The worlds and modalities of engagement of design participants: A qualitative case study of three medical innovations

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Individuals with different backgrounds such as engineering, medicine, industrial design, business, healthcare management and computer science often contribute to the design of a medical innovation. But how do such heterogeneous design participants actually combine their expertise to develop a medical device? Adapting Bucciarelli's concept of "object worlds", which recognises that those who contribute to a design process inhabit different worlds and see the object of design differently, this paper examines the perspectives of 8 design participants who contributed to the design process of three Canadian medical devices. In-depth analyses of semi-structured interviews clarified what design participants saw through their particular "lens", how their responsibilities, knowledge and motivations combined and how they engaged into the design process.

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Scholars acknowledge that the design of medical innovations is a complex and multifaceted process that involves a diversity of participants (Blume, 1992; Dixon, Brown, Meenan, & Eatock, 2006; Farley & Rouse, 2000; Faulkner, 2008). While engineers and industrial designers play a key role in the problem-solving process, other participants with backgrounds in medicine, health sciences, business and healthcare management, and computer sciences may also make important contributions to the design process. These contributions will vary in content and intensity over the course of a project – for instance, identifying clinical needs, testing prototypes, or commenting on a product's usability – but they all influence how the design process unfolds and what the "final" technology will look like and accomplish. While there is a wide range of stakeholders who are not design participants *per se*, the literature indicates that they can both create opportunities and set constraints that influence the design process (for example, through financial support or

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regulations) (Faulkner, 2008). Those concerned by a health care innovation may include the medical community, potential patients and their relatives, capital investors, third-party payers, regulators, suppliers, R&D and health policymakers and lobby groups (Clarkson, 1995). The core question explored in this paper is thus: how, in practice, do participants in the design of medical devices position their work and deploy their thinking and activities within this complex and diffuse set of constraints and expectations?

Recognising design as a social process, a number of studies have shown that individuals contribute to design processes by bringing to a team different types of skills and expertise (e.g., through disciplinary training such as electrical engineering or ergonomics) and personality traits (e.g., risk-avoidance vs. risk-taking, human-centred vs. object-centred focus) (Berends, Reymen, Stultiëns, & Peutz, 2011; Chen, 2005; Cross & Cross, 1995; Howard, Culley, & Dekoninck, 2008). The literature has also paid attention to the role that clinicians or patients may play in either "inventing" or shaping an innovation (Faulkner, 2008; Hyysalo, 2005; Shah & Robinson, 2007). However, not much is known about how, in practice, design participants with different disciplinary backgrounds and responsibilities toward the project perceive the value of the innovation to be designed and engage into the design process.

Seeking to bridge this knowledge gap, we present data from interviews conducted with individuals ($n = 8$) who participated in the development of three separate medical devices: 1) a catheter-based cryotherapeutic treatment for arrhythmia disorders; 2) a decision support software to help manage birth delivery; and 3) a home telehealth solution promoting disease management and continuity of care for chronically ill patients. By qualitatively analysing these three cases in a single study, our goal is to increase both the depth and the scope of the theoretical insights that can be empirically generated (Corbin & Strauss, 1990). To do so, we adapt Bucciarelli's (1994) concept of "object worlds", which recognises that those who contribute to a design process inhabit different worlds and *see* the object of design differently.

We first review the literature and suggest that design participants use specific "lenses" to look at the medical device to be designed and to position themselves with regards to the "worlds" its development bring forward (for instance, the world of medicine and the world of manufacturing). Then, by comparing and contrasting what issues such lenses bring forward in three empirical cases, we argue that different "modalities of engagement" characterise the work of each design participant. By modalities of engagement, we mean the particular frame of thinking and action that influences how design participants contribute to the design process and engage with the various worlds encountered throughout this process. Our discussion shows that these modalities reveal an important yet underestimated part of the complexity characterising

design as a social process (Cross & Cross, 1995). These modalities bring more coherence to the complementary roles that design participants play and to the way their expertise, motivations and responsibilities may combine into the development of one artefact.

1 *Design participants and the worlds they inhabit and encounter*

In this paper, we use the term "design participants" to refer to individuals who are not necessarily trained in industrial design or engineering, but who are intimately involved for a substantial period of time in the design process of a given innovation. In the context of our empirical study, design participants included physicians, biomedical engineers, industrial designers, computer scientists and nurses. The medical devices we examined arose from university spin-offs, representing the main if not the sole product to be developed and commercialized. Some of the participants got involved in the design project when it was still situated in a public research institution and, over time, came to "wear different hats" including acting as high-level executives of the newly established company. Hence, not only their backgrounds were different, but also their responsibilities toward the project.

