Who's looking? Invisible problems with interactive medical devices

Ann Blandford, George Buchanan, Paul Curzon, Dominic Furniss and Harold Thimbleby


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Ann Blandford
UCLIC
University College London
Gower Street
London WC1E 6BT, U.K.
a.blandford@ucl.ac.uk

George Buchanan
Centre for HCI Design
City University
Northampton Square
London EC1V 0HB, U.K.
George.Buchanan.1@city.ac.uk

Dominic Furniss
UCLIC
University College London
Gower Street
London WC1E 6BT, U.K.
d.furniss@ucl.ac.uk

Paul Curzon
School of Electronic Engineering and Computer Science
Queen Mary, University of London
Mile End Road
London E1 4NS, U.K.
p.curzon@qmul.ac.uk

Harold Thimbleby
Department of Computer Science
Swansea University
Singleton Park
Swansea SA2 8PP, U.K.
H.Thimbleby@swansea.ac.uk

Abstract
There is evidence that widely used interactive medical devices such as infusion pumps pose interaction difficulties. Yet this evidence is widely dispersed, and difficulties in programming, interaction and socio-technical design have rarely been a focus for study. Interaction difficulties are effectively invisible. To understand why, it is necessary to study the cultural and organizational contexts within which devices are designed, deployed and used. In this paper, we present examples illustrating interaction difficulties and outline features of the context that keep those difficulties invisible.

Keywords
Medical devices, device design, human error, regulatory framework.

ACM Classification Keywords
D2.10 Design, H5.2 User interfaces.

General Terms
Design, Human Factors.

Introduction
Periodically, an incident in which widely used interactive medical devices are implicated hits the headlines. For
example, the report on the death of Denise Melanson [4] highlights the calculation and programming errors that resulted in medication that was intended to be administered over four days being delivered in four hours. In a subsequent user trial replicating the situation as closely as possible, 3 out of 5 participants made programming errors, and all had some difficulty working with the device. Another example is the report on Lisa Norris [8], who also died – in this case, following repeated high doses of radiation therapy due to an operator being unaware of the need to apply a scaling factor in the calculations. Both of these incident reports refer to other “similar” cases for which less information is available.

The role of design in reducing or mitigating errors is becoming more widely recognised. For example, a Panel on Transforming Healthcare report to the US President calls for “research on user-interface hardware and software to promote the development of better solutions to the problem of human computer interaction in healthcare” [7]. Smetzer and Cohen [9] have recognized the issue of misprogramming of drug delivery devices. They note (p.275) that “misuse of infusion pumps and other parenteral device systems is the second most frequent cause of medication errors during drug administration”. They discuss the impacts of various factors, including device programming, physical aspects such as tubing, and wider system aspects such as relatives administering patient-controlled analgesia drugs, on medication errors; they advocate Failure Modes and Effects Analysis (FMEA) as a means for assessing system safety. Fairbanks and Wears [2] also highlight the role of design in provoking or mitigating errors, focusing on the design of defibrillators; they argue that design changes “offer the prospect for real and sustained change”. However, such reports have as yet had little impact on practice.

It is difficult to get detailed information on incidents that increase system vulnerability but do not result in adverse outcomes. A study by Husch et al. [3] highlights how few incidents are reported. They studied infusion pump use in a busy hospital over a 9 hour period, covering 426 instances of intravenous infusions. They identified a total of 389 errors, occurring in 285 of the infusions. In other words, 66.9% of the infusions studied involved one or more errors. Many of these errors would be classed as minor (e.g. no rate on label, which might lead to a more serious error but does not cause direct harm). However, 55 of the errors identified were either rate deviation or incorrect medication. This can be compared with the number of errors in the same categories that were reported through the formal reporting system – namely 48 reports over a 2 year period from the same hospital. On the one hand, this shows that even potentially harmful errors are often not perceived as resulting in harm; on the other hand, the low reporting rate means that errors are effectively invisible, and it is impossible to learn from the “near misses”, as happens in other industries [1].

