SAFER DRUG DELIVERY: IMPROVING THE DESIGN OF INFUSION DEVICES

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Infusion devices are used on a daily basis to pump fluids, medication or nutrients into a patient's circulatory system. Incident data suggests that problems are regularly occurring with them, many are attributable to human error. This work-in-progress paper chronicles on-going research involved in discovering the root causes of the errors. Causal analysis will help to create design guidelines for infusion devices, which will use design to preemptively prevent errors. The work has been commissioned by the National Patient Safety Agency (NPSA) as part of its design for safety programme, and the envisaged publication will sit alongside design guidance previously written for the packaging of oral and injectable medicines.

Background

Over 15 million infusions are administered to patients in NHS hospitals each year. Incident data suggests that problems are regularly occurring with them, many of which are attributable to human error. From 1990 to 2000, there were 1495 reports of unsafe incidents involving infusion devices (MDA, 2003). At least one quarter of these are attributed to user error, and in the majority of incidents involving fatalities, no fault was found with the devices. This implicates user error as the leading immediate cause and poor design as the likely root cause.

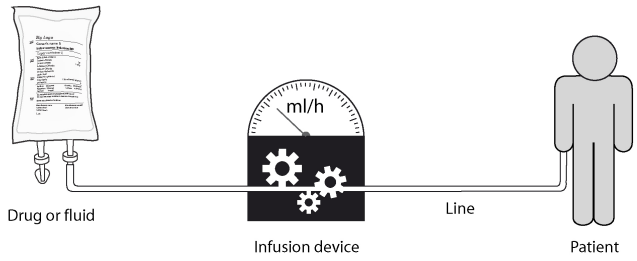

Figure 1. The complete infusion system

An infusion device is just one component of the infusion system, as shown in Figure 1. The device does not come into direct contact with the fluid. Instead it pushes it along by interacting with the giving set (line) or the syringe. For the patient to receive the correct treatment, the hospital staff must choose the correct drug/fluid with the applicable infusion device, use the corresponding giving set, and deliver into the correct site in the patient.

The term 'infusion device' covers a number of different types of pump, each of which has its own individual operating mode that must be learnt. They fall into six general categories as displayed in the table below. Pumps may also be classified according to the level of pumping accuracy that they provide.

The complexity of these devices, combined with the lack of standardisation across devices appears to be contributing to the large number of incidents, while unintuitive interfaces can only compound the problem. Current regulations seek to standardise pumps to a minimum level of functionality and neglect to consider necessary usability requirements.

Table 1. Different types of infusion devices

Pump	Use
Volumetric pump	For large volumes, at higher flow-rates
Syringe pump	For smaller volumes (<50ml) at lower flow-rates
Patient Controlled Analgesia (PCA)	For patients to administer their own pain relief
Ambulatory pumps	For more mobile patients, who may be outpatients
Epidural pumps	For use with epidural and spinal medicines
Non-electrical devices	For use with less time critical drugs, generally with outpatients. Tend to be disposable.

Research methods

Whilst this research aims to create design guidelines and contribute to standards for infusion devices, it is important to build upon existing research in this area. A literature review was therefore one of the first steps to be carried out, accessing existing expertise within the NPSA.

Many papers were found relating to specific incidents with pumps, but very little of the literature seemed to acknowledge design as a contributing factor. There were however recommendations relating to systemic solutions, such as internal equipment management and staff training.

The Bath Institute of Medical Engineering (BIME) performs pump evaluations for the Medicines and Healthcare product Regulatory Agency (MHRA), and has published numerous reports on the functionality and usability of pumps. These reports proved to be a useful source of information and helped to achieve a holistic view of the errors.

Figure 2. User demonstration of syringe pump

Interviews were held with users from a variety of backgrounds, including nurses, anaesthetists and procurement personnel. It was particularly important to talk to people from differing specialties and wards, as there are a wide variety of pump designs and this leads to a variety of experiences. For example, a paediatrics nurse will working with different pumps in different situations compared to a midwife. Personal experiences and preferences were captured through interviews, along with a discussion of key issues and problems. A variety of interview techniques were employed, some within more formal settings, whilst others were more relaxed. A number of the interviews were recorded, as were any demonstrations with pumps (see Figure 2).

An ideal pump kit was developed in order to aid communication with the users. With this, users could decide upon the dimensions of the pump, the size, type and position of the display screen, what information should be displayed where, and the labeling and location of buttons.

Additional time was spent on the wards observing staff at work and video ethnography techniques were used to help analyse actions afterwards. This enabled comparisons between what people say they do and what they actually do. It also facilitated task analyses to pinpoint problem actions, situations and interactions with device and patient.

Infusion device manufacturers were also consulted throughout the research process in order to enable better understanding of industry issues, manufacturing and technological constraints and any other opportunities. It is key to get the manufacturers on board with the project, as the guidelines are to be implemented on a voluntary basis. As well as working with individual manufacturers however, it is also necessary to achieve consensus amongst the manufacturers on certain issues, for example, on standardising symbols. Contact was made with the European EuCoMed Special Interest Group for Infusion Pump Manufacturers, in order to concurrently develop these ideas.

