MediCHI: Safer Interaction in Medical Devices

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Abstract
Medical devices embedded with computer systems have been widely adopted in many healthcare situations with the intention to deliver accurate and effective medication. However, due to the nature of medical devices, usability issues and the complexity of their context of use, designing and evaluating interactive medical devices from a human error management perspective has always being challenging, particularly in high-risk areas. This workshop sets out to bring together international researchers and designers working in relevant fields to discuss, review, compare and demonstrate effective practical approaches that can be adopted to improve the design of medical devices for safer interaction in the future.

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Human Error; Design for Safety; Human Computer Interaction; Medical Devices; Incident Reporting and Learning

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Introduction
Interactive medical devices, such as ambulatory infusion pumps, dialysis machines and Bluetooth vital sign

Adverse Incidents Related to Medical Devices

In August 2006, a 43-year-old Canadian woman with advanced nasopharyngeal carcinoma died as a result of an accidental overdose of fluorouracil, which is one of the very few chemotherapy drugs that require continuous intravenous infusion at a very low rate over a long period of time, usually over days. After the nurse made an unnoticed calculation error, the infusion pump performed an infusion at a rate that was 24 times too fast [4]. Human factor design flaws not only increased the cognitive load associated with performing the calculation correctly and operating the pump, but rather than identifying and managing user error, the technology failed to detect the miscalculation and allowed a high-risk chemotherapy drug to be delivered at an excessive infusion rate.

In March 2011, a retired businessman was found deceased on his machine at

monitoring systems, are currently undergoing a boom in popularity, both in hospitals and in patient homes. Unlike ordinary consumer products, the nature of these devices is much more complicated in terms of the operating environment, the level of integration needed, the amount of training required, the stress levels involved, and the physical capability of device operators the user, etc. Interaction design errors in medical devices have been creating unnecessary risks and leading to tragic losses. They also contribute to healthcare costs, and are expensive for manufacturers when implementation commitments have already been made. It is therefore important to identify and amend design errors before introducing medical devices to market, possibly at the early stages of device development.

Conventional usability studies for analyzing interaction design tend to focus on factors of speed or user satisfaction rather than safety and error rates. Furthermore, in professional environments, error rates are too low to be assessed effectively using laboratory studies. It can also take a long time to gain ethical approval in order to conduct situated field studies (e.g., observations in working hospitals). Therefore, new approaches that enable rigorous and uniform analysis of interaction design are needed to provide reasonable assurance that a medical device is safe and fit for purpose.

Safer Interaction in Clinical Settings

In the US, the landmark *To Err is Human* report puts death from preventable errors in hospitals at a comparable rate to deaths from road accidents [1]. In the UK, the President of the Royal College of Physicians called for a national system for recording adverse medical events in 2001, after saying mistakes in NHS (the UK National Health Service) hospitals may be contributing to the deaths of almost 70,000 patients a year [2].

For many years, effort has been made by all stakeholders to improve healthcare and ensure patient safety. However, the outcome has not kept up with our expectation. Failure to design interactive medical devices to prevent and manage human errors in clinical contexts has jeopardized not only patient safety, but also the trust they put in healthcare practitioners and the reputation of medical device manufacturers.

Post-market Surveillance at FDA (US Food and Drug Administration) reveals that human factors issue is counted as one of the top six causes of the Medical Device Reports received. Typical issues include: inadequate or absent descriptions or characterizations of errors; checklist or rating scale approach to validation rather than systematic assessment of user performance and experience; not testing with representative users of the intended population of users. Several incident root cause analyses performed after severe adverse events revealed that many of these interaction design problems were foreseeable and, therefore, preventable [3].

Safer Interaction in the Home Environment

As the financial and well-being benefits of healthcare at home become more obvious, terms like "home chemotherapy" and "home hemodialysis" are no longer new to many patients. However, the interactive medical devices designed to support such treatments are far from reliable when it comes to ensuring safe interaction.

