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Eliciting Usage Contexts of Safety-Critical Medical Devices

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ABSTRACT
This position paper outlines our approach to improve the usage choice of suitable devices in different health care environments (contexts). Safety-critical medical devices are presumed to have undergone a thorough (user-centred) design process to optimize the device for the intended purpose, user group and environment. However, in real-life health care scenarios, actual usage may not reflect the original design parameters.

We suggest the identification of further usage contexts for safety-critical medical devices through ethnographic and other studies, to assist better modelling of the challenges of different usage environments. In combination with system and interaction models, these context models can then be used for decision-support in choosing medical devices that are suitable for the intended environment.

Author Keywords
Context and situation; Ethnographic studies; Health care; Safety-critical interactive systems.

ACM Classification Keywords
H.1.2 User/Machine Systems: Human Factors. H5.2. Information Interfaces and Presentation: Theory and Methods. J.3 Life and Medical Sciences.

INTRODUCTION

Today's health care practices typically involve the use of a multitude of devices to support health practitioners in their work. A number of these devices are *safety-critical*. This means that in an event of failure or malfunction of such a device, the patient is at risk of suffering serious injury or even death.

User-centred design aims to optimize usability for both soft- and hardware. Usability defines "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (Bevan, 1995). We note here the required interplay between specified users, goals and context. This paper particularly addresses usage of medical devices in *other than the originally specified contexts*.

Experience of practices in hospitals and other health care environments has shown that many devices intended for use in one environment will eventually be used in a different environment (Beenkens & Stolk, 2010). This means that safety-critical devices may be taken out of their well-defined original context of use, leading potentially to environmental challenges that the original design of the device had not anticipated. Examples include 1) a syringe pump that was designed and acquired for use in palliative care that is now used in a rescue helicopter, or generally, 2) devices for measuring bodily parameters that are designed for indoor use but are now employed outdoors (e.g., in emergency situations or for out-patients).

Example Problem 1: Syringe Pump

Analysing the first example, we find that a switch of usage context of syringe pumps adversely affects a number of interactive design features such as alarm audibility, display visibility, usability of buttons and haptic feedback.

Many syringe pumps use an audio alarm to indicate potentially safety-critical states (e.g., blockages or low volume of remaining fluid). On the palliative ward, the audio alarm can be expected to be easily audible and thus alerts the care staff appropriately. In a rescue helicopter, however, the noise level is much higher, leading to an increased likelihood that the audio alarm indicating a safety-critical state may be missed. Many syringe pumps use small-screen computer displays that are not backlit. In reasonably well-lit environments such as a palliative care ward, this poses no problem. Using the same pump in a helicopter, in which light conditions can vary from extreme glare to low visibility, readability of the display can become challenging. The buttons used on syringe pumps are relatively small but perfectly suitable for indoor use with bare hands or surgical gloves. However, precise use would become difficult when medical staff have to wear protective gear, or when being operated under tumultuous flying conditions. Finally, feedback about button use, changed settings or alarms may also use haptic feedback and vibration. Those are appropriately unobtrusive in a palliative care ward, but would be imperceptible in the vibrating environment of a recue helicopter.

Example Problem 2: Indoor Devices

In the second example, the identified problems are of a more general nature. However, it is easy to see that a display showing the result of the respective measurement of the devices in an indoor environment has to meet less challenging requirements, than when used outdoors. Outdoors, for example, glare from the sun or a twilight shadow can affect the readability of an instrument display designed for hospital setting. Here the problems are

similar to the well-known challenges encountered with mobile phone displays, which are designed to be used outdoors. Furthermore, out-patient use of devices mean that the environment is not necessarily set up for effective use of medical equipment. Further disruptive factors in different environments could be mud, rain or snow in emergency situations. These kinds of factors might cause the device's user to misread a measurement—a small usability problem that might have potentially catastrophic consequences.

In both examples, a system that was safe to use in the environment, which it originally was designed for, became a potential safety hazard when used in a different environment.

SOLUTION APPROACH

Bowen and Reeves have developed techniques that can be used to formally prove the correctness of medical devices. Their approach combines information about a system's features and specifications with information about the expected user interaction with the devices. They have integrated the process of user interaction design into a formal software development process by combined existing methods for formal system specifications with methods for formally modelling user interaction with devices (Bowen & Reeves, 2008, 2013).

Bowen and Hinze have shown, with a simplified real-world example, how these formal techniques can be extended by modelling context information that is stored in an ontology. They described the structure of interactive modal devices whose behaviour is dependent on the mode, or context, of the device. A user's interaction with such devices may vary according to the physical location or environment in which they are situated. They analysed the example of a modal interactive medical syringe pump used in multiple contexts. They used ontologies to describe the environmental context and to reason about the effects of different contexts on the use of such devices (Bowen & Hinze, 2012).

We are currently exploring further options for modelling of usage context of interactive medical devices. Once a robust method for modelling the rich usage context of interactive medical systems is identified, the combined model (consisting of functionality, interaction and context specifications) can be used as foundation for a decision-support application for health care providers. This application will assist them in assessing the suitability of a device for a particular purpose and environment.

