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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.

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].

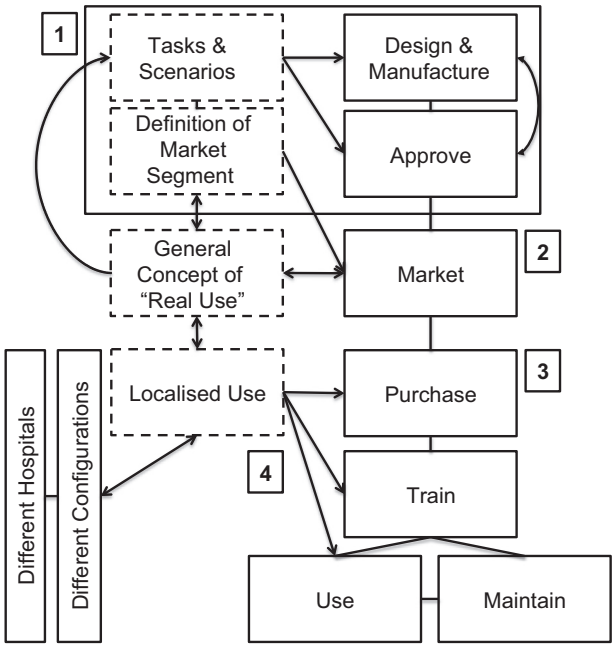


Fig. 1. Stages in the product lifecycle and flows of influence.

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

were included in a repository of evidence and supplemented using textbooks (e.g. [26]), internet resources (e.g. [27]), and procedure manuals (e.g. [28]). Scenario content was created and linked to sources of evidence using the same approach as [18]. The stages relating to the construction of scenarios were:

(1) A **review of user research** collected as part of wider research project activities (field studies and interviews).
(2) Creating a series of persona-scenario combinations and **assembling a repository** of underpinning evidence.
(3) **Checking the scenarios** e.g. going back to the user group in question, to confirm the extent to which the material is true to life.

2.1. Reviewing user research

The observational data had been gathered and structured through the application of Distributed Cognition for Team-working (DiCoT) [29–31]. The DiCoT framework was originally developed to provide a structured method of analysis based upon Distributed Cognition, which broadens design reasoning to include multiple people and artefacts [32,33]. DiCoT has been applied across numerous domains such as emergency medical dispatch [31,34], patient process management [35] and agile software development [36,37]. DiCoT provides a series of principles where the unit of analysis is expanded from the individual to the wider system. The approach can be used to describe how information is transformed and propagated through work (e.g. coordination between technology, tools, artefacts, room layout and people). For example, the information flow model (one of five models) gives an account of what the system does, including main inputs and outputs, as well as details concerning inherent process (e.g. what would staff do before, during or after an infusion procedure).

DiCoT therefore formed the basis for the user research [19–25], employed to construct the scenarios. In some cases, interview data from the original studies was used as evidence, whilst maintaining source anonymity. In other cases we arranged meetings with the authors and transcribed or noted dialogue. We combined notes and transcripts with the papers and reports. During this process, additional references were recommended (e.g. procedure manuals, textbooks, journal articles, conference proceedings, training materials, workbooks and competency lists). Together, these data sources comprised a rich source of evidence for creating scenarios of use.

2.2. Assembling a repository

Sources of evidence (articles, notes, references, reports, interviews) were loaded into qualitative data analysis software NVivo (QSR International, Victoria, Australia). The repository included the user research [19–25], e.g. studies relating to Accident and Emergency, Haematology & Oncology, The Intensive Care Unit, The Medical Equipment Library (central stores) and Surgery. A review of the initial studies resulted in a need to follow up on certain parts. For example the sentence:

> "Senior educator nurses have discouraged the practice of programming VTBI"
>
> VTBI = Volume To Be Infused [24]

prompted the inclusion and review of training documentation/trainer interviews.