Although Kleinsmann and colleagues suggest that innovation processes may be examined at the actor-, project- or company-level (Kleinsmann et al., 2010: p. 7), for those happening in small and medium size enterprises such as university spin-offs, these three analytical levels can hardly be analysed separately. First, the actors who are either the "inventors" of the innovation or are recruited in the course of the innovative project are clearly key assets of the newly established company: they embody the required knowledge. Second, the way the project unfolds and is managed is a crucial part in the story of a medical innovation. Third, corporate strategies and business considerations will necessarily intervene throughout the project, for instance, when additional human or financial resources must be injected in order to meet deadlines or solve unforeseen technical or commercial challenges (Berends et al., 2011; Bruce, Cooper, & Vazquez, 1999). As underscored by Hyysalo (2005), the "horizons of business and product opportunities" are not only closely interlaced, but they also determine the expertise that will be mobilised throughout the project. As our analyses will make more explicit, since the innovation to be designed is the very *raison d'être* of the emerging company, high-performance at each of the three analytical levels is pivotal for the success of the whole endeavour. Hence, the work of design participants is largely determined by their (evolving) position in the company and the expertise they embody.

To help understand in greater detail how design participants perceive and negotiate the object to be designed, including what should be its technical performance and how it should be manufactured, disseminated and used, Bucciarelli (1994) developed the notion of "object worlds". This notion emerged from careful ethnographic fieldwork of the unfolding of design

processes in medium and large firms. Here, an object world acts like a frame of reference and defines the domain of thought and action within which designers "move and live when working on any specific aspect, instrumental part, subsystem, or subfunction of the whole" (Bucciarelli, 1994: 62). Bucciarelli offers the example of a book page to illustrate his point:

> A naïve empiricist would sense its weight and estimate its size; another reader might note its color or texture; a chemist on the design team would describe its resistance to discoloration, its acidity, and its photosensitivity. A mechanical engineer would be concerned with its tear or its tensile strength, its stiffness, and its thermal conductivity. An electrical engineer would speak of its ability to conduct or to hold a static change. All of these attributes of the object, the same artifact, are understood within different frames of reference, and they all might contend in a design process (1994: 71).

In the above quote, an object world seems largely circumscribed by the designers' disciplinary perspective, which enables them to become "immersed" into the object's behaviour, function and purpose. Bucciarelli's definition thus remains very much focused on the properties of the object to be designed.[1] For own purposes and given the empirical analysis we aim to achieve, our study requires an analytical definition that can embrace more broadly the social and technical environments in which medical device design participants operate (van Gorp, 2007). They in fact have to interact with, and respond to a very broad constellation of actors.

Bucciarelli (2002: 220) uses the term "design collective" to refer to the large set of individuals and groups who may have a legitimate say in the design process, either directly or indirectly. In the case of medical devices, a design collective would include potential *users* (clinicians, patients and their relatives) and a variety of *stakeholders* who may provide policy and/or financial support (R&D policymakers, capital investors, shareholders) or set specific constraints (regulators, health policymakers, third-party payers) (Boenink, 2010; Farley & Rouse, 2000; Vicente, 2004). This is why we use "worlds" (not "object worlds") to refer to the universe in which design participants locate their own contribution and to the universes they encounter when dealing with the concerns of the broader design collective (for instance, clinical safety and effectiveness, intellectual protection, or medical liability issues).

Furthermore, we suggest that what each design participant sees about the innovation to be designed and the worlds it brings about is framed through a particular "lens" (Harfield, 2007). Although design participants may not necessarily consciously choose the lens from which they look at the object, they are aware of its presence since this is what brings into focus certain aspects of the object to be designed and the work they have to do. The literature suggests that three aspects in particular are likely to affect what such lenses may bring into focus. First, *knowledge and expertise* usually explain the inclusion of certain participants

in the design process and largely define their specific expected contribution (Bucciarelli, 1994; Kruger & Cross, 2006; Ramlogan, Mina, Tampubolon, & Metcalfe, 2007). Second, a design participant's *tasks and responsibilities* are defined in relation to both the object to be designed and the product development strategies of the company (Bruce et al., 1999; Bucciarelli, 1994; Chen, 2005; Damanpour & Wischnevsky, 2006). For instance, some design participants may be designated to act as project managers, to secure intellectual property or even to explain progress to Board members and shareholders. Third, what design participants see in the innovation is shaped by a set of *motivations and interests*, which will make them interpret in a certain way the value it may bring to users and stakeholders (Boenink, 2010; Harfield, 2007). Hyysalo (2005) suggests paying attention to the "key shared motive" that is pursued throughout the innovation process, which is of course subject to collective negotiation and may be realigned over the course of a project (Berends et al., 2011; van Gorp, 2007).

To summarise, our conceptual framework adapts Bucciarelli's concepts in order to explore, more globally, how design participants position themselves with respect to the social and technical environments in which they operate, look at the innovation to be designed and bring different contributions to the design process (see Figure 1). We suggest that design participants' practices are influenced by the company that is seeking to commercialise the medical device and by the broader design collective wherein users and stakeholders may create opportunities and set constraints. Their knowledge and expertise, tasks and responsibilities, and motivations and interests shape what design participants may see in an innovation. Ultimately, the goal of such a framework is to characterise the specific way in which each design participant engages into the design process and, by comparing and contrasting different modalities of engagement across participants, to help understand how expertise, motivations and responsibilities are combined into the development of a medical device.

