

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

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