IMPROVING PATIENT SAFETY THROUGH DEVICE DESIGN AND USABILITY

Tony Rose¹, Catriona Blake², Beverley Norris³, Colum Lowe³

System Concepts Ltd¹, Medicines and Healthcare products Regulatory Agency², National Patient Safety Agency³

The promotion of patient safety by reducing error is a key priority for major health services around the world. One way of reducing the number of patient safety incidents is by eliminating errors in the programming and usage of medical devices. This paper describes a project to support the procurement of medical devices by ensuring that device ergonomics and usability are considered as key criteria in the purchasing process. It is based on an analysis of 392 device-related events reported to the NPSA via its National Reporting and Learning System (NRLS) during 2005. This paper reviews that data, describes the analysis and presents some of the overall themes to emerge.

Introduction

The promotion of patient safety by reducing error is a key priority for major health services around the world. It is estimated that in the UK alone, some 850,000 patient safety incidents occur annually in the NHS, representing around 10% of admissions. These adverse events cost approximately £2 billion a year in additional hospital stays. In particular, it is estimated that 400 people die or are seriously injured in adverse events involving medical devices every year (Department of Health (DH), 2001).

The National Patient Safety Agency (NPSA) was established in July 2001 to improve patient safety in the UK by reducing the risk of harm through error. It does this by collecting and analysing information on patient safety incidents, aggregating this with other safety-related information, and developing solutions to ensure that the lessons learnt are fed back into practice, service organisation and delivery.

One way of reducing the number of patient safety incidents is by eliminating errors in the programming and usage of medical devices (Sawyer, 1996). In this respect, the NPSA shares some of the goals of the MHRA (Medicines and Healthcare products Regulatory Agency), which is the UK government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. According to MHRA figures (2006), as many as 12% of the device-related incidents reported to them in 2005 could be attributed to ‘use errors’ (i.e. errors in the usage of a particular device). The question therefore arises: how many of these errors could have been avoided if the devices had been designed for usability at the outset? And following on from this, how can we influence the procurement processes within the NHS to ensure that device usability is seen as a key purchasing criterion? Likewise, how can we engage with the healthcare industry to influence the design & testing of medical devices?

This paper describes a project to support the procurement of medical devices by ensuring that device ergonomics and usability are considered as key criteria in the purchasing process.
This guidance will be made available in the form of a checklist of design features to consider and usability questions to ask when purchasing medical devices (e.g. Zhang et al, 2005, Wiklund, 1995). It is hoped that the checklist will also be augmented by a supporting booklet to illustrate the various points, with case studies and examples of good and bad design.

An initial draft of the checklist has already been developed, based on an analysis of 392 device-related events reported to the NPSA via its National Reporting and Learning System (NRLS) during 2005. These events include nine incidents of severe injury and 17 of moderate injury. This paper reviews that data, describes the analysis and presents some of the overall themes to emerge.

Data Collection

The NPSA collects information on patient safety incidents through its national reporting system (NRLS), the first such national system of its kind in the world, and currently receives around 50,000 reports per month from NHS organisations across England and Wales. These incidents are reported by NHS staff members through a variety of routes, including local risk management systems and web based e-forms (including an open access e-form). The individual reports are anonymised and treated as confidential, and are not investigated or verified by the NPSA. An extract from an incident report, involving the incorrect programming of a laser is shown below:

“Laser power set too high (1000mW instead of 100mW) for the required retinal photocoagulation treatment required. This error arose out of laser having being used by a previous operator at much higher power than is usual. Power settings remained in laser software memory from previous treatment despite shutting down the system. Patient received retinal burn at 1000mW of argon green”

Searching the NRLS

The NRLS database was searched for incidents involving medical devices (excluding imaging devices) within the time period from 1/5/2005 to 1/5/2006. This search “(monitor, pressure, dialysis, incubator, laser, infusion, thermometer, ventilator, driver) AND (design, interface, key, button, switch, default, menu, display)” returned a total of 459 incidents, of which 61 did not meet the selection criteria (i.e. were duplicates or the device was not involved in the incident), which left 398 incidents for further analysis. These were inspected and iteratively clustered to reveal a number of recurrent themes, which are summarised in Table 1. The vast majority (96%) of these incidents occurred in acute hospital settings, and most involved either the failure of the device or some sort of error in use.