2 *Methods: a qualitative case study*

The respondents we interviewed were identified in the context of a broader case study that began in mid 2008 and in which we examine how the development process of medical devices takes into account and addresses the needs, expectations and constraints of users (clinicians and patients) and of health care systems. We chose a rich set of cases that cover a large spectrum of clinical functions (therapeutic, decision support and monitoring), and which are used by different users in a range of medical specialties (cardiology, obstetrics and chronic care) in either hospital or home care settings. These cases include:

- A line of cryoablation catheters for the treatment of arrhythmia disorders (referred to as Innovation A or heart ablation catheter);
- A decision support software to monitor prolonged labour and abnormal foetal heart rates and prevent birth-related injuries such as shoulder dystocia (Innovation B or labour decision support software);

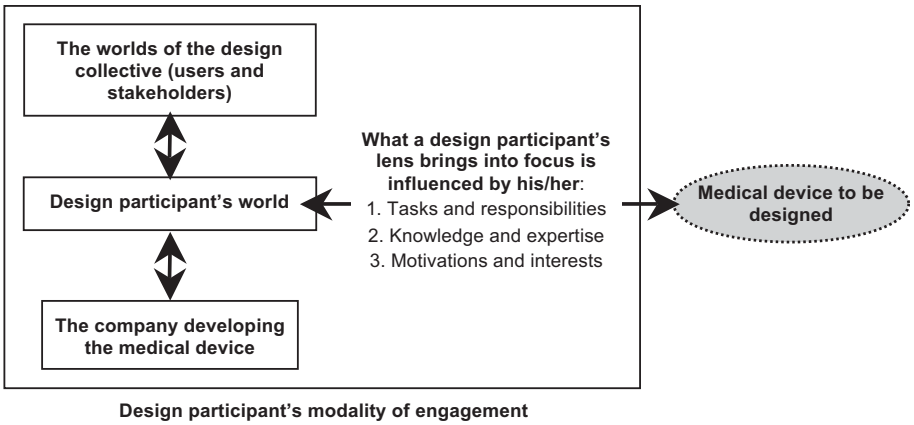

Figure 1 Conceptual framework

- A home telehealth solution comprising remote patient monitoring, disease management and a set of coordination tools to promote continuity of care for chronically ill patients (Innovation C or home telehealth system).

For each of these cases, we first contacted the individuals who had been pivotal in the creation of the university spin-off and part of the design team. We then contacted respondents who had been involved in the design and development of each medical device, who had either been referred to us by the first wave of interviewees (applying a snowballing strategy) or had been identified through a website analysis of each manufacturer and a Google search. Up to eight face-to-face interviews were conducted (in the fall of 2009 and winter of 2010); they were all recorded and transcribed verbatim and lasted from 90 to 120 min. Starting with the concepts described above, our analyses sought to provide an in-depth understanding of each respondent's narrative. This was achieved by first reading each interview transcript carefully and then creating and refining categories through the parallel development of detailed comparative tables (Corbin & Strauss, 1990; Rubin & Rubin, 1995).

3 *Results*

For each medical device, we examine in detail the world in which design participants operated and what they saw through their particular lens when contributing to the design process. Then, we summarise and compare the modalities of engagement of each participant.

3.1 *Innovation A-heart ablation catheter: a technical quest that must be engineered and commercialised*

Cryoablation is a procedure that uses extreme cold to eliminate abnormal electrical conduction in heart tissue. It addresses a number of different heart problems, but especially atrial fibrillation (A-Fib), an irregularity of the heart rhythm that can lead to health problems such as stroke. Interviewee A.1 is

the biomedical engineer who, while working at a University Cardiology Institute, took up the technical challenge of transforming an existing electrophysiological mechanism—cold temperatures applied to neutralise dysfunctional cells such as the cells that cause the abnormal heart rhythm—into a flexible catheter-based procedure that could safely reach a patient's heart (see Table 1). His world is that of a determined entrepreneur, someone who succeeds in overcoming technical, clinical and commercial challenges thanks to a carefully defined business plan and evolving project management strategies. By having been "part of a team who delivers", A.1 felt like he had "been at the right place, at the right moment, with the right people." Interestingly, while the company kept growing over the years (up to 200 employees at the time of the interview), the role of A.1 became ever more narrow and specialised, including persuading capital investors to support their young company. As shown in Table 1, the lens through which he saw the innovation brought forward a combination of technical and clinical issues. He was well aware of the clinical problems associated with arrhythmia and the technical limitations of the devices currently used in its diagnostic and treatment. For instance, he argued that the "conventional" procedure—radiofrequency-based ablation that uses warm temperatures—relied on "blind" X-rays and electrocardiograms (EKGs), tests that could not tell whether the "right" cells had been destroyed.[2] He explained that the effect of cold temperatures on heart tissue was reversible, which represents one great technical asset of cryoablation when compared to radiofrequency. A.1 was totally immersed in the technical challenges, such as mastering the behaviour and clinical effects of cold temperatures on animal and human tissue, and the quest to identify and procure gases that could deliver the right temperature at the right place (a ban on the use of Freon in Canada forced the company to find an appropriate alternative).