To be fully functional, the context model requires sufficient and correct context data describing the different usage environments encountered by health care providers and the impact different environment factors have on the use of devices.

ASSESSMENT OF USAGE CONTEXTS

The remainder of this position paper focuses on the proposed method of assessment of real-life hospital environments. The idea is to capture and analyse data relating to existing practices to determine key factors that impact on the safe usage of medical devices.

Research Questions

As originally described in (Bowen & Hinze, 2012), the goal of context elicitation will be to answer the following questions:

1. Should a particular device ever be used in a particular situation?
2. Is device A or device B a better choice for use in situation S?
3. What additional or different user training or information is required to use device A in situation S?

To answer these questions, we need to identify the situational factors that impact on the safe usage of interactive devices. We suggest analysing both tangible and intangible situational factors:

a) *Tangible factors* include measurable parameters such as light, noise, vibration and others. These factors are typically relatively easy to measure by sensors placed in the usage environment of the device.
b) *Intangible factors* include, but are not limited to, stress levels, positioning of a patient, e.g. lying vs. sitting, available space in the treatment environment, or the requirement for gloves to be worn. Intangible factors are more subjective in their description.

Method

In order to determine the situational factors discussed above, a number of ethnographic studies are planned to be executed. However, planning and set-up of these studies is a complex task that requires detailed planning.

Firstly, to determine the usage contexts of safety-critical medical devices, the buildings, wards, rooms and locations in which devices are commonly used need to be identified. These may be located within the hospital, in its vicinity, or at eternal locations. It is to be expected that a number of different locations are affected, not all of which will be accessible to the researchers.

Depending on the affected locations, suitable ethnographic observation methods need to be identified. We assume that combinations of observational studies and interviews would be suitable. Observational studies will allow us to identify the typical usage of the devices, such as who is selecting devices, and who is operating them for how long and in which situations.

Based on these preparatory steps, we can then identify typical usage scenarios, for which longer-term observations can be executed to identify both tangible and intangible factors influencing the use of a device.

We assume that both observations and interviews will be required due to the inherent limitations in the given environment. Participants might reflect on the impact of situational factors other than those actually experienced while practicing responsible patient care. Such reflections may be more easily obtained through observational studies. However, since we are dealing with health-critical environments, not all operating contexts will be available for observation.

Moreover, practitioners may wish to perform certain actions or report on general good practice but in realistic situations they may react differently to their plans. It is quite likely for them to not be aware of this happening. Thus, these situations can best be identified by observations in addition to interviews.

Hence, a combination of both techniques, observation and interviews, is warranted.

All study proposals will be approved through the University of Waikato Human Research Ethics Committee and the equivalent committee/board for the relevant organization (e.g. the Waikato District Health Board Research Ethics Committee).

With these considerations in mind we developed a first approach to a study design for the assessment of usage environments of safety-critical medical devices.

Study Design

To gain best results and to design most suitable studies, the research will have to be undertaken in a series of studies, each of them geared towards observing the use of selected devices or situations. A first analysis considers four steps.

Step 1: explore locations

This step identifies locations in which selected safety-critical devices are used. Identifying the locations sets the foundation for contacting relevant personnel and obtaining ethical consent.

Step 2: explore usage scenarios

This step identifies and explores typical scenarios of device use, including people involved and activities performed. This will give insight into high-level activities (usage scenarios).

Step 3: determine factors

This step aims to determine the relevant tangible and intangible factors by observing several usage scenarios identified in step 2.

Step 4: explore factors

Steps 1 to 3 are preconditions for the further exploration of each of the factors. Possible relevant aspects might include the following:

- How do we measure each tangible condition?
- Can we determine appropriate ranges for all tangible factors?
- What is the impact of different ranges that have been determined?
- What are categories of intangible factors?

Step 5

This step aims to determine the impact of tangible and intangible factors on the usability of a device by a user in a given situation. We measure usability in terms of:

- ease of performing a task,
- speed of performing a task,
- cognitive effort involved with performing a task,
- a user's understanding of having performed a task correctly, and
- actual correctly performed tasks.

Further studies might be required depending on the results found.

Once appropriate data has been gathered, the chosen way to represent and incorporate these factors into our broader formal model for the devices, i.e. the model of the usage context can be tested; starting with a test of the successful data integration.

To answer our three research questions, a mapping needs to be created between the situational requirements of safety-critical medical devices and the tangible and intangible situational factors identified in our studies.

The context model then can be used for a decision support tool for the choice of suitable devices for different purposes and environments, which, with this rich underlying data can be fully assessed.

SUMMARY

This position paper gives an overview of the background of a project, on which we are currently working, and outlines our planned next steps.

The project looks at using formal modelling methods to increase the usage safety of safety-critical devices. The method is going to model functionality, interaction and situational context. While functionality and interaction have already been integrated into a mutual modelling approach, this paper suggests methods for assessing usage context, for integration into this modelling method.

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