What's shown in the side bar are just two examples out of many. Designing interactive medical devices doesn't get any easier if the device is not intended to be used in a

home in the midst of dialysis [5]. A misconnection of the saline bag to the venous end of the extracorporeal blood circuit (instead of the arterial end) led to approximately 2.3L of his blood being pumped into the saline bag, resulting in hypovolaemic shock and death from exsanguination. Previously, the patient had been successfully trained at the hospital over a 20 weeks period before started home hemodialysis. He died within the first month of home use.

busy hospital or by healthcare practitioners working in busy environments. Patients are not clinical practitioners (although may be experts in managing their condition). A patient's home will often contain a high degree of complexity with respect to the relationship between the social environment and the device operator's physical and psychological capabilities. This relationship will influence the decisions and errors that a user makes.

Design to Assist Reporting and Learning in Error Management for Safer Interaction

To manage use errors for safer interaction, one must study and learn from previous errors related to interactive medical devices. For this purpose, incident reporting and learning systems are established and reinforced by regulatory agencies around the world. Examples include the US FDA's Medical Device Report (MDR) regulation, the formal UK National Reporting and Learning System (NRLS). Despite the well-known and well-advertised strengths and benefits of incident reporting and recording systems, there are obvious barriers to tackle, such as inaccessibility and complexity. A collaborative hospital study [6] has stated a collection of possible causes of under-reporting and poor quality of reports available. From a practitioner's point of view, it is hard to report and record if an incident or a slip is simply unnoticed or unrecognizable in the first place. On top of that, lack of clarity regarding what should be reported, and limited feedback regarding how the reports might lead to improvements in the existing system, contribute to poor reporting.

Without meaningful reporting, and hence without data, it is not surprising to see some regulatory agencies stumble at every step of evaluating the design of medical devices from a human error management point of view. Guidance of evaluation is largely around mechanical and electronic testing. Standards on Human Factors in medical devices are often considered as vague and not informative [7]. The relevant ISO/IEC standards (e.g., ISO/IEC 62366) emphasize documentation and management of foreseen problems, rather than rigorous usability and safety evaluation tailored to meet the needs of the home environment. This is partly because conventional usability methods are inappropriate, and partly because there are significant challenges experienced when implementing standards of this type.

Workshop Goals

This workshop sets out to bring together global researchers and designers working in relevant fields to discuss, critique and demonstrate the practical approaches that can or might be adopted to improve the design of medical devices, to provide for safer interaction in the future. The organizers are from academia, regulatory agencies and industry working on HCI and interactive medical devices. The structure follows previous successful workshops run by the organizers in the UK, China and Canada. The key goals of this workshop are as follows:

- To promote a shared understanding of the issues addressing the need for safer interaction and integrating between the various research strands.
- To discuss and exchange information on the tools and techniques involved in developing safer medical devices.
- To discuss the user experience in manipulating the physical characteristics of an interface and how do we evaluate the effectiveness as an input control.

The workshop aims to establish common ground between academia, industry and regulatory agencies in order to promote synergistic links and shared

understanding. We will agree on the knowledge exchange forms amongst participants from different backgrounds. This will lead to future collaboration and impact in the field of medical device design and evaluation. We will do this through establishing meaningful interventions.

Workshop Submission

This workshop seeks position papers, as drafts for journal publication, and demonstration proposals associated with the following themes:

- **Design of Personal/Home Interactive Medical Devices**: where the complexity of the social environment and the device operator's physical and psychological capabilities, has an influence on decision making and error rate; and
- **Design to Manage Human Error in Clinical Settings**: which includes designing interactive medical devices with human error management features, new design approaches or tools to ensure safer interaction. It also addresses the potential for improved incident reporting and learning system to better capture and record the incidence of user error.

Publication Plan

Accepted workshop submissions will be published online through the peer-reviewed MediCHI workshop proceeding. Participants will have the opportunity to revise and resubmit (we would encourage co-authoring with other workshop participants as appropriate) to a special issue of the Journal of Designing in China.

As a longer term goal, the organizers also plan to facilitate the development of joint papers to other relevant journals, such as Personal and Ubiquitous Computing, British Medical Journal, etc., amongst MediCHI participants based on common interests identified on the day of the event.

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