Interviewees A.2 and A.3 acted as external consultants and their tasks were focused on solving the design and manufacturing challenges posed by the need for a flexible catheter that fits well in a surgeon's gloved hands. Since both are associates of a design consultancy, their world is to "stay in the lobby" (A.2), not to enter the "hermetic world" (A.3) of the biomedical engineering R&D departments of their clients. Their lenses were largely defined by the discipline of industrial design (i.e., a focus on ergonomics and manufacturing processes) and by the way they defined their expertise. For instance, both insisted on the fact that an industrial designer does not "invent anything". Rather, an industrial designer seeks solutions to problems by integrating and establishing relations with different elements. Interestingly, although they may have challenged some of their client's (i.e., the spin-off company) technical and design assumptions, they were comfortable recognising their lack of knowledge about what the object to be designed "does", which implied responding to most of the surgeons' preferences and requests as they were transmitted by their client.

Table 1 Heart ablation catheter: the design participants' worlds and what they see through their lens

Innovation A: Heart ablation catheter					
A.1: Biomedical engineer and business administrator, co-founder of the company		*A.2: Industrial designer, consultant*		*A.3: Industrial designer, consultant*	
Respondent's world	*Through the respondent's lens…*	*Respondent's world*	*Through the respondent's lens…*	*Respondent's world*	*Through the respondent's lens…*
One does not invent anything; one uses the information that becomes available in his/her environment and that enables moving forward or not Science is like a Lego; one builds what he/she can with the pieces that are available Someone whose role becomes narrower over time as the company gets bigger Persuading others ("selling fish to the ocean") Being trusted, being part of a team who delivers Being at the right place, at the right moment with the right people	Cardiac arrhythmia Limitations of X-rays and EKGs Radiofrequency-based treatment for arrhythmia and its unintended consequences Developing a technology that can confirm whether the catheter is positioned properly or not before destroying cardiac tissue Cold temperatures and their delivery at the tip of a flexible catheter Looking for gases that generate various levels of low temperatures and the need to understand their clinical effects A technical failure that nevertheless generates a gain Technologies that constantly evolve Animal and clinical studies	Designers do not invent new things but seek solutions to problems An external consultant who stays in the "lobby" Someone who delivers drawings Manufacturing, tooling and assembly Being responsible for the quality and stability of the production of pieces that need to be assembled correctly into one product Being a generalist, having to "believe" what the client says, asks for Not knowing exactly what the innovation does and responding to the requirements put forward by the client who does Researching new technology Taking up new challenges	Assembling pieces that may not like each other and come from different suppliers Design briefs Software through which drawings are generated Experience that accumulates, cannot be bought and constant learning Potential solutions that are abandoned Eliminating undesirable solutions Objects that are not manipulated properly Throw away components often used in the medical sector The "Yeah, I guess it should work" Knowing a variety of production processes for various materials	Designers do not invent anything; they integrate, they establish relations between elements Associate of a design consultancy for whom medical devices may represent 10−15% of their projects Manufacturing, tooling and assembly (i.e., finding how to best design a device that will be mass produced, assembled and packaged) Designers' role is to explore and venture inhabiting the worlds of the user, the client, the supplier…	Manufacturing problems and costs Technical constraints and virtuosity wherein several factors interact (size, temperature, flexibility, electronics, body fluids, mechanics, heart tissue, cooling gas, surgeon's posture, patients' artery, etc.) "Eccentric" scenarios wherein different and potentially extreme solutions are tried out Trial-and-error Technical assumptions that need to be frozen and/or that need to be challenged 3D printing (rapid prototyping) that enables testing ideas swiftly

The lens of A.2 and A.3 is no less "technical" than that of A.1, but it brings forward many more details about the challenges raised in finding the "right" manufacturing processes (e.g., reducing the rate of rejected pieces, finding trustable suppliers, ensuring norms are respected). The world of A.2 was comprised of solutions that were being set aside (both undesirable and potentially more desirable than the one chosen) and of the need to know a variety of production processes for different materials.[3] For A.3, solving problems involved both imagining and testing "eccentric" scenarios and "freezing" a number of assumptions that would be useful constraints in the design process. This is where technical virtuosity was found, one that acknowledged the interaction of several contextual factors, such as gas and body fluids circulating in tiny tubes, ergonomic devices that fit both right- and left-handed operators, and accommodating a surgeon's posture as well as a patient's artery.

This first case indicates that while these design participants' motivations converged smoothly in an efficacious and pragmatic problem-solving process, they played different roles organised around a clear division of tasks, established on each participant's knowledge boundaries, and respective position towards the spin-off company.

3.2 Innovation B-labour decision support software: bringing about a paradigm shift in clinical practice

Innovation B consists of a set of decision support tools for obstetrical risk management, including software and hardware, a database and various monitoring devices. Its goal is to prevent birth-related injuries such as shoulder dystocia, and to better manage prolonged labour and abnormal foetal heart rates.[4] Interviewee B.1, an obstetrician, had the original idea behind the innovation, which emerged from her clinical research (which examined variables and patterns associated to birth-related injuries) and her practice (noting that guidelines were unhelpful and clinical judgment "too subjective"). While this interviewee clearly inhabits the world of obstetrics, she described herself as constantly searching for theories, ways of thinking, expertise and tools that are foreign to obstetrics (see Table 2). B.1 clearly refused to be hampered by the world of "this is the way it is" and was seeking to revolutionise the way her peers conceptualised and dealt with birth-related injuries. Her lens brought forward a diversified set of worlds that she either sought to "import" or integrate into the world of obstetrics (e.g., risk reduction culture, theoretical mathematics, complex pattern analysis, computer engineering), or avoid (e.g., artificial intelligence which was a "dead end" or experts that speak "jargon" and cannot translate their knowledge into something concrete).

