Mind the gap

What interactive medical device manufacturers need

Chris Vincent

Recent alerts and recalls regarding the use of infusion pumps highlight the importance of an interdisciplinary approach to equipment design. HCI specialists are well placed to contribute and there are resources that allow developers to take account of the interaction between users, the tools that they use and the environments in which they live and work. HCI professionals need to make it easy for developers to adopt a user-centred approach and research is underway to establish current practice and future needs.

Each year, members of the UK health service perform approximately 15 million infusions. A small number (about 700) result in an adverse event [1]. Several mechanisms are in place to learn from incidents, protect patients from harm and maintain quality of care [2]. An area of potential concern relates to the users' inadvertent misprogramming of the device. These types of interaction error can be easily missed [3]. Much has been achieved in safeguarding the public and professionals from poor device design; however, there is still a need to understand where the medical device industry requires support and how HCI professionals can contribute.

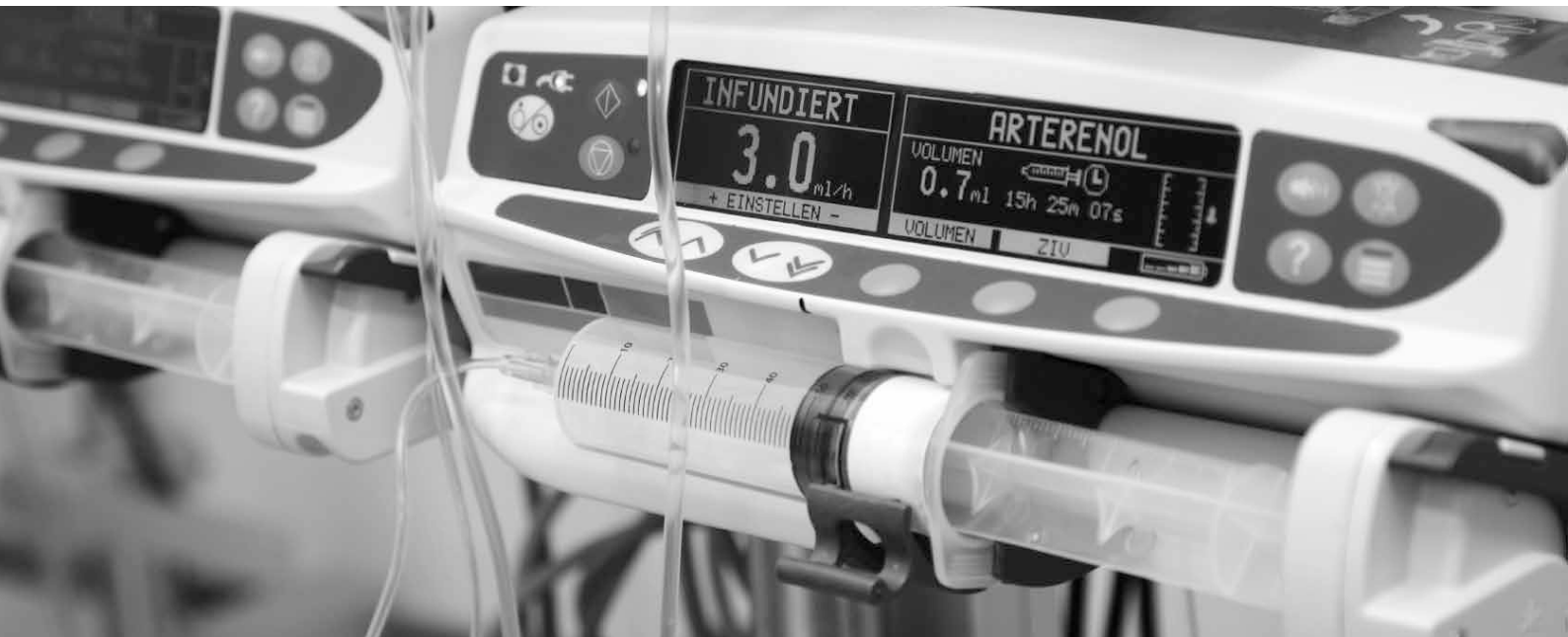
For the majority of medical devices used in the European Union, patients, public and clinicians are protected by a statutory framework – the Medical Devices Directive [4]. This sets out essential requirements for audit, inspection, design, production, marketing, risk assessment and post marketing surveillance of a broad range of devices. The regulation comprises core essential requirements in addition to a series of optional harmonised standards. In terms of user interaction, the essential requirements are often non-specific, as in the two examples that follow:

> The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users …

> Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features …

In the US, the Food and Drug Agency (FDA) is more prescriptive in requiring developers to demonstrate how human factors considerations were applied during product development. Consequently, there are several examples of manufacturers adopting a human factors approach [5, 6]. Following an extensive recall of infusion pumps, the FDA has announced an initiative to improve the safety and effectiveness of infusion pumps. In a recent white paper, cause for concern is raised regarding user interface issues, such as "confusing or unclear onscreen user instructions …" [7].

