs. The government representatives usually do not have decisional powers on the Board of Directors of the firm that receives financing. Civil servants provide support and help the firm to improve its management in the hope that it will attract further (private) investment.

In the evaluation of emerging firms, policymakers call upon the expertise of entrepreneurs and investors. They do not make judgments on the value of the technology or on the business potential of the firm. They only evaluate conformity to the rules of the programs and seek to administer these programs impartially and non-arbitrarily.

"we're very much in an accompaniment mode. Between when we receive the project and what gets submitted to the committee, there's often quite of a difference. Precisely because we help people telling them, 'well this will not be well received by the committee, so you should change this, have you thought of this', etc. Thus, we do this work." (POL1)

"If the ministry is there ... it helps entrepreneurs to seek and obtain funding. It secures investors." (POL1)

The role of policymakers is to level the playing field and to reduce risks for investors, thus facilitating their commitment to technology-based firms and, ultimately, fostering economic growth.

#### What confers value to a technology?

For innovation policymakers, the value of a health technology depends on its ability to contribute to economic growth, i.e., to create firms and employment in the country.

"We try to see how we can use this sector to generate economic growth levier économique." (POL2)

"Our role to some extent is also to see whether we make good use of... by helping this company, do we, from an economic and innovation standpoint, do we serve well the province." (POL2)

"Our take on this is that the goal of the exercise is to do economic development. So [...] the purpose of success, for our Ministry [...], is number of firms, the number of jobs. So companies that have success and that are successful at creating jobs." (POL3)

The judgment brought to bear in the selection process examines the innovative nature of the technology and the firm's potential for growth, rather than the relevance of the technology or its ability to address healthcare system challenges.

"There is no indication given as to the type of technology to be submitted. (...) each project is evaluated on its own merit. There is no specific indication, except for initiatives that have sometimes been taken in certain fields. For instance, the biopharmaceutical strategy has produced financial gain for the sector. Or the dynamic projects in our most recent Quebec research and innovation strategy, in which there were selected sectors: aerospace, technology and information, forest biorefinery. In the second-to-last budget, there were stimulating projects in personalized healthcare. Therefore, these financing initiatives will allow technology development in that sector. But in terms of the technologies developed in general, the important thing is that they meet criteria for excellence and potential." (POL3)



# The Media

# Who are the media?

- Canadian mainstream press, particularly the "business" sections
- Canadian press specialized in business affairs

# What expertise do they have and what roles do they play?

The media is a communication microcosm that is fed proactively and reactively by journalists, business experts and firms. The expertise disseminated in the media comes from several sources:

- Technology developers
- Investors
- Clinical researchers
- Financial market analysts
- Regulatory authorities

These multiple types of expertise are brought together according to the knowhow and knowledge of business journalists. The media present predictions, facts, noteworthy events, economic estimates, expert appraisals of firms and technologies.

"[Spin-off] has yet to declare a profit and revenues have been slower than expected, said analyst Claude Camire. But Camire, who follows the company for Paradigm Capital, calls [spin-off] 'a good story.' He expects shares to reach \$4.50 during the next 12 months, compared with about \$1.80 now. Camire points to an endorsement this year by McKesson Corp., the largest health-care software provider in the United States, which added the [technology] to its suite of software. [...] Other clients include medical malpractice insurance providers Aon Risk Services and TriState. Camire said revenues from annual licensing fees have been much lower than he expected because of delays in completing software and internal marketing shuffles. 'It sounds like these problems are behind them.' He is calling for revenues in the current fiscal year, which ends in March, of \$8 million, with a loss of 29 cents a share. In fiscal 2008, he predicts a first profit of 25 cents a share and revenues of \$20.7 million as hospitals equip themselves with the newer technology." (PGB-15)

Sharing such information and analyses may affect the firms and the implementation of their technologies, particularly by influencing the confidence of investors.