Interviewee B.2 was also enthusiastic about bringing about a major technical and cultural shift in obstetrics, which she compared to the recent revolution in gastroenterology associated with the discovery of bacteria causing ulcers. Her dual training in paediatric nursing and computer engineering helped her

Table 2 Labour decision support software: the design participants' worlds and what they see through their lens

Innovation B: Labour decision support software			
B.1: Obstetrician and clinical researcher, co-founder of the company		*B.2: Paediatrics nurse and computer engineer, employee of the company*	
Respondent's world	*Through the respondent's lens…*	*Respondent's world*	*Through the respondent's lens…*
University research where a lot of money is available for innovative projects	Being aware of the problems in obstetrical practice	IT in healthcare wherein both her nursing and computer engineering knowledge combine	Decision-support and clinical information systems
A tinkerer and adventurer who takes risks and is thrilled to be on the leading edge, who never thought she would create a business because it's not her motivation	Lack of progress in obstetrics	Wearing several hats, from clinical content developer, to training of users, to product management, and to marketing	Computers that do not replace people but provide analyses that improve one's decisions
Seeking ideas and solutions outside of obstetrics	Searching in various areas/domains and finding a theoretical mathematician	Patient safety	Delegating to a computer cumbersome calculations which frees up one's mind, so it can be devoted to the more important things
Exhausting a number of unsuccessful pathways	Mathematical abstractions that can be applied to social or biological problems	The challenge of dealing with the "outside" world, getting them to understand and see something very differently than they actually do	Not starting from scratch and dealing with the legacy of the old system
Refuse to be hampered by the world of "this is the way it is"	Stimulus–response functions, wherein the range of possible values changes according to changing conditions	Making the "world just a little bit better"	An IT application that is being used on live people
Bored by standard medical research (not the place for her), which is evaluative, not inventive	Communication engineering Discarding the "noise" from the "signal" of foetal heart rates	Getting very positive feedback from potential users in conferences	Creating scenarios and trying to break boundaries
	Artificial intelligence and the dead end of rules contradicting themselves		Learning about obstetrics, technology, business, strategy, marketing, sales and training Insurance companies, especially in the US where obstetrics is highly litigated
	Experts who can only speak jargon who must be avoided		A society that is ever craving for more, faster, broader and more exciting stuff
	The importance of safety and quality in medical devices		

nonetheless to see the innovation to be designed as a pragmatic, rational matter. Through a series of tasks that needed to be done effectively, and through a constant learning process that led her to develop a large repertoire of skills (from project management to marketing), her motivation was to make the "world just a little better" in the area of medical safety for "moms and their babies".[5] Her understanding of the value of the innovation was very much grounded in her understanding of the world of clinical users, because as she observed, "computers are never tired, make mistakes, or have arguments with their wives". Among her concerns and daily activities was a sense of responsibility towards the development of an information technology (IT) application that could be used on "live people". Through her lens, she found stimulating the challenge of creating scenarios to test whether the parameters of the program were reliable, and dealing with the legacy of a system that was constantly being upgraded and modified (i.e., building on the intricate traces of prior programmers and architectural constraints).

In this second case, design participants' motivations clearly converged while their roles and ways of navigating the healthcare innovation worlds differed: B.1 was someone who explored uncharted territories in order to bring back key resources and knowledge to the world of obstetrics, and she found a precious and dedicated ally in B.2 whose dual training enabled her to take on a large spectrum of responsibilities, both in terms of design and business tasks.

3.3 Innovation C-home telehealth solution: helping "real" patients and responding to health care systems challenges

Innovation C is aimed at promoting continuity of care for chronically ill patients, enabling them to remain at home while a case manager (a nurse) remotely monitors their health status. The system offers a general architecture within which clinical care protocols have to be developed by health care providers (the end users), tailoring their content for monitoring a variety of chronic conditions such as heart failure, hypertension, diabetes and patients preparing for heart surgery. From their home, using a phone equipped with a large screen, patients fill in information following the directives the system sends them on a daily basis. While working in a public IT research centre, Interviewee C.1, a mathematician and computer scientist, had a "theoretical" idea (e.g., involving a network of intelligent agents that can "sub-contract" information transactions among each other) that he thought could be applied fruitfully to the real world (see Table 3). By chance, he ended up partnering with a regional hospital and, over time, this led him to abandon his original idea in favour of a more traditional solution (e.g., relying on server queries/responses). His world was one of someone who "migrated" from one domain to another, and which remained far remote from the entrepreneurial mode that characterised the other two sets of design participants in our study (Innovations A and B). For instance, he believed that securing IP protection for an IT application was meaningless, arguing that "doing things differently" does not qualify as an

Table 3 Home telehealth system: the design participants' worlds and what they see through their lens

