IMPROVING INFUSION PUMP SAFETY: AN ANALYSIS OF AGGREGATED EVALUATION RESULTS

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Design for Patient Safety (2004) recommends the NHS use its purchasing power to influence manufacturers' designs and improve the safety of products and services. The Evaluation Laboratory at the Bath Institute of Medical Engineering evaluates infusion devices for the Centre for Evidence-based Purchasing (CEP). Evaluations include technical testing, user surveys and heuristic reviews. The results are published as CEP reports, which influence NHS purchasing decisions. Since 2003 BIME has evaluated ten infusion pumps. The aim of the current project is to use the results of these evaluations to identify common usability problems. The results could provide the basis for design guidelines, which could, ultimately, improve patient safety.

Introduction

Infusion pumps were introduced over 30 years ago to help deliver nutritional fluids and medication. Since then they have evolved into a range of sophisticated devices, such as PCA pumps for patient-controlled analgesia, portable 'ambulatory' pumps that allow patients to remain mobile, syringe pumps for intensive care and anaesthesia, and general-purpose pumps, which are used heavily in a range of clinical settings (Snodgrass, 2005).

Infusion pumps are now an indispensable tool in modern healthcare, but their complex design has been recognised as a risk factor for administration errors. The scale of the problem is troubling: medication errors cause injury or death to 1-2% of patients admitted to hospital in the US, and the incidence is probably similar in the UK (Williams, 2007).

The Bath Institute of Medical Engineering (BIME) evaluates infusion pumps on behalf of the NHS Purchasing and Supply Agency Centre for Evidence-based Purchasing (CEP).

The aim of the current research is to analyse the data from ten recent evaluations, to identify common design problems and potential solutions.

Methods

Heuristic evaluations

Three to five BIME evaluators with expertise in usability, infusion pumps or both evaluate each pump against a list of heuristics based on those of Zhang *et al* (2003) and note any heuristic violations (usability problems). The results from all evaluators are combined and any duplicates removed. Evaluators then independently rate the severity of each problem by considering its likelihood and potential consequences. A scale of 0-4 is used, where 0 = not a usability problem, 1 = cosmetic problem only, 2 = minor usability problem, 3 = major usability problem and 4 = usability catastrophe (Nielsen, 1993), and an average is calculated.

Aggregated results

From 2003 to 2007 BIME conducted heuristic evaluations on three large-volume general-purpose pumps, five target-controlled infusion (TCI) pumps (used in anaesthesia), a syringe pump and a portable pump. Aggregating the results of these evaluations gives a total of 755 usability problems. We limited our analysis to the 125 problems of major or catastrophic severity (Figure 1).

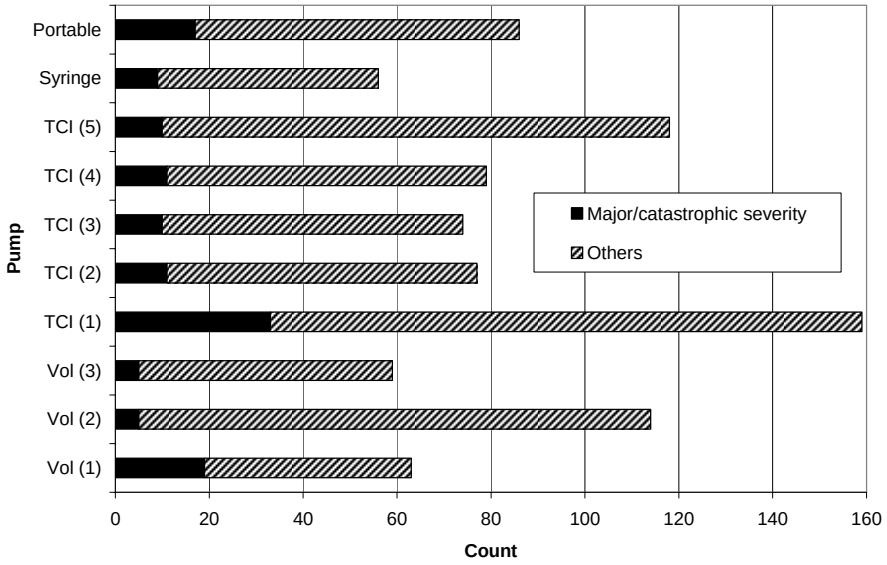

Figure 1. The number of usability problems for each of the ten pumps

The usability problems were categorised according to their effects, their underlying cause, and the stage of operation at which they were likely to occur.