Why are interaction design problems invisible?

In our initial investigations, we have identified several factors that contribute to the invisibility of interaction design problems, and the corresponding human errors. Some relate directly to the visibility of interaction design in procurement, in use and in incident reporting:

1. Procurement does not have human-factors guidelines. A recent UK purchasing guide for insulin pumps [6] omits any discussion of interaction design
but notes (p.9) that “Individuals with poor cognitive function should not be responsible for self-management of a pump.” Hospitals buy devices on a range of criteria, including cost and consumables costs; usability and error prevention are not usually central criteria.

2. *The focus of clinicians* is on patient care, and they will do whatever workarounds are necessary to address patient care, rather than considering in what ways the devices they work with could be better designed, or the details of why an interaction went wrong in any way.

For example, we have seen ventilators fail and need rebooting mid-operation. If there is no harm, there is nothing to report. Hence serious design issues do not get reported unless they clearly — to the non-technical specialists at the sharp end — lead to patient harm.

Because clinicians are not focusing on interaction design, they have limited ability to report on details of the interaction following an incident.

3. *There is minimal questioning of device design,* not just among clinical staff, but across all professions involved in decisions. For example, the incident report on the Lisa Norris case [8] (p.2) notes that “... at no point in the investigation was it deemed necessary to discuss the incident with the suppliers of this equipment since there was no suggestion that these products contributed to the error”, and yet a reading of the report from an HCI perspective suggests that there were clear problems over the integration of software modules, and that the system was unnecessarily difficult to understand and use.

Other factors are organizational, including organizational culture, reporting mechanisms and problem ownership:

4. *The pervasive blame culture* discourages reporting. This culture is widely recognized [5], and it can be an obstacle to investigations, and even to studies. For example, in working with nursing managers to design observational studies of staff using infusion devices, we have to address their concerns that an improved awareness and reporting of interaction errors may result in a perception that performance is getting worse – a perception that would be damaging to patient confidence and to the reputation of the organization.

5. *The lack of high quality data* on interaction errors makes it impossible to ascertain how often interaction errors are a contributory factor in incidents. Barach and Small [1] quote an estimate of 100 000 preventable deaths in US hospitals annually, but few incident reports include details of interactions. Incident reports generally give no indication of what information the clinician was working from, how any calculations were performed, what checks were in place, or how the drug was administered (including details of the devices used or the user interaction with those devices) – details that are essential for designing safer devices and safer systems.

6. *There is a lack of ownership of the problem.* Each country has a different regulatory regime, so it is difficult to generalize. The situation in the UK is summarized by Sujan et al [9]. In brief: responsibility for the safe design of interactive medical devices is split across several authorities, with the Medical and Healthcare Regulatory Agency taking responsibility for ensuring that devices perform as designed, the National Patient Safety Agency informing policy on aspects of safety including human error, the National Institute for Health and Clinical Excellence having recently taken over responsibility for informing procurement decisions,
and Licensed Authorities certifying new devices as conforming to relevant legislation such as the Medical Devices Directive [11] which, in turn, includes minimal information on device design. Interaction design of established technologies such as infusion devices is not central to the concerns of any of these bodies.

**A research agenda on improving interaction design to reduce patient harm**

There are many factors that can contribute to hazardous incidents in healthcare. While there is an extensive literature on the role of broader organisational factors in patient safety (e.g., the “blame culture” [5] and organisational complexity [9]), there is limited discussion or reporting of the role of interaction design in contributing to safety. The contribution of interaction design to medical incidents is substantially underreported. There is a pressing need for much more extensive research on the causal relationships between human behaviour, device design, situations of use and medical incidents. To maximise the impact of such research, it is also essential to extend the dialogue on this topic to accommodate the perspectives of clinicians, manufacturers, policy makers and patients.

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**References**