Innovation C: Home telehealth system					
C.1: Mathematician and computer scientist, co-founder of the company		*C.2: Hospital-based nurse, co-developer of the software content*		*C.3: Regional health board-based nurse*	
Respondent's world	*Through the respondent's lens…*	*Respondent's world*	*Through the respondent's lens…*	*Respondent's world*	*Through the respondent's lens…*
Only technological breakthroughs are "true" innovations; doing things differently does not qualify as an innovation Informatics (not entrepreneurship) Migration from a theoretical idea (intelligent agents) to the development of a concrete application Helping "real" people: patients	The health sector, which seemed an interesting area of application for his theoretical ideas initially targeted at the financial sector Discovering with managers from a regional hospital that patients who are really sick would benefit from having a personal agent, as well as healthcare providers who could better monitor those patients from a distance The innovation they created is in the language linking an action-and-follow-up plan to a goal Interfaces for healthcare providers and patients	A good innovation is one that responds to a need Nursing Wearing different hats (chief of project, user, developer of the clinical content, promoter) Anticipation: thinking about clinical pathways, patients' early symptoms, decision-making and potential consequences A trainer who travels around the province to explain how to use the IT application	Collaboration between the clinic and technology Clinical parameters, evidence-based practice and algorithms IT requirements, interfaces, network connections, etc. Chronic care (diabetes, chronic obstructive pulmonary diseases, cardiac problems) Treatment optimization, not just early detection of changes in health status Interactions between drug/treatments, a patient's day to day health behaviours and health outcomes The need for scientific evaluation	A good innovation is one made with clinicians, that reflects who they are; only locally adaptable IT applications can make it in the health sector A healthcare manager who wants to see whether the IT solution is applicable to the patient population under her responsibility	Being potentially able to prevent a deterioration in the health status of a chronically ill patient and avoid hospitalisations Being potentially able to provide direct care to chronic patients at the right moment while reducing the number of routine nursing visits Solving unforeseen technical problems The proofs that need to be established through a solid, scientific evaluation

innovation, and describing business as "hell". His lens brought into focus the needs of "real patients" and of the overburdened health care system. His motivation was thus more closely aligned to the current concerns of health care system managers.

Although interviewees C.2 and C.3 were both nurses working in the public health care system, they played different roles in the development process. C.2 was mandated by her hospital to set up a pilot study to assess the clinical feasibility of home monitoring (first piloted with a "young" and probably computer savvy population: women categorised as having high-risk pregnancies) and develop the clinical care protocols. She clearly acted as the "co-designer" of Innovation C since without her, no functional IT application could have been developed; she brought the clinical expertise C.1 did not possess but which was needed for translating the "theoretical idea" into an operational system.[6] Here, C.2′s lens relied on evidence-based clinical practice (i.e., using research results to define how specific chronic conditions should be handled), wherein one seeks to identify and translate a number of clinical parameters into a user-friendly IT application. Her lens was also sensitive to the behaviour of chronically ill patients and to the way nurses deal with clinical uncertainty (in particular, making judgments without "seeing" the patients through their own eyes).

C.3 was first involved in supporting a second piloting of the system, this time with an older chronic care population (chronic obstructive pulmonary disease). Like C.2, she was also concerned about research evidence, but from a slightly different perspective. Her lens was that of a regional health board manager, seeking means to optimise human resources management in a context of restricted budgets and growing health care needs. What C.3 envisioned and wanted to demonstrate through a rigorous and independent research was the possibility of having a fewer number of nurses remotely monitoring a larger number of patients, thus being able to concentrate home nursing visits to those patients most in need. Hence, C.3′s expertise and motivations added weight to the idea that Innovation C must meet the needs and challenges of health care systems.

This third case illustrates how design participants' motivations may strongly converge toward improving chronic care service delivery by seeking to adapt a solution to the local reality of the health care system. The combination of expertise among these participants was particular in that only a co-design approach between C.1 and C.2 could generate a functional IT solution, and C.3′s contribution—although quite remote from the company—was pivotal in laying the groundwork for a putative dissemination of the innovation.

3.4 Design participants' modalities of engagement toward the innovation

While contributing to the development of the same innovation, design participants' respective lens led them to focus on slightly different features of the

Table 4 A summary of each design participant's modality of engagement

Innovation A	**Heart ablation catheter: A technical quest that must be engineered and commercialised**		
Modality of engagement	A.1 A builder	A.2 An external contributor	A.3 An external contributor
Tasks and responsibilities	Making happen a successful innovation through a successful business plan Responding to capital investors' requirements	Responding to the client's requests	Responding to the client's requests
Knowledge and expertise	Biomedical engineering Business management IP protection	Industrial design Ergonomics Manufacturing	Industrial design Ergonomics Manufacturing
Motivations and interests	Pursuing a technical quest within an entrepreneurial mode	Creatively solving a product design and manufacturing problem	Creatively solving a product design and manufacturing problem
Innovation B	**Labour decision support software: Bringing about a paradigm shift in clinical practice**		
Modality of engagement	B.1 An assembler	B.2 A multi-tasker	
Tasks and responsibilities	Exploring around and finding the right kinds of expertise, people and resources Responding to capital investors' requirements	Performing all tasks required to deliver a successful innovation	
Knowledge and expertise	Obstetrics Clinical research	Nursing Computer engineering Project management	
Motivations and interests	Generating a paradigm shift in obstetrics	Persuading the world about the need for a paradigm shift in obstetrics	
Innovation C	**Home telehealth solution: Helping "real" patients and responding to health care systems challenges**		
Modality of engagement	C.1 An adapter (domain migrant)	C.2 A translator	C.3 A disseminator
Tasks and responsibilities	Finding a workable IT solution for telemonitoring chronic care patients at home	Converting clinical care protocol into an IT application	Assessing whether and how telemonitoring of chronic care at home may solve current challenges in the health care system
Knowledge and expertise	Mathematics Computer science	Nursing IT content development	Nursing Health care administration
Motivations and interests	Helping real patients	Making the right IT application for chronic care patients	Reorganising chronic home care delivery

