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Usability standards meet scenario-based design: Challenges and opportunities

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ABSTRACT

The focus of this paper is on the challenges and opportunities presented by developing scenarios of use for interactive medical devices. Scenarios are integral to the international standard for usability engineering of medical devices (IEC 62366:2007), and are also applied to the development of health software (draft standard IEC 82304-1). The 62366 standard lays out a process for mitigating risk during normal use (i.e. use as per the instructions, or accepted medical practice). However, this begs the question of whether "real use" (that which occurs in practice) matches "normal use". In this paper, we present an overview of the product lifecycle and how it impacts on the type of scenario that can be practically applied. We report on the development and testing of a set of scenarios intended to inform the design of infusion pumps based on "real use". The scenarios were validated by researchers and practitioners experienced in clinical practice, and their utility was assessed by developers and practitioners representing different stages of the product lifecycle.

These evaluations highlighted previously unreported challenges and opportunities for the use of scenarios in this context. Challenges include: integrating scenario-based design with usability engineering practice; covering the breadth of uses of infusion devices; and managing contradictory evidence. Opportunities included scenario use beyond design to guide marketing, to inform purchasing and as resources for training staff. This study exemplifies one empirically grounded approach to communicating and negotiating the realities of practice.

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1. Introduction

1.1. Overview

Although scenarios are frequently applied to support User Centred Design (UCD) [1], research is required to understand how they can be applied to the development of medical devices and clinical information systems [2]. In these domains, it is unclear how the technique overlaps with the standard usability engineering process (IEC 62366:2007), where the use of scenarios is focussed on identifying and mitigating risk. This may overlap with, but not equate to, their application for user-centred design practice, e.g. allowing a development team to build up a picture of how users will interact with a device.

We consider how scenario-based design, as typically applied in Human–Computer Interaction (HCI; e.g. [3]), might be practically applied in a medical context. To focus the study, we developed and tested an approach to developing scenarios on infusion pump use. Infusion pumps are medical devices, designed to deliver drugs and fluid to a patient. We focused on this example because infusion pumps are safety critical, and widely used for a variety of purposes, by a range of different kinds of people. We consider how the use of scenarios applies to this type of technology, and how it overlaps with existing development processes.

1.2. Scenario-based design for infusion pumps

The design of medical devices is shaped through a number of standards and guidance documents [4,5]. Although voluntary, manufacturers are expected to adopt these processes, because they are recognised by regulators. The process outlined in the internationally recognised usability engineering standard (IEC 62366) [5] states the need for scenarios, but does not necessarily overlap with a scenario-based approach. Scenarios, as described in the standard, are used to represent a sequence of events or tasks; however, there are questions as to how much detail this content should include and what form it should take. For example, should

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scenarios include issues like how busy the user is, what shortcuts they use, what needs they prioritise (e.g. safety v speed), variability in their behaviour and the wider integration of the device (e.g., match with supporting artefacts such as prescription charts [6] and information systems)?

Despite the fact that standards reference HCI textbooks which detail the construction of rich and engaging descriptions of context [7,8], there has been little previous research on how typical HCI practice fits with medical device development. This is partly because scenarios can be used in different ways at different stages (e.g. certification, marketing, purchasing and adoption for a given customer). Fig. 1 sketches a product lifecycle for interactive medical devices such as infusion pumps, highlighting kinds of scenarios that might be used at different stages.

Tasks and scenarios are used during development and certification (as per 62366) (phase 1 as shown in Fig. 1). They may be general to avoid constraining equipment use. They are also used to test for the potential for use error. Assumptions made at this point shape the official definition of what a product should be used for ('intended use').

Scenarios are used during the marketing of a product or system for a given user group or market segment (phase 2). They may be used to identify potential customers or show the benefit that equipment provides.

Scenarios are used during purchasing and localisation (phases 3 and 4). Those deploying equipment are likely to have a policy on how a product or system will be used, but "real use" may be different. Scenarios can be used to jointly reflect on real use, to account for these differences (as in [9]).

From a HCI perspective, scenarios are a tool to represent use, feeding the development of artefacts [10,11]. Scenarios have been shown to provide a way of both highlighting new opportunities for customisation and tracking the user reaction to them. They represent needs and constraints in an accessible way, by allowing people from different backgrounds to contribute [12]. They promote joint consideration of how a product functions, and can be used to flag missing detail or differences in opinion [13].

