Employing Usability Heuristics to Examine the Issue of Guidewire Retention after Surgery

Tim Horberry1,2*, Yi-Chun Teng1, James Ward1, and P. John Clarkson1

1 Engineering Design Centre, Department of Engineering, University of Cambridge, UK
2 SMI-MISHC, University of Queensland, Brisbane, Australia

Abstract

Background: Central Venous Catheterisation (CVC) is a medical procedure that has been linked with cases of retained guidewires in a patient after surgery. Whilst this is theoretically a completely avoidable complication, a guidewire of up to 60cm being retained in a patient’s vascular system poses a major risk. In recently reported cases, guidewires retained inside patients have not been detected for several years. Aims: The ultimate aim was to develop appropriate, operator-centred safe design solutions that reduce guidewire retention errors. Method: This paper focuses specifically on the application of Nielsen’s ten usability heuristics [1] to the issue of retained guidewires. Following the development of a task analysis of the procedure, three researchers (from medical, safety and human factors backgrounds) independently applied the usability heuristics, then met to analyse the findings. Results: A range of usability problems were identified in the Central Venous Catheterisation procedure, and solutions to the identified issues were then proposed: these focused on the design of equipment, or the wider guidewire insertion procedure. The paper details the identified usability problems and possible redesign solutions from the 10 usability heuristics. Conclusion: Overall, the application of the usability heuristics was found to be a useful method both to explore medical device interface problems and to generate possible countermeasures. Further work to eliminate/engineer out the possibility of guidewires being retained is briefly reported.

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Background

Central Venous Catheterisation (CVC) is a medical procedure involving the insertion of a catheter (a small tube) into a patient’s vein. To help insert the catheter, a guidewire is used. The CVC procedure consists of the following steps [2]:

- a hollow needle (called a trocar) pierces the skin to gain access to the target vein;
- a guidewire then passes through the needle to enter the vessel and the needle is withdrawn;
- the path to the vein is then enlarged by passing a dilator over the guidewire and into the vessel such that it facilitates the subsequent catheter entry;
- the dilator is removed, and the catheter is inserted into the vein; and
- once the catheter gains venous entry, the guidewire is withdrawn and the catheter secured against the skin.

A guidewire, a catheter and a guidewire inside a catheter are shown in Figure 1.

This method which employs the ‘Seldinger technique’ (named after its creator), is now the most common method of CVC [3]. Before this, catheterisation was often undertaken by directly piercing the vessel with a large needle, but the size of this needle carried significant risks, such as punctures [2].

Despite this improvement, using the Seldinger technique can lead to complications, not least of which is the inadvertent loss of a guidewire. Occasionally it can be pushed too far

Figure 1: Example of catheter and guidewire: a) guidewire (with pen for scale), b) catheter, and c) guidewire inside catheter.

Corresponding author: Tim Horberry. Email – t.horberry@uq.edu.au
into the vein, and subsequently retained within the patient’s body, without immediate detection [3]. In theory guidewire loss is a completely avoidable situation provided the operator holds onto it at all times; however, a recent study estimated the guidewire loss to be 1 in less than 4,000 procedures [4]. Given the high number of guidewires inserted worldwide (e.g. 200,000 per annum in the United Kingdom (UK) alone [5]) this can be a significant issue.

On-going efforts are being made worldwide to reduce the incidence of retained guidewires [3]. But, given that guidewire retention errors occur in a complex medical environment (that is, often subject to time pressure, distraction, stress and fatigue), then incorporating a human factors and ergonomics (HFE) perspective may be beneficial to improve patient safety. This overall research aimed to address the issue from a HFE perspective to examine the guidewire-related interactions within this complex sociotechnical medical system. The ultimate aim was to develop appropriate, operator-centred safe design solutions that may reduce guidewire retention errors. Within this overall research program, a range of user-centred methods were used (e.g. interviews, observations, task analyses) but this paper focuses specifically on one HFE method: the application of Nielsen’s ten usability heuristics to the issue of retained guidewires.