The media do more than simply "present" information: they offer a specific framing of the reality of the firms and their technologies. They treat on the same foot the clinical value of a given technology and its commercial value, and the clinical problem it seeks to address and the potential market it may conquer. For instance, an article asserts that the market for a breast cancer imaging device is "an obvious one" because the disease "strikes one in nine women, making it the most common cancer in females." These at-risk women are relocated within a market analysis metric:

"The device at your local clinic undoubtedly uses X-rays, as do the other 1,000 units across the country. According to a 1999 study by Frost & Sullivan, 30,000 of them worldwide must be replaced over the next decade. The market for mammography equipment is worth an estimated US\$250 million a year. These devices save lives —but they're hardly state-of-the-art." (PSB-4)

The media also disseminate information prepared by the communication experts of the firms about their executives and staff recruitment, current and potential position, present and future technology developments, etc. Obtaining regulatory approval is a major milestone for firms and their investors; it is regularly reported on in the business pages, almost always with a description of its effect on the value of the shares. "[Spin-off] shares rose more than 21 per cent Thursday after the company said it had received a Health Canada license to commercialize its breast cancer optical imaging device. Stock [...] jumped seven cents to 39.5 cents on the Toronto Stock Exchange, with more than 950,000 shares changing hands. [...] 'We are very pleased by Health Canada's licensing of [technology] which constitutes a major milestone and a first step in our strategy to penetrate a global market of US\$1.8 billion; it is a testimony to the fact that our product is safe, effective and of high quality and ready for commercialization,' [spin-off's] president and CEO [name] said in a release. 'Health Canada's green light will give Canadian hospitals, clinics and research centres the opportunity to deliver the benefits of [spin-off's] optical imaging technology to their patients and thus offer the prospect of better diagnosis for Canadian women affected by breast cancer and, eventually, this technology will help clinicians around the world improve breast care for women' (PGB-5)."

By selecting and framing information considered relevant, the media contribute to the legitimization and reinforcement of the institutional rules underlying the world of investment and finance.

# What confers value to a technology?

For the business media, the value of a technology lies in the combination of its clinical and commercial potential. The media are not the place to critically evaluate the clinical value of a new health technology or its value within the broader universe of healthcare needs.

The central narrative of the business media reinforces the idea that the focal point of health technology development is, in fact, the production and marketing of a product that generates revenues for entrepreneurs and investors.

# In the final analysis

Our research program explored a phenomenon largely neglected by health services and policy scholars, that is the macro-social dynamics and institutional forces that structure the health technology development pathway. Overall, new technologies do not result from the sole creative power of individual entrepreneurs.

From a healthcare system perspective, the following perplexing observations require attention:

1) Health policymakers are not involved in health technology development. Their health system-level perspective, which is arguably broader than a clinical one, is not given consideration until the technologies are ready to be commercialized. Health organizations are considered **purchasers** or settings to **showcase** technologies. Health experts are not seen as relevant **stakeholders** who could contribute to health technology development.

- 2) Investors and financial markets have a predominant influence over the process. Innovations that are seen as less risky by investors address large and reachable markets, enable physicians to generate revenues and are likely to be acquired by established medical device manufacturers.
- 3) Innovation policymakers heavily rely on investors, whose contribution is considered essential to economic growth. Support to health technologybased ventures is provided because these firms are seen as an economic growth vehicle, not because they develop technologies that may prove valuable for healthcare systems.
- 4) The relevance of new technologies and their ability to address the challenges of healthcare systems are never part of the upstream considerations. Innovation policies and the institutional rules underlying venture capital and regulatory approval are not sensitive to healthcare system-level considerations. The development of technologies that may prove valuable is fortuitous.
- 5) Small innovative firms that wish to successfully commercialize their technology are pushed to adopt a specific business model that support the creation of value for clinicians, investors and shareholders. Spin-offs emerging from publicly-funded research settings have to follow a trajectory that requires rapid growth and the prospect of being acquired by a larger, established manufacturer.

Our research program has shed light on health technology development processes and revealed key challenges in the design and commercialization of innovations whose key users are not medical specialists. The likelihood that an innovation will be reimbursed is part of the rules of the game we described. Otherwise, the need to find a purchaser affects the nature and value of the technologies that are ultimately developed. Would it be possible to produce health innovation differently? Would financial support from governments through investments rather than subsidies, as proposed by the Quebec Ministry of Economic Development, Innovation and Export (see Lawrence, 2015<sup>5</sup>), produce radical change? Nothing could be less certain. Shall we consider a different technology design paradigm?

# What's next?

# Responsible innovation in health: a new paradigm to explore

Although many innovations have the potential to solve significant problems, address the social determinants of health and foster the sustainability of healthcare systems, established business models and financial dynamics limit their emergence and diffusion.

Responsible innovation scholars acknowledge that entrepreneurs can provide technological solutions of greater societal value. When applied to health, the concept of responsible innovation emphasizes technologies that are:

- Designed with a focus on user needs, particularly those of less specialized users
- Affordable
- Relevant considering the global burden of disease
- Sustainable
- Able to reduce inequality
- Etc.