The benefit of assembling the repository was that during the writing process, claims made in the scenario could be linked with evidence contained in the repository. This occurred through a process of in vivo coding (e.g. assigning descriptive labels to phenomena). Sources of evidence (usually 2 or more) were linked to sections of the scenario, which were highlighted and assigned a node (a unit of meaning). Evidence was usually coded at the sentence level, but occasionally at the paragraph level. An example of evidence used to create the content was:

> "The nurse shut the door of the pump after inserting the line and was impatiently pressing the OK button" [22]

These parts were linked to a section of the scenario content; for example:

> "inserts the line, programs the pump, she sets the VTBI…. " (Scenario 1)

In this way it was possible to maintain traceability between the scenario and evidence base.

The sources of evidence were not always in agreement. The process of reconciliation and integration was achieved in several ways: member checking occurred; drafts were circulated for comment; instances of the same phenomena were cross checked across multiple sources of evidence; the content of the scenarios was reviewed by those external to the research and writing process (described in the following section), and a general approach of consensus building was adopted by meeting with those involved in the user studies.

The resultant set of scenarios is summarised in Table 1, and an example scenario is shown in Fig. 2. This scenario relates to Jim, a patient diagnosed with CLL (Chronic Lymphatic Leukaemia). One of the interpretations of this scenario is that equipment alarms can have a negative impact by waking sleeping patients unnecessarily. The set of 10 scenarios (provided as Supplement information) were selected by considering the relevance to equipment design. The intent was to provide coverage of a range of possible usage contexts and ways of interacting with a device. For example, the set contained extreme and unusual usage contexts (e.g. an air ambulance), as well as routine ones. The majority of the scenarios contained a link to an associated persona (based on the process outlined in [18]). They contained user goals (criteria for success), as well as a section on background and context. This section was used to indicate the events running up to a focussed story involving an interaction with equipment. The scenario related to real world practice, which could include frustrations or complications (i.e. they were not idealised scenarios).

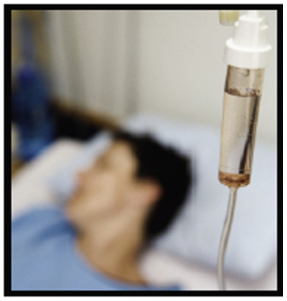
2.3. Validating the material

The scenarios were sent to multiple reviewers (Table 2), to check whether content was realistic and representative of healthcare practice. A semi-structured script (Table 3) was used to collect feedback regarding the truthfulness of the material, and this was linked back to the scenario content. Where possible, the feedback was audio recorded and then loaded into NVivo to allow refinement of the content. We kept track of the evidence that was used to create the content, and that which was used to refine it (e.g. feedback from reviewers). The feedback was used to check the realism and representativeness of the scenario. As the exercise progressed we found that representing a single ground truth was very difficult (this is expanded upon in the results section). This meant that the feedback was in conflict with the scenario content, and sources of evidence were in disagreement. This was because there was no such thing as standard practice or a "one right way" of doing things. This was revealed by differences in the ways that the same task was practiced across multiple work contexts and a difficulty in amalgamating what were often conflicting accounts of practice. We therefore shifted our focus to the benefit that the feedback provided for education and elicitation, rather than the use of scenarios as a representational tool.

PERSONA0T.docx Last updated 24/02/2014

Background and Context
Jim is staying overnight in the oncology ward. At the beginning of his treatment he could receive chemotherapy in the Day Care Unit (DCU). As he has begun to get sick there is a need to keep him on a ward. Jim has had a recent bout of diarrhoea and the staff must get fluids into him promptly. He is hooked up to an infusion pump that is delivering fluids. He is lying down, in a bed. The ward is quite dark (it is late at night) and most of the patients are asleep, although a few are sitting up, reading books. His current infusion was set up about an hour ago. He doesn't know how long it will go on for, he just hopes that he doesn't need to go to the toilet again and he is being really careful to not move his arm too much. The nurses have put a bandage over the access point (cannula) so it shouldn't get caught in anything. Jim knows that if he bends his arm too much then the device will alarm. Last time this happened the pump created a terrible racket and the nurses took a while to come over and sort it out. For some reason they wouldn't make it quiet until they had had a good look at his arm.