Results

We identified more usability problems with setting-up the pumps than with starting, running, pausing or stopping the pumps; about a fifth of the problems could occur during any stage of pump use, (Table 1).

Table 1. Percentage of usability problems by pump state

Initial set-up	43%
Start	3%
Run	16%
Pause	10%
Stop	5%
All states affected	22%

For most of the usability problems (72%), the most likely effect was to increase the risk of an adverse event. Other effects were an unplanned break from infusion (15%), overdose (9%), unwanted mixing of medications (2%) and unplanned delivery of fluid (2%).

The most conspicuous of the fourteen underlying causes include: inadequate information, faulty logic, inadequate system barriers, unnecessary complexity, inadequate functionality and inadequate displays (Figure 2).

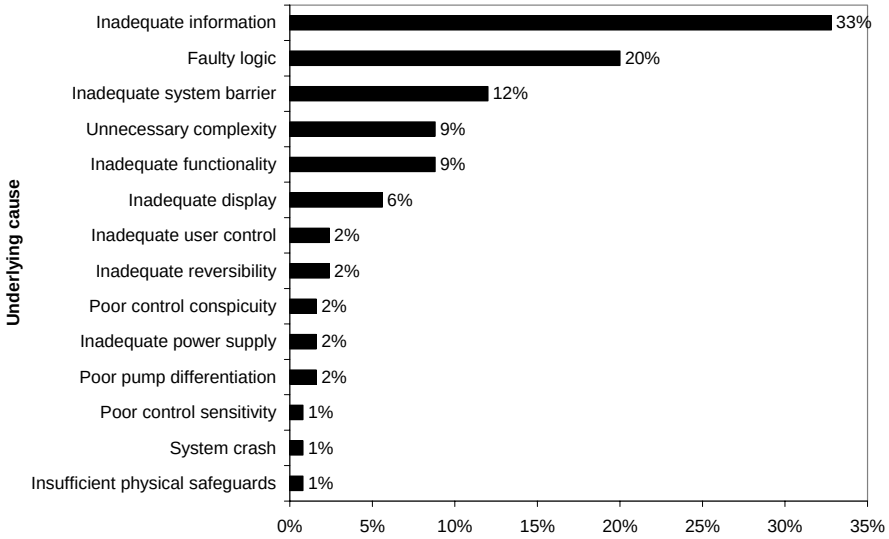

Figure 2. Underlying causes of usability problems

Recommendations

We developed 30 recommendations which we believe would eliminate all the usability problems identified in this study. These recommendations are grouped into five categories (Table 2) and discussed briefly in the following sections.

Table 2. Number of problems addressed by each recommendation category

Information	44
Programming and navigation	36
Hardware	26
System barriers	12
Displays	7

Information

Many of the recommendations for information listed below are simple, yet more than a third of the usability problems identified in our evaluations would be eliminated by improvements to the clarity, presentation and timing of information. Navigation problems in particular could be reduced if information were given at the right time. Good feedback can be the difference between a successful system and one that frustrates and confuses (Norman, 2007).

The data logs recorded by smart pumps (see System Barriers) are a new type of information that can be used to identify whether, where and when infusions are programmed outside drug library limits, drawing attention to problems with the way pumps are used, such as mismatches between drug libraries and current practice. Clinical advisories are another feature of smart pumps that can be used to give staff helpful drug-specific information at the right time.

