Designing for patient safety

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Abstract. The publication of the IOM report on health information technology (HIT) and patient safety has sparked the discussion about HIT safety. After a panel MIE2011 panel about the occurrence and causes of HIT safety problems, a MIE2012 panel about regulation of HIT safety, this panel seeks to address how HIT can be designed for patient safety. The panel will address three themes: the current state of HIT safety problems, the role of human-centered design for designing patient safe systems and its consequences for the sociotechnical context.

Keywords. Health Information Technologies, Patient Safety; Human-Centered Design; Sociotechnical Context

Introduction

The smoldering debate about health information technology (HIT) safety has been reignited by the publication of the Institute of Medicine’s (IOM) report ‘Health IT and Patient Safety: Building Safer Systems for Better Care’ (1). Beginning in 2005, a number of seminal studies have described safety risks and adverse advents that are associated with the use of HIT [2]. Results from these publications are echoed in discussions on the American Medical Informatics Association’s implementation discussion list and Scot Silverstein’s blog about good and bad HIT. The consensus of these sources is that the design and implementation of HIT is problematic and often leads to flawed systems (2).

The IOM report recognizes that HIT is part of a complex sociotechnical system that may pose risks for patient safety; however, there is little published evidence regarding the magnitude and severity of this problem. In this report, safety is seen as an emergent property of a sociotechnical system that includes both the HIT software and how it is used by clinicians. The IOM report specifically notes that poor usability, poor workflow integration and complex data interfaces are threats to patient safety, and makes a series of recommendation for improvement. Special emphasis is given to the need of reporting HIT patient safety problems.

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In the light of the problems of poor usability and workflow integration as a cause of HIT-related patient harms, this panel seeks to address the question how HIT that is safe for patients can be designed.

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HIT forms part of a sociotechnical system, which is health care. Adopting this perspective safety emerges from the interaction of contextual factors. Comprehensive safety analysis should consider how these factors affect each other in an attempt to reduce the likelihood of an adverse event, rather than focusing on eliminating “root cause” [6]. This raises ultimately leads to the challenge how HIT can be designed to be safe for patients.

In order to respond to this challenge the panel will address three questions. First, what is the current state of knowledge about technology induced patient harm. The second question will focus on human-centered design and finally it will be argued that human-centered design is intrinsically linked to an understanding of the organizational context.

Dr Magrabi reported in a study of the FDA MAUDE database that of the reported 678 HIT incidents reports 96% were machine related and 4% to human-computer interaction and eventually four deaths were related to HIT problems (3). At the one hand many HIT problems remain undetected because of reporting is not required. Dr Magrabi will provide an update of her findings and discuss statistical methods to refine the search the contents of incident reports (4).

At the other end Dr Borycki adapted Donabedian’s well-known quality framework to understand technology induced errors and to develop a strategy to mitigate these errors (5). The quality dimension structure refers to presence of surveillance and/or reporting systems for regulation of technology and having alerting systems in place. The dimension process includes organizational procedures to document and report incidents and accidents to the appropriate authorities and stakeholders. Finally, the dimension outcome relates directly to the reduction of errors, improvement of design, development and implementation of HIT and increasing its safety.

User-centered design requires a thorough knowledge of cognitive processes to capture the interaction of humans and technology. Dr Kushniruk will discuss diverse methods to design systems. There is an experimental component to it in the form of cognitive task and workflow analysis and modelling, cognitive walk through and simulations, and a field study component in the form of ethnography, which includes interviewing and observations in practice settings (6).

Dr Beuscart-Zéphir and Dr Pelayo will discuss how the revised European directive for medical devices required manufacturers to implement a usability engineering process (UAP) to be integrated with the design and development of technology and risk management (7). They will report how UAP compares to user-centered design, on the experiences with and the slow uptake of UAP. Finally they will discuss to what extent HIT vendors can learn from these experiences and the feasibility of using UAP in HIT design and development.

Finally, designing for safety cannot be separated from its environment. Usability is not an intrinsic property of HIT, something that can be built into system. Context of use, which means organizational conditions and regulations are equally important. Medical guidelines for example are embedded in a decision support system, and when they
change it may affect the usability. Dr Aarts that designing HIT for patient safety is not static, but requires continuous adaptation to changing circumstances and workflows (8).

References