The research program "In fieri" is an international initiative led by Pascale Lehoux. It was financed by the Canadian Institutes of Health Research under the title "Responsible innovation in health: Designing technologies for sustainable

<sup>5</sup> Lawrence S. 2015. Q&A with Quebec's Minister of Economy, Innovation and Exports Jacques Daoust. *Biotechnology Focus*, September 1, 2015, <u>http://biotechnologyfocus.ca/qa-with-jacques-daoust-quebecs-minister-of-economy-innovation-and-exports/</u>. Page visited on September 10, 2015. healthcare systems." The overall goal is to examine what responsible innovations are from a healthcare system perspective as well as their entrepreneurial and financing underpinnings.

# Appendices

# **Methods**

- Qualitative interviews with actors involved in, or affecting the design and commercialization of health innovation
- Case study of 5 spin-offs in the Montreal region (Quebec, Canada) emerging from a publicly-funded setting that developed:
  - An optical molecular imaging device for diagnosing breast
  - A line of cryoablation catheters for the treatment of arrhythmia
  - o A decision-support software to prevent birth-related injuries
  - o A home telehealth solution for chronically ill patients
  - A computer-assisted navigation system to support minimally invasive orthopaedic surgery

Fieldwork component	Dara sources	Specification
Preliminary data collection phase	Exploratory interviews with CEOs and high-level	Length: 60-120 min.
<ul> <li>To generate an overview of the phenomenon, to gather key information about five spin-offs</li> <li>To select the three cases to be documented in the subsequent phase and adjust data collection tools accordingly</li> </ul>	executives of five spin-offs* and with experts in regulatory affairs and technology transfer (n=11)	Notes were recorded during and after each interview
	Electronic documents retrieval, indexing and analysis: Press releases (n=568) Annual reports (n=21) Promotional documents (n=23)	Content retrieved in 2008 from the websites of the spin-offs; these documents described the activities of the spin-offs since their inception (mid 1990s) and addressed their key audiences
<ul> <li>Detailed data collection phase</li> <li>To generate an in-depth understanding of technology developers' practices and rationales</li> <li>To document external</li> </ul>	Semi-structured interviews with clinicians and scientists who were part of the design team and contributed to the creation of three spin-offs (n=9)	Length: 90-120 min. Recorded, transcribed verbatim and checked by respondent
stakeholders' practices and contribution to technology development processes	Semi-structured interviews with capital investors (n=6) Semi-structured interviews with regulators (n=3) Semi-structured interviews with policymakers (n=5)	Length: 35-120 min. Recorded, transcribed verbatim and checked by respondent
	Industry events observation (n=6)	Notes were recorded during and after each event
	Media coverage analysis (n=814)	Databases: CBCA and Biblio Branchée All media content in English or French that mentioned the spin-offs, their CEOs and products between 1998 and 2009
<ul> <li>Analysis and debriefing phase</li> <li>To analyse and share findings, obtain feedback</li> </ul>	Scientific and policy-oriented presentations of preliminary findings (n=14)	Debriefing after the event with the research team
and collect additional data	Mixed focus groups with technology developers, clinicians and patient representatives (n=19)	3 concurrent groups engaged into 2 structured deliberations of 60 min. each Recorded and transcribed verbatim