Methods

Usability Heuristics

Usability problems in the interface of a work system can be explored by inspecting whether the interface adheres to well-established usability principles, in other words heuristics [1]. In the medical domain, employing usability heuristics to evaluate the safety of medical devices was first undertaken by Zhang and colleagues in 2003 [6] and since then have been successfully applied to other medical processes, such as telemedicine usability [7] and radiotherapy systems [8].

More recently, in Australia, they have been used to evaluate and improve observation chart design to help the detection of patient deterioration [9]. For Zhang et al [6], usability heuristics are one of the most cost-effective methods of finding usability problems. Identifying usability issues can help detect ‘trouble spots’ that are likely to cause medical errors [6]. Similarly, others have argued that heuristic evaluation can identify the most serious problems with the least amount of research effort [7]. Usability heuristics can be used to assess conceptual designs, prototypes or completely implemented designs/systems in a broad range of clinical contexts [6-9]. Indeed, Chan et al [8] noted that they can be used with existing systems to help improve training, modify procedures and to systematically report usability issues back to manufacturers.

In this current research Nielsen’s ‘Ten Usability Heuristics’ [1] was applied to the interaction between the physician and the central line kit. It should be noted that other usability heuristics exist: a review of the use of heuristics in medical research by Tang et al [7] found that approximately half the studies used Nielsen’s original ten heuristic whereas the remainder employed a modified version. Therefore, no single set of usability heuristics exists that is suitable for all clinical contexts, and a recent Australian study by Preece et al [9] developed their own set by combining existing heuristics with their own ones derived from task analysis and general clinical experience. Additionally, many previous studies note that deploying usability heuristics is unlikely to identify all the usability problems that exist, and that combining usability heuristics with other methods, such as interviews, observations and task analyses, is often the most effective approach [6-9]. Despite these acknowledged limitations, the current research employed the original set of usability heuristics from Nielsen [1] and then compared the findings to other methods, such as end-user interviews.

Unlike human reliability techniques, such as the Human Error Assessment and Reduction Technique (HEART), the application of usability heuristics does not give quantitative data on the assessed probability of failure [3]. But they do help highlight usability/user-interface issues with CVC from which potential redesign solutions can then be proposed. In the case of guidewire retention, although the relative rates of errors are reasonably low (perhaps 1 in 4,000 procedures, as noted above), due to the high number of medical procedures that use guidewires, the absolute number of guidewires being retained is a significant issue. Therefore, although guidewires have been in use for a long period of time, new methods to identify potential redesign solutions to improve the overall procedure is still of key importance.

Procedure

Using an overall procedure for usability heuristics that had previously been used by other researchers in the medical domain [6-9], the research employed three independent assessors. The assessor team comprised a human factors specialist, a medical safety specialist, and a 3rd year medical student. All of these three assessors first obtained familiarity with guidewire insertion by means of interacting with a CVC kit, watching a live demonstration from a medical expert, interviewing other subject matter experts about the process at a UK hospital trust, constructing a draft task analysis of the process, examining CVC written procedures and reading the literature. Thereafter, in a small workshop setting the three assessors discussed in general terms the application of the ten usability heuristics. Following this, each assessor then independently completed their assessments of the usability problems with the guidewire procedure. Finally, in a subsequent small workshop the three assessors compared their findings, resolved any assessment differences and brainstormed potential solutions to the identified issues.

Ethics approval for the research was obtained from the University of Cambridge, UK.

Results

Table 1 outlines Nielsen’s ten principles, the guidewire-related usability problems found and the re-design solutions proposed for the identified issues.

Discussion and conclusions

Similar to the findings of other medical researchers [6-8], our work has found that employing usability heuristics can help pinpoint issues and lead to possible solutions regarding the issue of guidewires being retained. Previous research
Usability problems
The design of the catheter kit provides little cue about the system status, and the visibility is especially poor at certain points with respect to the guidewire. The nature of the procedure means that the risk of retaining the guidewire is the highest when the catheter is inserted over the wire and excludes its visibility. There are no auditory, tactile or visual warnings in place to alert the user should the guidewire be inserted so far that it risks losing visibility within the catheter. Added to this problem is the lack of universal, standardised distance markers on all guidewires. And even when the markers exist, they commonly consist of non-conspicuous colours. Consequently, if the wire is about to be or has been inserted too far, the absence of extra warnings and designs to alert the operator means that there are no other indications about system status beyond the position of the guidewire itself.

