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Human factors in the design of medical devices – Approaches to meeting international standards in the European Union and USA

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ABSTRACT

This paper focuses on the challenges of meeting agency requirements as it pertains to the application of human factors in the medical device development (MDD) process. Individual case studies of the design and development process for 18 medical device manufacturers located in the US and EU were analyzed and compared using a multiple case study design. The results indicate that there are four main challenges in implementing international standards. These include a lack of direct access to users for the purposes of device development; a lack of understanding by users with regards to the impact of their feedback on the development process; contract formalities limiting user exchanges; and the attitude of clinical users directly impacting on the device developer's invitation to participate in the development processes. The barriers presented in this research have the potential to be resolved but only with greater commitment by both medical device users and developers.

1. Introduction

The design of medical devices starts with a need and a description of the concept or problem (Ogrodnik, 2013). In order for a new device to be used within the clinical environment, certain development procedures must be undertaken, such as a regulatory plan and design optimization through verification/validation (Whitmore, 2004; Zenios et al., 2010; Ogrodnik, 2013). Furthermore, the integration of human factors in the medical device design process is required to reduce risk and improve patient safety (FDA, 2011; MHRA, 2016). Additionally, Design Control is a fundamental requirement to meet regulatory approval for international standards (FDA CDRH, 1997; Ogrodnik, 2013) as it documents the history of development and ensures that the origins of any decision made during the development process are traceable. In order to improve the ability of designers and auditors to ascertain the safety and efficacy of a product, the use of design controls has been adopted in order to specify the appropriate method for device review at several key stages (Gilman et al., 2009). The framework of this model meets United States (US) Federal Regulation 820.30 for Design Control (Justiniano and Gopalaswamy, 2003; Gilman et al., 2009; Panescu, 2009). For example, in determining user needs, ethnography and/or contextual inquiry is undertaken in order to write formative usability objectives that meet industry standards for the Association for the Advancement of Medical Instrumentation (AAMI) (AAMI, 2009)/American National Standards Institute (ANSI) Human Engineering Standard 75 and International Electrotechnical Commission (IEC) (IEC 62366: 2007/(R) 2013). Wilcox (2012) explains the use of ethnographic research in medical device development in order to learn what actually takes place as opposed to what people say takes place and then using that information to create devices that reduce error and improve productivity. This paper focuses on the challenges of meeting these agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU). This furthers the research of Vincent et al. (2014) wherein barriers, such as communication breakdowns between users and design teams, hindered the integration of human factors in medical device design (Vincent et al., 2014). For reference, the human factors standards applicable to medical device development are as follows:

- IEC 62366-1:2015, *Medical devices - Application of usability engineering to medical devices*, published by the International Electrotechnical Commission.

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- IEC/TIR 62366-2:2016, *Medical devices - Part 2: Guidance on the application of usability engineering to medical devices*, published by the International Electrotechnical Commission. (Note: this standard was not published at the time of this study)
- AAMI HE 75:2009, *Human Factors Engineering — Design of Medical Devices, Section 9 — Usability Testing*, published by the Association for the Advancement of Medical Instrumentation.
- Medical Device Safety — *Integrating Human Factors Engineering into Risk Management*, June 18, 2000, available on the U.S. Food and Drug Administration's website.
- FDA's guidance document *Applying Human Factors and Usability Engineering to Medical Devices,* which addresses usability testing, issued on February 3, 2016, available on the U.S. Food and Drug Administration's website. (Note: this guidance document was in draft during the time of this study)
- ISO 14971:2007, *Medical devices — Application of risk management to medical devices*, published by the International Organization for Standardization.

In the UK, the Competent Authority is the Medicines & Healthcare products Regulatory Agency (MHRA). The MRHA enforce the following regulations (MHRA, 2016):

- The Medical Devices Regulations 2002 — SI 2002/618 (consolidated legislation)
- The Medical Devices (Amendment) Regulations 2003 — SI 2003/1697
- The Medical Devices (Amendment) Regulations 2007 — SI 2007/400
- The Medical Devices (Amendment) Regulations 2008 — SI 2008/2936 (transposes Directive 2007/47/EC into UK law (came into force March 2010))

In 2016, The MHRA published draft guidance titled, "Human Factors and Usability Engineering — Guidance for Medical Devices Including Drug-device Combination Products" (MHRA, 2016). This document was not available when empirical data collection for this study was undertaken, however, it provides an overview of the regulatory framework, the standards, process of usability engineering, simulation and post-market surveillance for the EU. As evidenced by these international requirements, the application of human factors is critical to the device approval process.