SCENARIO 3: *Jim can't sleep*



"Its amazing anyone gets any sleep around here"

Criteria for Success
Jim needs to sleep.

The Story
Jim is tired, gaunt and pale. The doctors are beginning to get concerned about Jim and the way that he is responding to the chemotherapy. It is late at night and not much is happening on the dimly lit ward. About an hour ago a nurse set up an infusion pump next to Jim. Although the infusion pump screen and buttons were backlit, she used the light of her mobile phone to check the line and make sure that everything was set up correctly. Jim is very anxious about the fact that his infusion pump might alarm and disturb the other patients. The last time this happened was when he moved his arm slightly, although on a few other occasions he hadn't got the foggiest as to why the pump was alarming. His arm is rigid and tense and he is not very comfortable. Jim wishes he knew how long he was going to have to stay like this for. He is also worried that the nurse might not hear the alarm. Earlier in the day, Jim could see that the nurses were being put under pressure by having to deal with all of the alarms on different equipment. He doesn't want to upset them. He wonders what the alarm sound means and how long it will be until he can be disconnected from the equipment. He also worries that he might have broken the pump. What does the amber light mean? Jim thinks back to a nurse using another piece of equipment. He was taking his pulse. That thing made a racket as well. The nurse didn't seem to be benefiting much from the blips and bleeps and tried to follow the instructions to shut it up. Just when they thought they had sorted it, the thing started chirping again. Jim and the nurse had a laugh about this, but he could see that the nurse was a bit embarrassed. Jim thinks back to his home and his wife Helen and wishes he wasn't in hospital. He wonders if Helen is asleep, how she is, and how the children and grandchildren are? He hopes that his current condition isn't going to influence the chemotherapy and wonders if he will ever get to leave the hospital.

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Fig. 2. Example scenario content. See also Supplementary information.

2.4. Gathering feedback about the utility of the material

We asked a series of HF/UCD practitioners, working on medical device projects, to comment on the utility of the material. This was to understand the constraints of the scenarios and how they overlapped with industrial practice. The content was provided to practitioners, who commented on utility during multiple parts of the product lifecycle, namely design, requirements generation and marketing. The material was compared to similar content produced during medical device development projects. The activity built on previous work examining the constraints under which medical device design and development take place [38]. In reporting the results, we chose to focus on three questions (from a larger set provided as Supplementary information), namely:

- Is the information presented in a format that allows it to be incorporated in the development process?
- When would it be used in the development process?
- Who are the people within your organisation that you think would benefit from using it?

3. Results

We found previously unreported challenges and opportunities for the use of scenario-based design. Challenges include: integrating scenario-based design with standard usability engineering practice (62366); covering the breadth of uses of infusion devices (where practices vary within hospitals, and across healthcare systems) and managing contradictory evidence. Opportunities

Table 2
List of participants.

Line	Ref	Profile	Recording method
1	RES-00-01	HCI/ERGONOMICS RESEARCHER	Notes (meeting)
2	RES-03-01	HCI/ERGONOMICS RESEARCHER	Notes (meeting)
3	RES-05-01	HCI/ERGONOMICS RESEARCHER	Notes (meeting)
4	RES-04-01	HCI/ERGONOMICS RESEARCHER	Notes (meeting)
5	RES-02-01	HCI/ERGONOMICS RESEARCHER	Notes (email)
6	RES-01-01	HCI/ERGONOMICS RESEARCHER	Notes (meeting/email)
7	RES-03-02	HCI/ERGONOMICS RESEARCHER	Transcript (audio recording)
8	RES-05-02	HCI/ERGONOMICS RESEARCHER	Notes (email)
9	HS-02-01	DEVICE TRAINER	Transcript (audio recording)
10	HS-03-01	SENIOR NURSE	Transcript (audio recording)
11	REP-01-01	PATIENT REP	Notes – phone call
12	HS-01-01	MEDICAL PHYSICS	Transcript (audio recording)
13	HS-04-01	HEALTHSERVICE MANAGER	Transcript (audio recording)
14	RES-06-01	HCI/ERGONOMICS RESEARCHER	Notes – phone call
15	MDC-06-04	MEDICAL DEVICE MANUFACTURER	Notes (email)
16	CON-11-01	MEDICAL DEVICE CONSULTANT	Notes (email)
17	CON-12-01	MEDICAL DEVICE CONSULTANT	Notes (meeting)