Results and Discussion

Table 1 shows twelve major themes that emerge from the incident data, ranked according to the number of incidents. Clearly, the most common theme is the failure of the device mid-procedure. However, a significant number of incidents (29) are also attributable to incorrect programming of the device (see Checklist points 1-7, 11-17). Infusion pumps account for the majority of these types of incident, with 19 incidents out of the 29. The commonest type of failure was using the wrong rate – either using the last setting (e.g. wrong bolus (a rapid short infusion above base infusion rate), volume to be infused not set) or using the wrong units (e.g.
mg/hr, ml/hr, μg/ml, etc.). In addition, some of the failures appear to be not setting the full range of parameters (such as alarm levels), or muting alarms in error.

### Table 1. Predominant themes in the incident data

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of Incidents (%)</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Failure of device mid-procedure with alarm</td>
<td>81 (20%)</td>
<td>Anaesthetic machine failed and alarmed.</td>
</tr>
<tr>
<td>2 Machine not switched on</td>
<td>45 (11%)</td>
<td>Air pressure relief mattress was not switched on.</td>
</tr>
<tr>
<td>3 Failure of device mid-procedure possibly without alarm</td>
<td>31 (8%)</td>
<td>Includes 16 reports of no alarm. Mostly anaesthetic machines.</td>
</tr>
<tr>
<td>4 Wrong programming</td>
<td>29 (7%)</td>
<td>E.g. mode selection problems, wrong units, parameters not set-up properly. Mostly infusion devices.</td>
</tr>
<tr>
<td>5 Use error</td>
<td>20 (5%)</td>
<td>14 errors such as not switched device off, e.g. epidural infusion was ordered off but it was found running sometime later.</td>
</tr>
<tr>
<td>6 Machine switched itself off</td>
<td>19 (5%)</td>
<td>19 incidents where the machine switched itself off, apparently without an alarm.</td>
</tr>
<tr>
<td>7 Display failures</td>
<td>19 (5%)</td>
<td>15 incidents where display failed and 4 display freezes. Mostly anaesthetic machines.</td>
</tr>
<tr>
<td>8 Batteries</td>
<td>19 (5%)</td>
<td>Failed unexpectedly, including 4 in transport; 15 failures where unclear if alarmed; 2 reports of failure and no alarm</td>
</tr>
<tr>
<td>9 Patient tampering</td>
<td>10 (3%)</td>
<td>Infusion pumps only.</td>
</tr>
<tr>
<td>10 Medical gases not switched on or misconnected</td>
<td>10 (3%)</td>
<td>5 examples where gas lines had not been connected properly. 5 examples where the gas had not been switched on.</td>
</tr>
<tr>
<td>11 Could not access controls due to tamper cover</td>
<td>9 (2%)</td>
<td>9 incidents where user didn’t appear to realize purpose of cover and did not have key. Infusion pumps only.</td>
</tr>
<tr>
<td>12 Under-infusion</td>
<td>14 (4%)</td>
<td>Likely that many of these incidents relate to upstream occlusions not being recognized by alarms (if fitted) or by staff. Infusion pumps only.</td>
</tr>
</tbody>
</table>

Interestingly, a large number of incidents (81) relate to the device simply not being switched on. This may occur if the user is distracted during the task of setting up the device and forgets to finish it, or the “on” button has not registered despite being pressed (particularly for devices that provide no positive feedback at the interface). Such devices may need to be redesigned to provide more obvious signs that they are switched on, or to trigger an alarm if they have been programmed but are not delivering, or simply to provide some sort of feedback when a button is pressed. This issue may need to be highlighted to both users and manufacturers.