The recommendations are listed below:

1. Instructions and information should be intelligible
2. Instructions should be kept with pumps
3. Important information (including alerts and alarms) should be provided when needed, to guide and prompt the user
4. Icons and symbols should be self-explanatory and follow established conventions
5. Feedback (including error messages) should be unambiguous
6. Non-essential information should be hidden so it is not a distraction
7. Appropriate terminology should be used (avoid jargon and proprietary terms)
8. Information types (e.g. normal and error) should be clearly differentiated

Programming and navigation

Modern pumps have many more options and functions than early pumps, which is perhaps why so many pumps have dual-function buttons. Dual-function buttons, faulty logic and poor mapping can make navigation difficult for users, who get lost in the navigation, not knowing where to go next, what options are available, or how to get back to where they were.

The programming and navigation recommendations are listed below:

1. Dual-function buttons should be used sensibly (e.g. having the same button for changing modes *and* silencing alarms creates confusion)
2. Navigation should be safe (i.e. appropriate default values should be set), logical and match user expectations/mental model (confirmed through usability testing)
3. The system should allow users to undo steps and navigate back – for example, to make changes to programming values before starting the infusion
4. Unnecessary complexity should be avoided
5. The pump should be easy to learn to use in a single training session

Hardware

Basic pump performance – the ability to deliver infusions reliably and accurately – has more or less stabilised (ECRI, 2007) in recent years, but faulty, unreliable pumps still cause problems (NPSA, 2008). Rigorous pre-market testing, particularly of innovative features, is essential.

If the loading of medication or solutions were intuitive, errors would be unlikely. Line loading could be improved by better use of physical and logical constraints – i.e. it should be obvious which way the tubing is loaded. More importantly, pumps should fail safe when errors occur, so patients are not at risk.

The seven hardware recommendations are listed below:

1. Components should be robust and resist damage from knocks or heavy use
2. Known faults and deficiencies should be fixed (through product development)
3. Line-loading should be intuitive and fail-safe
4. Pumps should have a good battery life and provide clear warnings when battery is low
5. Controls should be obvious, support natural mapping and be labelled appropriately
6. It should be easy to tell the difference between pumps, such as syringe drivers which deliver over 24 hours and syringe drivers that deliver over an hour
7. Controls should respond as expected

System barriers

Some pumps sold in the UK are also sold to other markets, where clinical practices can be very different. Preventing access to non-UK configurations on UK pumps would reduce the opportunity for error.

So-called ‘smart’ pumps are those with dose error-reduction software (DERS), comprising drug libraries and built-in dose limits to reduce programming errors. Bar-coding of medication, pumps and potentially staff and patients is another method that could eliminate calculation and programming errors at the bedside. As already mentioned, the majority of usability problems occur during pump set-up. In helping to eliminate errors at this stage, features such as DERS and bar-coding could reduce pump-related errors considerably.

The full list of recommendations is reproduced below:

1. Non-configurable barriers should be designed to prevent unsafe acts
2. Options available after set-up should be restricted (e.g. it should not be possible to change the name of the drug after the infusion has started)
3. Configurability should be restricted to the intended market
4. Bar-coding technology could reduce errors made when calculating the dose
5. Dose error-reduction software could reduce the risk and difficulties of infusion set-up

Displays

Following the standard graphic design rules, listed below, would have prevented seven usability problems.

1. Appropriate colour coding and other visual cues should be used
2. Displays should be of an adequate size to present information clearly
3. Displays should not be cluttered
4. Displays should not make reading of decimal points difficult or susceptible to error
5. Displays should display basic pump settings and information, even during an alarm

Summary and conclusion

By aggregating and analysing data from the heuristic evaluations of ten infusion pumps, a range of usability problems and their underlying causes have been identified. The most likely stage of pump operation that these problems occur (set-up) and the most likely effect of the problem (increased risk of error) have also been identified.

The results have been used to derive a set of 30 recommendations, many of which are simple but all of which underline common weaknesses in infusion pump design.

Whilst we acknowledge that many manufacturers make considerable effort to improve the usability of their devices, we also know that there is room for improvement, especially as pumps become more sophisticated. We therefore encourage all manufacturers to heed these simple recommendations to improve the performance, reliability and usability of their infusion pumps.

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