medical device to be designed and of the social and technical environments in which they operate. For instance, A.1 emphasised adverse clinical effects and dealt with capital investors, while A.2 emphasised ergonomics and dealt with suppliers. The way they talked about the value the innovation may bring to users and stakeholders also differed in subtle ways. For instance, reorganising home care delivery mattered for C.3, while C.2 mostly sought to provide nurses and patients with the "right" IT application. These variations are not surprising in themselves, but need to be articulated in order to understand how design participants' contributions combined. Table 4 summarises for each innovation the key responsibilities, expertise and motivations that characterised the work of each design participant and the modality by which each engaged into the design process.

The design of the heart ablation catheter relied on the determined engagement of A.1 who was first and foremost a "builder", that is, someone who led large parts of the project, made several pieces of the puzzle fit together, including later on the development of an in-house manufacturing capacity. The contribution of the "external contributors" A.2 and A.3 was governed mainly by a contractual relationship established with the company, wherein a form of "remote" engagement towards the innovation to be designed took place: A.2 and A.3 were motivated by creatively solving a problem that was framed in terms of design and manufacturing challenges. When compared to Innovations B and C, not only was the language used less emotional, but the stakes were not as personal. Expertise in biomedical engineering, business strategies, project management, industrial design, ergonomics and manufacturing processes was exploited with an explicit shared motive, that of providing surgeons anywhere in the world with a technology that can be manufactured and marketed. Design participants' work was thus characterised by a clear division of tasks, where a large part of the development remained under the control of the company whose goal was to both develop a new medical device and generate business.

The design of the labour decision support software was led by B.1 who was also very determined to make the innovation happen, but whose role was mainly to seek out and facilitate the "assembly" of the heterogeneous pieces that were likely, once brought together, to map closely into what she had first intuitively imagined. Her vision of what the object should accomplish was pivotal. From this perspective, her colleague B.2 acted as the perfect "multitasker" whose dual training enabled her to navigate back and forth between the world of the clinic and the world of an IT developer. She was totally engaged in reconciling these two worlds into an application that would be usable by obstetricians and nurses. Their biggest challenge remained in persuading the "conservative" obstetrical community that Innovation B would positively revolutionise its world. The engagement of B.1 and B.2 was, from this perspective, close to a strongly felt personal and clinical mission.

The design of the home telehealth system offers an interesting contrast to the two other cases. C.1, the designer who first came up with the idea, not only "migrated" from the world of mathematics and computer science to inhabit the world of healthcare (he did so literally by moving his office inside the hospital), but he also adapted to a great extent his initial solution so that it better suited the needs of nurses, patients and health care systems. C.1 co-led the development with C.2, which not only reflected an effective division of tasks, but was also clearly something that *had* to happen for Innovation C to exist. The clinical knowledge enabling nurses to monitor patients from a distance had to be "translated" by C.2 into the language of IT programmers. The role played by C.3 was different but clearly influential in that she acted as a critical and active "disseminator", someone who saw, from a regional perspective, why and how the innovation could help reorganise chronic care delivery and facilitate human resources management.

4 *Discussion*

By analysing the contribution of eight individuals to the design processes of three medical devices, this paper sought to clarify how design participants position their work and deploy their thinking and activities within a complex and diffuse set of constraints and expectations. Positing that design processes are made, among others things, of social dynamics, our study examined the roles participants played over the course of a project, emphasising how their knowledge, tasks and motivations differed and combined. The implications of our findings are twofold.

First, by reframing Bucciarelli's concepts into a set of heuristic devices that pushed the analysis beyond the properties of the object to be designed, our paper clarifies how design participants start to envision an innovation from their own world (biomedical engineering, obstetrics, mathematics) and then may: 1) build it by piecing together all the required components within the context of an emerging entrepreneurial world (heart ablation catheter); 2) search for and assemble pieces coming from foreign worlds in order to revolutionise their own world (labour decision support software); or 3) migrate to another world and adapt their original idea so it may better fit into that world (home telehealth system). Hence, our conceptual framework helps uncover how design participants define the worlds they inhabit and are knowledgeable about, and the worlds through which they search for ideas, solutions and knowledge. In all of the cases, the object to be designed takes shape because knowledge circulates from one domain to another and is adapted or transformed along the way (Kleinsmann, Buijs, & Valkenburg, 2010). As exemplified in the cases of the labour decision support software and the home telehealth system, acknowledging an *absence* of knowledge is also significant; it pushes design participants to search for external expertise or engage into a co-design mode. As stressed by several participants, they were not "inventing" anything; rather, they were sorting out and trying to pair the set of (technical and human) problems and potential solutions their lens brought into focus (Harfield, 2007).