# Table 1: Research method

# Academic publications

- Lehoux P, 2010. Technology in the Financial Healthcare Debate: How Design May Reinforce Certain Values and Not Others. Australasian Medical Journal, 3(8), 434-439.
- Lehoux P, Hivon M, Williams-Jones B, Urbach D, 2011. The worlds and modalities of engagement of design participants: A qualitative case study of three medical innovations. *Design Studies*, 32(4), 313-332. doi:10.1016/j.destud.2011.01.001
- Lehoux P, Hivon M, Williams-Jones B, Miller FA, Urbach D, 2011. How do medical device manufacturers' websites frame the value of health innovation? An empirical ethics analysis of five Canadian innovations. *Medicine, Health Care and Philosophy*. doi:10.1007/s11019-011-9312-5
- Lehoux P, Williams-Jones B, Hivon M, Daudelin G, Miller FA, 2012. A 6-minute video-clip to ponder values fostered by health technology. *Australasian Medical Journal*, 5(10), 560-564.
- Lehoux P, Vachon P, Daudelin G, Hivon M, 2013. How to summarize a 6,000-word paper in a 6-minute video clip. *Healthcare Policy*, 8(4), 19-26.
- Hivon M, Lehoux P, Longo CJ, Williams-Jones B, Miller FA, 2013. Building Business Relationships Through the Web: How Medical Technology Companies Enroll Stakeholders in Innovation Development and Uptake. International Review of Social Research, 3(2), 89-112.
- Lehoux P, Miller FA, Daudelin G, 2013. Horizon 2020 and the need to reinvent health technology. *Lancet*, 382, October, 1402-1403.
- Lehoux P, Miller FA, Hivon M, Demers-Payette O, Urbach DR, 2013. Clinicians as health technology designers: Two contrasting tales about user involvement in innovation development. *Health Policy and Technology*. <u>http://dx.doi.org/10.1016/j.hlpt.2013.05.003</u>
- Lehoux P, Daudelin G, Hivon M, Miller FA, Denis JL, 2014. How do values shape technology design? An exploration of what makes the pursuit of health and wealth legitimate in academic spin-offs. Sociology of Health & Illness, 20(20), 1–18. doi:10.1111/1467-9566.12097
- Lehoux P, Daudelin G, Williams-Jones B, Denis JL, Longo C, 2014. How do business model and health technology design influence eachother? Insights from a longitudinal case study of three academicspin-offs. *Research Policy*, 43(6), 1025–1038. <u>http://dx.doi.org/10.1016/j.respol.2014.02.001</u>

- Lehoux P, Miller FA, Daudelin G, Urbach DR, 2015. How venture capitalists decide which new medical technologies come to exist. *Science and Public Policy*, 1– 11 doi: 0.1093/scipol/scv051
- Lehoux P, Miller FA, Daudelin G. Converting clinical risks into economic value: The role of expectations and institutions in health technology development. Submitted.
- Lehoux P, Miller FA, Daudelin G. How does venture capital operate in medical innovation? *BMJ Innovation,* forthcoming.
- Lehoux P, Daudelin G, Miller FA, Denis JL. Revisiting the contribution of institutions : How economic policy, capital investment and market approval transform health technology-based ventures. Submitted.
- \* You wish to download one of the articles and are unable to do so? Contact us.

# Training of students and postdoctoral fellows

- Olivier Demers-Payette Ph.D. Implication des utilisateurs dans le développement des innovations médicales : une analyse sociotechnique de la collaboration et de ses enjeux pour l'organisation des soins, (Involvement of users in medical innovation development: a socio-technical analysis of collaboration and its issues for healthcare organization). Doctoral thesis in Public Health, School of Public Health, University of Montreal, 2014.
- Mathieu Beaulieu, Ph.D.(c), La construction sociale et l'hybridation des logiques marchandes et du système de santé dans l'émergence, le succès et la pérennité des entreprises de technologies innovantes en santé (Social construction and hybridization of commercial reasoning and the healthcare system in the emergence, success and sustainability of innovative technology firms in the health sector) (tentative title). Doctoral thesis in Public Health, School of Public Health, University of Montreal.
- Nadège Giroux, BA in anthropology, trainee.
- Hudson Pacifico da Silva, postdoctoral researcher
- Loes Knappen, postdoctoral researcher

#### Videos

- "Construire, assembler, adapter : trois façons de concevoir une technologie médicale" <u>https://vimeo.com/48372194</u>
- "The values embedded in medical technologies" <u>https://vimeo.com/47094761</u>

 "How do values shape technology design? An exploration of what makes the pursuit of health and wealth legitimate in academic spin-offs" ». Summary video of the article published in Sociology of Health and Illness, 2014 <u>https://www.youtube.com/watch?v=EL2MGOEI9Ec</u>

# **Activities**

- TEDX Montréal Quartier Latin "Design pour la santé Design for health", October 2010.
- "De quelles technologies avons-nous besoin pour faire face aux défis des systèmes de soins?" Discussion workshop on the design of medical technologies, bringing together designers, clinicians and patients; June 2012.

# Other

- Lehoux P. "L'innovation technologique". Presentation to the Standing Committee on Health, House of Commons, March 7, 2013.
- Hinnovic dossier "Financing Innovation Design", <u>www.hinnovic.org</u>, August 2015.

# Collaborations

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# Values and expertise in health technology development

Summary report of a five-year research program

December 2015

URL: http://infieri.umontreal.ca/Bilan2015/SummaryReport.pdf

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