Additional time was spent exploring existing non-medical consumer devices and their interfaces. This helped to gain an insight into what people prefer, what sells well, and what people expect from their products in terms of interface design and feedback.

Research Goals

The research findings are now being honed into a series of design recommendations under the three key focus areas of hardware, software and peripherals. It is the intention

to present the full findings of this research at the conference in July 2008, by which time the recommendations will be illustrated in a near final draft of the guidelines. This will eventually be published as part of the NPSA's Design for Patient Safety series and distributed to all infusion device manufacturers.

Work in Progress

Design has long been overlooked by the medical industry, and this was reflected in the literature search, which yielded very little relating to device design. Whilst the manufacture of infusion devices is a maturing industry, it has yet to reach the convergence in usability that items such as cars have attained. Consequently huge variability in products is accepted and expected, with very little work exploring the relationship between different products, usability and error incidence.

Meetings with manufacturers sought to explore reasons for product direction and development. Whilst promoting standardisation it is important to understand supply-side factors and manufacturer motivations, and allow for brand distinction.

Research issues

Interview techniques were varied over the course of the research in a deliberate attempt to understand the nature of user interviews, and explore alternative ways of achieving results. Users were found to be more inclined to relax and open up in an informal chat setting, particularly when spoken to whilst on the move or working. Attempts to have a formal interview were not well received and users were noticeably more constrained and less relaxed in these settings. This may have also been due to the concerns staff being away from their patients.

Issues were also encountered in how to communicate ideas effectively to users. The interviewees struggled to envisage alternative ways of interacting with infusion devices, particularly if they had only experienced one particular device. The 'ideal pump kit' was developed in order to navigate around this hurdle. It helped users to disengage from medical constraints and consider alternative scenarios. Exploring the possibilities also enabled a realisation of the difficulties experienced with existing devices.

Design issues

In order to successfully improve any kind of medical device, the product needs to be considered in context, in the environment within which it normally functions. Such consideration encompasses how it will be purchased, stored, maintained, as well as who uses it when, how and for what purpose. The users of infusion devices will have widely different skill sets, with differences in their aptitudes and attitudes towards the devices. They will also be affected by how often they encounter the devices in their work routines, which in turn will lead them to have different expectations.

It emerged that the 'ideal pump kit' (see Figure 3) was an excellent way to learn about these differences. By allowing each type of user to configure their own pump, they could highlight the factors that affected their own particular use and allow insight into the requirements of their speciality discipline. For example, when infusing medicines in paediatrics, the total volume of fluid to be administered is dependent upon the patient's weight. This led a paediatrics nurse to choose to emphasise the 'total volume to be infused' for her main screen, rather than the flow rate, in order to ensure the volume had been calculated correctly.

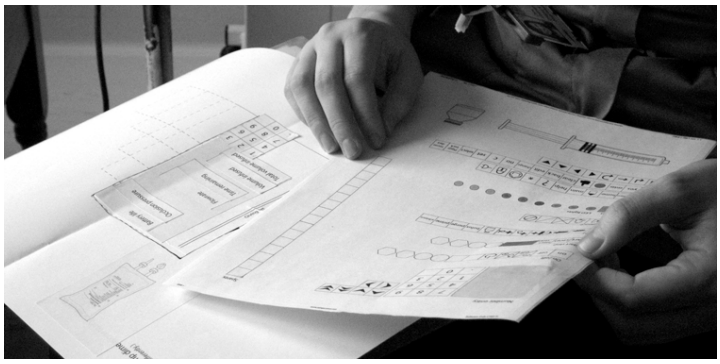

Figure 3. Using the ideal pump kit

Discussion

Infusion devices currently have the second highest level of error incidence of all medical devices. Many reports discuss the importance of staff training in how to use infusion devices, yet currently, this training is necessarily device specific due to the inherent differences between devices. There is a need for a degree of standardisation, which would minimise these differences and allow training to occur at a more generic level.

This move towards standardisation must also be reflected in the product software. Programmers need to have more realistic expectations of user abilities, as current assumptions are leading to confusing technical interfaces that cause great difficulty. Software should not be developed in isolation, but through interaction with users and observations of how the pumps are used in practice.

Devices also need to be flexible enough to accommodate users of all abilities and backgrounds. The increasing complexity of modern devices comes at the cost of usability and it is easier to forget the skills required for operating more complicated devices, particularly for infrequent users. Pumps need to be straightforward, with simple interfaces that guide users through the programming process and enable more skillful device management.

Whilst a well designed pump is based on an understanding of the users' needs, it is just as important for the user to have an appreciation of the pump. Thus the user should always undergo adequate training and follow the correct infusion procedure, in order to maintain levels of patient safety. As shown in Figure 1, an infusion device is just one part of the infusion system, and the importance of getting the other components correct should not be overlooked. These factors in combination provide a systems-level challenge to be addressed.

As with previous design guidelines issued by the NPSA, a revision and second stage to the work is expected post distribution. This will help to ensure maximum industry take up, an important goal if the guidelines are to achieve their objectives.

References

MDA Device Bulletin: Infusion Systems, March 2003, MDA DB2003(02) Accessed 01/03/08
www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON007321