For clarity, the definition of who a user is in terms of a medical device can vary. It can be a clinical provider (physician/doctor/nurse), the patient, a parent or caregiver. For example, Money et al. (2011) identify the user as any healthcare worker who may be required, either regularly or occasionally, to locate, examine or access blood vessels of patients or to assist with these tasks. De Ana notes that careful analysis of all stakeholders is required to determine precisely who the user is for any device in development as it may be that, through the use of the device, the user may change from the provider to the patient or vice versa (de Ana et al., 2013).

Kaye (AAMI, 2013), commenting on the fundamental challenge in medical device design, states, *"… … the ability to identify and understand, particularly during design, possible use problems and the potential for harm associated with the use of medical devices. Additionally, many system-use problems were context-specific, subtle, complex, and hard to identify. However, use related problems can be detected via formative testing and evaluation by users" (AAMI, 2013 p.9)*. This can be seen as being indicative of the importance of early and direct user involvement before medical device development. Observational research, such as contextual enquiry and usability testing, formalize user involvement in the design process at specific points, with all users being sensitive to device usability along with safety and efficacy (Wiklund and Wilcox, 2005). However, it is not possible to have every element of the design perfected to all user expectations in addition to meeting the needs of safety, efficacy, and technical feasibility. Fairbanks and Wears (2008) sum up the perception of users towards industry, stating that device manufacturers should *" …. presume there to be a design problem rather than a user problem and work from that starting point to find avenues for improvement … we cannot be satisfied with weak solutions that provide the illusion of action but will accomplish little or nothing, such as a new policy, exhortation, and training." (Fairbanks and Wears, 2008 p. 520)*.

In a study by Money et al. (2011), in-depth interviews were conducted with representatives from 11 medical device manufacturers. They asked the manufacturers to identify whom they believe the intended users were; what role they had in the process; and what value (if, any) did they believe the users added. They used thematic analysis to review transcripts and found there were perceived barriers to specific user groups in obtaining ethical approval, the speed at which such activity may be carried out, and belief that there was no need to seek user input given the 'all-knowing' nature of senior healthcare staff and clinical champions (ibid). Additionally, only one manufacturer claimed to regularly use formal user-centered design methods within the development process. Hence, the only evidence of engagement with users was the formal methods that were mandatory and dictated to manufacturers by standards and purchasing agencies. Money et al. (2011) suggest that when focusing on IEC 62366, device manufacturers should conduct research using human factors engineering methods to make their use more feasible; include provision of training on their use; better communication between those making purchase decisions and the actual users of devices; and connect more readily with ethical approvals to engage with users with minimal levels of bureaucracy while protecting patients and healthcare staff (Money et al., 2011).

As a result of agency mandates and standards such as IEC 62366, users (customers) are most often involved in need determination, usability assessment and development of surgical technique (Ogrodnik, 2013). Usability is considered as being important although not enough on its own to guarantee product success. Usability techniques can be used to improve a given situation but they do not reveal if a given situation is better or more enjoyable (Battarbee and Koshinen, 2005).

A realization that human error in operating a device can be a major cause of patient death or injury (Cafazzo and St-Cyr, 2012) identifies a need for collaboration throughout the design process rather than at formal mandated intervals. As collaborative design techniques become more widely adopted, the role of the user has started to change. In consumer product design, this calls for participation of users within the design process as co-creators (Sanders, 2002), thereby nurturing collective creativity with users as active, competent participants (Binder et al., 2008).

Lin et al., (2001) comment that manufacturers have the capacity to enhance patient safety by putting greater emphasis on the human factors engineering process in the design of devices. This position is expanded by suggesting that government medical regulators may be able to enhance patient safety by putting an emphasis on human factors engineering design criteria when undertaking final product approval and regulatory decisions