In the UK, there have been several alerts issued by the National Patient Safety Agency (NPSA). In 2004 a safer practice notice was



released, recommending interventions regarding procurement and equipment management. The resulting purchasing toolkit required buyers to assess usability and requested that user views are fed back to manufacturers [1]. Recently, a series of resources have become available, including guidelines regarding the design of electronic infusion devices [8].

International design standards, such as AAMI HE74, AAMI HE75, ISO/IEC 60601-1-6 and ISO/IEC 62366, recommend an iterative development approach involving phased design reviews and continual user input and evaluation. The cycle includes user research, conceptual development, generation of design requirements, design output (specifications), verification, validation, evaluation, deployment and post-market surveillance (as required by the Medical Devices Directive). Tools such as usability testing and risk analysis may be applied during multiple stages of the cycle.

Conceptual development and user research provides an understanding of the relevant domain. This includes reviewing process and procedures, market research, associated product complaints, adverse incidents, context of use and system constraints. Tools such as scenarios, storyboards, use cases, personas or task analysis may apply and practitioners can conduct focus groups, interviews or literature reviews. This informs usability requirements, for example "95% of first time users will be able to load a set and program an infusion within two minutes or less". There are several resources that can aid this process including usability heuristics [9] and formal risk management processes such as ISO 14971. While setting usability requirements is useful, it is not sufficient. The FDA, amongst others, is now asking: What about the 5% who fail to achieve this objective – are they putting patients at risk by not correctly programming the infusion?

Despite the volume of support available, there is still a genuine need to understand how developers apply tools, where there is an absence of resources, and how models of human capability can inform interface design.

How do manufacturers provide for the usability requirements that arise as a result of home use? Do issues like alarm fatigue present opportunities to improve design? Does experience with a legacy device type impact on the use of a new device type? Is there a sufficient understanding of how users react when distracted or when switching between multiple tasks? Do developers design interfaces that mitigate against likely sources of error and are there sufficient behavioural models to support this?

Interdisciplinary teams containing HCI specialists can contribute to many of these questions by recommending specific tools, techniques or measures and by providing clear and accessible advice that directly informs design decisions. HCI professionals can help the development team adopt formal methods to structure testing; they can also help produce tests that consider relevant human capabilities during the iterative process of prototyping, simulation and usability testing.

CHI+MED

Understanding how and why interface developers make design decisions is part of the CHI+MED research programme (http://www.chi-med.ac.uk/). It involves contributing methods that minimise the risk of human error and maximise patient benefit. Input from HCI practitioners and health care professionals is essential in understanding current practice and future needs, particularly with regard to interaction design. For more information, or to get involved, contact Chris Vincent at University College London Interaction Centre (UCLIC), c.vincent@ucl.ac.uk or +44 (0)20 7679 0694.

References

[1] National Patient Safety Agency London (2004). *Safer practice notice 01: Improving infusion device safety*. http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59788. Accessed 15 July 2010.

[2] Department for Health London (2000). *An organisation with a memory: report of an expert group on learning from adverse events in the NHS*. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083. Accessed 15 July 2010.

[3] Blandford, A., Buchanan, G., Curzon, P., Furniss, D. & Thimbleby, H. (2010). Who's looking? Invisible problems with interactive medical devices. In *Proc. of Workshop on Interactive Systems in Healthcare*, ACM CHI 2010, Atlanta, GA.

[4] *Council Directive 93/42/EEC concerning medical devices*. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML. Accessed 15 July 2010.

[5] Israelski, E.W. (2007). *The Symbiq™ (Next-Generation) IV Infusion Pump*. http://www.hospira.com/files/symbiq%20white%20paper.pdf. Accessed 15 July 2010.

[6] Smiths Medical (2008). *CADD®-Solis Clearance*. http://www.smiths-medical.com/plugins/news/2008/mar/cadd-solis-launched.html. Accessed 15 July 2010.

[7] Center for Devices and Radiological Health Silver Spring (2010). *White Paper: Infusion Pump Improvement Initiative*. http://www.fda.gov/medicaldevices/productsandmedicalprocedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm. Accessed 15 July 2010.

[8] National Patient Safety Agency London (2010). *Design for Patient Safety: A guide to the design of electronic infusion devices*. http://www.nrls.npsa.nhs.uk/resources/?EntryId45=68534. Accessed 15 July 2010.

[9] Zhang, J.J., Johnson, T.R., Patel, V.L., Paige, D.L. and Kubose, T. (2003). Using usability heuristics to evaluate patient safety of medical devices. *J Biomed Inform*, **36**, 23–30.