Second, the modalities of engagement that our analyses brought forward help to understand how design participants, when working on the same object, may combine differently the pool of knowledge, responsibilities and motivations that each of them bring on board (Bruce et al., 1999; Chen, 2005; Cross & Cross, 1995). Because our study included three cases, it revealed how the lead designer may act as a builder, an assembler or an adapter and how the other design participants may play complementary roles such as those of an external contributor, multi-tasker, translator or disseminator. It is not only the expertise and division of labour among the team members that matters; the motivations of the various participants also contribute to influencing what they see and value in the object to be designed (Boenink, 2010; van Gorp, 2007). Our findings also showed that each participant's expertise, responsibilities and motivations not only evolved over time, but also had different *weights* in the innovative process. For instance, while A.1 developed a significant expertise in IP and his tasks became more specialised, C.1 did not endorse traditional business responsibilities and shared with C.2 large parts of the design activities. While determining which model of team work is the most effective goes beyond the purpose of this paper, the lead participants' modalities of engagement (that of A.1, B.1 and C.1) could be seen as setting the tone, especially in the early phases of development (Berends et al., 2011; Howard et al., 2008).[7] They may do so through what Aspara (2009, 243) describes as mental models, that is, simplified calculative schemes or frames, as well as "cues, signals, and heuristics", that help evaluate the skills and expertise that is needed for the project to take off and evolve.

Further research could help advance, challenge or refine our empirical observations, in particular, by overcoming some of our study's limitations. For instance, our recruitment strategies were limited by the natural evolution that characterises medical innovation development. Between the moment our research proposal was submitted for funding (letters of support from each company were requested) and the moment we were funded and ready to conduct the interviews, all of the three companies identified for our project had been sold or were engaged in such a process. This explains why not more than eight interviews could be conducted since a number of individuals declined our invitation since they were no longer involved with the company. Our analyses of the design participants' contributions should thus be considered as a rigorous analysis of the views of those who have participated in our study, but not as a *complete* portrait of all the perspectives that contributed to the design process.

5 *Conclusion*

Our findings capture significant dynamics that are likely to be observed in other contexts. It would be interesting to examine whether different outcomes are associated with the modalities of engagement we observed. Do some design teams better succeed in bridging the different worlds of healthcare innovation? Examining whether there is a threshold in the size of

a design team and the heterogeneity of its combined expertise would be equally informative. Do individuals with "dual" training provide an edge to such teams? Finally, the fact that medical devices increasingly rely on new IT (for instance, computer-assisted surgery, remote monitoring or computerised imaging) also suggests that research into the "malleability" of such components and their constant revisions and upgrades would complement what is currently known about the design challenges of "hard" medical devices (Dixon et al., 2006).

By bringing forward what design participants saw through their lens and how they engaged into the design process, this study clarified that design participants position their own world in relation to the worlds of the broader healthcare innovation design collective. This positioning reveals how the boundaries of each participant's knowledge and expertise are defined (including what falls beyond), how different arrangements of tasks and responsibilities are made in practice, and how participants' motivations and interests, while varying subtly, gave a direction to the design process (van Gorp, 2007). While both the heart ablation catheter and the labour decision support software were geared at providing an additional tool to the clinical arsenal of medical specialists, responding to health care system challenges was a strongly shared motive for the home telehealth system. Whether designers should be concerned or not about the sustainability of the products they conceive remains an open question (Tatum, 2004; van Gorp, 2007); this observation, nonetheless, calls for more attention since medical technology directly affects the sustainability of both private and public health care systems (Faulkner, 2008; Lehoux, 2006).

Notes

1. Bucciarelli emphasised in his book (Bucciarelli, 1994) how a set of skills, competencies and tasks can bring about certain object worlds. In a subsequent paper (Bucciarelli, 2002), he examined in further detail how language and visual representations are mobilised by design participants to describe and discuss the object worlds on which they work.
2. A.1 also described at length the unintended consequences of radiofrequency-based ablation (e.g., debris that could cause blood clots, lack of precision which could necessitate the installation of a pacemaker into the patient's body).
3. A.2 also stressed the few moments where experiential knowledge such as a "yeah, I guess it should work" helped move the design process along.
4. The company's rationale is that birth-related injuries are predictable and preventable, as well as extremely costly from a medical liability perspective.
5. When showcasing the decision support software during training sessions, B.2′s lens also brought into focus enthusiast peers ("mouths falling open").
6. In contrast to Innovations A and B, where clinical knowledge was necessary to define *ex ante* what the medical device was supposed to do, clinical knowledge had to be "embodied" into Innovation C for it to be of any use.
7. Although design participants do not always "choose" with whom they work since a number of decisions depend upon the company's high-level executives, shareholders and capital investors (Farley & Rouse, 2000), their initial framing of the main product of the newly established company may be pivotal.

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