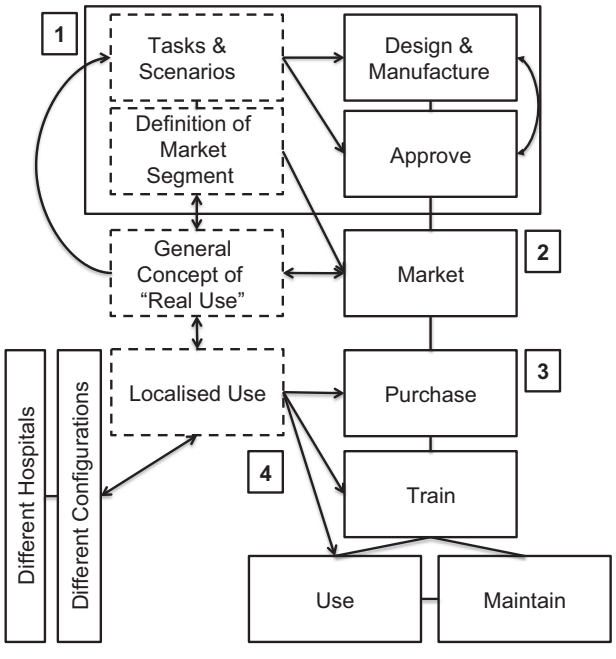

Fig. 1. Stages in the product lifecycle and flows of influence.

1.3. The challenge for medical technology

Although scenarios are widely used to capture and reflect practice, little attention has been paid to how they can be most effectively used when designing and deploying medical technology. Although HCI scenarios are traditionally applied to the design of technology, they may also support the localisation of technology (e.g. configuration & setting of safety features) [14]. In this case, scenarios would be used to support the match between the device and surrounding environment (phases 3 and 4 in Fig. 1). Such use, post certification, could be beneficial given evidence of infusion pumps imposing a programming sequence that does not match the hospital workflow [15]; of poor usability including "confusing or unclear on-screen user instructions, which may lead to improper programming of medication doses" [16]; and of "cues to distinguish between similar drug names [being] insufficient." [17]. In these cases real use is different from intended use but there appears to be limited means to express these differences.

Addressing such issues requires an understanding of the skills, motivations and understanding of different types of user, as well as policies of local healthcare organisations, and characteristics of the wider environment. The aim of this study was to investigate how scenarios can be constructed to explore some of these issues and how scenarios can be used at different points during the design, development and deployment of technology.

The study explored the use of flexible, lightweight and versatile statements of intended user (personas), as reported elsewhere [18], and usage (scenarios) – the subject of this paper. Our focus was on how to generate empirically grounded and validated content, and on the utility of the scenario technique at varying points across the product lifecycle. Validation related to the extent to which content was true to life, typical and representative of the hospital context. No previous studies have investigated how to apply these techniques in situations where development practice is prescribed; there are barriers and costs to accessing the context of use; and views of practice are typically incomplete, unclear or contradictory.

2. Methods

The scenario content was based upon observational studies [15,19–25], conducted as part of a multidisciplinary project investigating the safety and usability of medical equipment (www.chi-med.ac.uk). Ten scenarios were constructed, covering a cross-section of experiences relating to infusion device use (Table 1). The content aimed to support the design of medical devices, although we also sought to reflect on the process of generating and using scenarios.

As reported in a previous study describing the process of constructing personas [18]; results from the observational studies

Table 1
Scenario details.

Ref.	Scenario list
1	SCENARIO 1: Mary is administering a sequence of treatments
2	SCENARIO 2: Yasin is setting up treatments in an isolation room
3	SCENARIO 3: Jim cannot sleep
4	SCENARIO 4: Fred is setting up an epidural pump
5	SCENARIO 5: The equipment library (i.e. central store of hospital equipment) has run out of volumetric pumps
6	SCENARIO 6: Members of the ICU are providing postoperative care
7	SCENARIO 7: Suresh is helping to implement a hospital wide policy relating to infusion device use
8	SCENARIO 8: Frank is installing an infusion pump on an air ambulance
9	SCENARIO 9: The A&E trauma team need to rapidly infuse blood
10	SCENARIO 10: Miriam is practicing some tricky calculations

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