Potential Solutions
Have standardised, universal distance marking on guidewire to inform user the status of the wire with respect to the length of wire left outside the patient. Let the marker be more conspicuous by, for example:
- Having bright markings whose colours contrast with that of the guidewire.
- Introducing different tactile consistency to the distance markers.

2. Match between system and the real world:
The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.

Usability problems
N/A to this usage context.

Potential solutions
N/A

3. User control and freedom:
Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.

Usability problems
There is no "emergency exit" to allow undoing or redoing of the insertion once the guidewire is lost intravascularly. There is also a lack of "forcing functions" (e.g. loop at the external end of the guidewire) to constrain user behaviour.

Potential solutions
Implementing a highly visible distance marker can remind users that the guidewire needs to be retracted from the vein when it is at risk of disappearing into the patient. Likewise, the distance markers already present on some kits can serve similar reminders. An example is when more than 20cm is inserted, the labels should automatically remind user to withdraw guidewire to a safe distance. However, this demands the user to be highly vigilant at all times.

4. Consistency and standards:
Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.

Usability problems
Several central line kits from various manufacturers are in use within the same hospital trust, each with different guidewire types and lengths. Although the catheter kits may all meet British/ISO Standards, there are no explicit requirements for guidewire lengths for use with differently sized catheters, and this may lead to a lack of consistency. One other key issue is that not all guidewires have distance markers and this inconsistency may raise the risk of retained guidewires for the kits without these markers.

Potential solutions
First, establish a clear standard for guidewires specifically. Once this is done, only purchase catheter kits whose guidewires meet the criteria. The criteria could include for guidewires to have clearly visible distance markings. The length of guidewire should allow enough guidewire to be left outside the patient after it gains venous access such that the external portion of the wire is always longer than the catheter. This can minimise the risk of guidewire disappearing within the catheter.

5. Error prevention:
Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.

Usability problems
There are few controls to prevent the incident besides relying on a complete lack of human error by the end-user. Although distance markings are on some wires, they depend on the user remembering at all times that the wire cannot be inserted too far such that it disappears when the catheter is placed over it. The system currently fails to ensure that a certain length of guidewire always remains external to the patient such that the catheter is shorter than the part of wire outside at all times during its insertion. Thus, the design does not intrinsically prevent errors, but rather depends on the user to avoid making mistake. Unfortunately, it is easy to accidentally insert the guidewire completely into the patient especially when distractions are present.

Potential solutions
One previously proposed idea is to reduce the number of unnecessary central line placement in the first place which would naturally decrease the number of retained guidewires [10]. This does not address the rate of the error with respect to the number of procedure performed, but it can potentially decrease the overall incidence over time. Having a highly visible marker / kink in the middle of the guidewire could remind/prevent a user from inserting guidewire too far in.
6. Recognition rather than recall:
Minimize the user’s memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.

**Usability problems**
This can be an issue regarding the order in which the devices are used during CVC insertion. Note also that at present there is almost nothing in the system to allow end-users to recognise that a guidewire has been retained, but rather depends on the user to recall that the guidewire was not removed.

**Potential solutions**
Having a highly visible marker / kink in the middle of the guidewire can remind/prevent user from inserting guidewire too far in.
Set up check sheets for the operator to certify that they have removed it or actively monitor the medical waste tray to ensure the wire is present as partial measures to aid recognition.

7. Flexibility and efficiency of use:
Acceleration - unseen by the novice user - may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.

**Usability problems**
N/A to this usage context.

**Potential solutions**
N/A

8. Aesthetic and minimalist design:
Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

**Usability problems**
Design is seemingly as minimal as possible. In fact, it is probably too minimal in that no design features are present to target reducing the occurrence of wires being retained.