A similar number of incidents relate to the device not being switched off at the correct
time. For example, an epidural infusion was ordered off as the patient developed low blood pressure. However, when the patient was checked some time later it was found that the infusion was still running. The user should always check that the machine responds as expected. In addition a roller clamp on the administration set should always be used when an infusion is stopped. Also, the use of feedback on the controls would also help prevent these issues.

Failures of the device (possibly with no alarm) account for 31 (8%) of the incidents. In such cases it is possible that this can go unnoticed for several hours. Such incidents could be the result of healthcare professionals not actually hearing the alarm for example for a low battery, particularly if the alarm volume had been set too low (and users are often unaware of this facility or indeed how to reset it (Sobieraj et al, 2006)). Alternatively, this may occur if someone unauthorised switches the device off to stop the alarm (there is evidence that patients may tamper with their devices and that professionals are often unaware of basic lock-out features [usability checklist point 18]). Possible solutions to this type of incident are to ensure that (a) the batteries well maintained and mains power is used appropriately, (b) alarms are set at the suitable volume, (c) the devices are connected to a central monitoring station and regularly checked and (d) patients are told why they should not touch the device and lockout features are used appropriately. These themes on alarms directly fed into the usability checklist points 8-10.

The themes in Table 1 also reveal the importance of training. Users want flexibility in a device and a wide range of functions. However, this results in more complex devices that need some level of training and understanding before they can be used safely. In many safety-critical industries, such as aerospace, this entails periods of training before a device is used and ongoing training while it is in use. Conversely, many healthcare professionals are expected to use life-supporting devices with little of no training on the generic functions or the specific device. The incidents found in this search reveal the need for training on devices as well as improvements in their design.

There are many standards covering medical devices including a usability standard for electrical medical devices. This tries to ensure that there are minimum safety standards across the industry. However, standards are rarely design restrictive but provide a framework to design appropriate devices. Many of the themes found could be passed to the relevant standard committees for their consideration and to inform revisions of the standards.

Summary: A Usability Checklist for Medical Devices

**Display**

1. Is the display clear and uncluttered? For example:
   - Are the numbers and text easy to read? Are decimal points easy to see?
   - Are units easy to read and consistent? Are all relevant fields easy to see, for example the bolus setting for infusion pumps?
2. Is the display easy to read in all light levels and angles? Is there an anti-glare feature, and can contrast/brightness be adjusted? Are colours easy to see?
3. Are labels/icons easy to read and interpret?
4. Is the information grouped meaningfully?
5. Are warnings/indicator lights/system states easy to read and interpret? For example, is it clear when the device is running or on standby? Is the battery/mains status clear?
6. Are error messages easy to read and interpret?
7. Are the keys easy to use (consider sensory feedback, likelihood of hitting wrong key, selecting incorrect parameter, presence of clear labels)?

Alarms
8. Are alarms meaningful and easy to interpret, especially considering the context of use (for example sounds, lights)? Are they noticeable in the environment in which they will be used?
9. Are alarm settings and their current status clear and apparent or muted?
10. Can alarm settings be altered?

Programming
11. Is the navigation logical? Does the software lead you through the process (some devices can prompt users to guide them through complex procedures)? Can it deal appropriately with inconsistent/erroneous input?
12. Is the help function obvious to use and useful in aiding the user?
13. When entering or updating fields, is there feedback to indicate which values have changed?
14. Is there informative feedback on actions and is it clear when the end of a procedure is reached?
15. Is it easy to recover from errors (or go back steps in a process)?
16. Does the device deal appropriately with a power failure?
17. How are the default settings changed or saved? Do certain safety critical parameters always have to be manually entered? What happens on reboot?

Security
18. Is the key lock (if applicable) effective to use?

General
19. Can/how does it interface with a local network? For example, is there a central monitoring station? Electronic patient record keeping? Does it need this facility?
20. What previous user errors have been associated with this type of device? Local incident data can be used to identify common user errors for this type of device and determine if a particular design addresses any of these issues.
21. Is the data storage and history suitable for your purpose?

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