**Potential solutions**
Refer to solutions under other heuristics.

9. Help users recognize, diagnose, and recover from errors:
Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.

**Usability problems**
The procedure is rarely supervised, so the errors are unlikely to be detected by others. The system is not specifically designed to help end-user recognise, detect or recover from retained guidewires. For example, the wire does not give a visual or auditory warning if retained in the body.

**Potential solutions**
Refer to solutions under “1. Visibility of system status”, “3. User control and freedom” and “6. Recognition, rather than recall”.

10. Help and documentation:
Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user’s task, list concrete steps to be carried out, and not be too large.

**Usability problems**
When audited against best practice for procedures (eg the Health and Safety Executive’s 2009 ‘Procedure audit tool’ [11]), the ‘standard’ procedure is not well written. Equally, it is not exactly followed and importantly does not even mention removing the guidewire.

**Potential solutions**
Some departments (eg Intensive Care Units) have a stamp that users have to fill out after the procedure to confirm guidewire removal. In the short term this only facilitates early diagnosis and intervention should the wire be retained. In the long run the regular reminder may make the operator more likely to remember to remove guidewire. Note that this is not a standardised step everywhere.

[6,7,9] recommended employing three or more evaluators to independently apply the heuristics. The work by Chan et al [8] employed two evaluators and found that only 25% of issues were identified by both evaluators. In our work, the three evaluators generally identified the same problems; however, they mainly differed in terms of the solutions they proposed: the medical student often recommended training and administrative controls (such as check sheets for operators to confirm they have removed the guidewire) whereas the medical safety and human factors specialists largely recommended engineering design solutions (such as brightly coloured guidewires or standardising guidewire design further). Perhaps the main point to conclude here is that at least three evaluators should be employed for studies of this type, and that having different backgrounds in the evaluation team is generally beneficial.

Although usability heuristics can help to reveal issues and countermeasures, this does not necessarily reflect realistic issues experienced in operational conditions or effective countermeasures in practice. However, as noted earlier, heuristic evaluation often is most effective when combined with other methods, such as interviews, observations and task analyses. A wider guidewire-related research program (of which the current research is a part) undertaken by Horberry, Teng, Ward, Patil and Clarkson [12] employed eight other methods: observations of the procedure, a literature review, interviewing end-users, task analysis construction, procedural audits, two human reliability assessments (HEART and SHERPA: Systematic Human Error Reduction and Prediction Approach) and a solution survey with end-users. Comparing the findings of these other methods (both in terms of problems found and solutions identified) is slightly
problematic as some of the methods built upon each other: for example, some interviews were conducted before the heuristic evaluation to help the experimenters understand the domain, whereas others were after the evaluation to further expand the identified problems and verify the usefulness of the potential solutions.

Nonetheless, as a general conclusion, the heuristic evaluation findings largely agreed with the results obtained from the other methods, so suggesting some degree of validity by means of converging data sources. As an example, setting up check sheets for operators to certify that they have removed the guidewire or actively monitor the medical waste tray to ensure the wire is present were identified in the heuristic evaluation as well as in both the human reliability analysis and the interviews. Conversely, wider usability issues found in other parts of the research, such as sedating disoriented patients to facilitate smoother catheter insertion, was not identified by the heuristic evaluation [12]. As such, the findings here generally correspond with Zhang et al [6] when they stated that heuristic evaluation can detect 60-75% of medical usability problems. Given the time taken for the heuristic evaluation is often much less than is required for interviews with a representative number of end-users, then the usability heuristic method can be very cost effective.

The results presented here identified several possibilities for reducing the risk of guidewire retention after surgery, though these solutions may not be without risks themselves (for safety or efficiency) and they would require careful design and thorough evaluations with end-users before deployment. Such on-going work is the current focus on the research team in which the viewpoints of the other stakeholders in the CVC system are being actively sought: this includes central line kit manufacturers, procedural and training developers, and hospital guidewire procurement departments.

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