Note: 9 and 10 conducted together (focus group).

Table 3
Interview topics pertaining to the validation of the scenarios.

Topic	Question
Accuracy: How accurate is the material?	Can you give examples of factual inaccuracies?
Clarity: How clear is the material?	Can you give examples of the parts that are not clear? Can you give examples of similar material that is easier to understand? Was appropriate terminology used?
Currency: How current is the material?	Have the results of the underpinning research changed since the document was written?
Scoping: Is it clear when the material does and does not apply?	Is it apparent in which situations the material applies? Does the material make apparent the types of equipment it applies to?
Typicality: How typical is the content of the material?	Would those described usually be involved in the activity? Who are the others that are involved in the activity?
Plausibility: How plausible is the material?	Can you give examples of parts that are implausible?

included the use of scenarios beyond design to guide marketing, to inform purchasing and as resources for training staff.

3.1. Challenge: Integrating scenario-based design with standard usability engineering practice

We reviewed how a scenario-based design approach overlapped with a standard usability certification process (IEC 62366:2007). In this case, scenarios represent the tasks that a manufacturer expects the user to perform e.g. "realistic tasks based on user scenarios derived from previous task analysis and risk analysis" [39]. They also communicate the types of use error that result in hazard(s). Such scenarios need to contain unambiguous and testable statements, as they provide input to a wider risk management process. Their use impacts on the decision whether or not to market a device. They are not created to explore anything other than extreme variations in use (e.g. dropping a device), or generic use (e.g. instruction manual style descriptions). This contrasts with the user-centred design approach (scenario-based design), where content provides the basis for constructive thought during the development process. Diaper [40] remarks on the difference:

> "There is almost certainly a major difference between what is the mainstream task analysis view, that one should get task descriptions correct, and Carroll's proposal that one can overcome the difficulty of describing tasks accurately by relying of people's skills at interpreting stories to fill in much that is missing." [40]

Our findings reflect this tension. Our approach (similar to Carroll's [7]) could act as input to the usability engineering process; but by making scenarios that were open to interpretation, we compromised the extent to which they could be used during design and approval (phase 1 of Fig. 1) (e.g. as a test case). HF/UCD practitioners (15–17 in Table 2) were aware of this difference and were creating multiple sets of documentation. One was highly structured and focused (e.g. documentation produced to satisfy IEC 62366). The other was linked to user research, accessible and designed to allow team members to develop and reflect on their own knowledge. For example, from the perspective of a design practitioner commenting on the scenarios reported in this paper:

> "For me they are tools to make the results of user research tangible and usable during design and development – for those who were involved in the research as well as those who were not." CON-11-01

This approach was similar to our intended use for the scenarios, but is different from the role that scenarios play in the 62366 usability engineering process. Here (worst case) use scenarios act as specification for requirements relating to usability. They are task focused, indicate an end-state, and detail a single aspect or function associated with device use, e.g.:

> "A high volume of morphine is being administered to PATIENT in a high stress emergency care situation under low ambient lighting. USER needs to change the dose and cannot clearly read the display. The USER incorrectly increases the concentration of the morphine infusion rate." [5]

Our content provided for a broader exploration of how a device could be designed, but did not necessarily fit with the process outlined in IEC 62366. For example, Section 5.7 in the standard [5], labelled 'User interface design and implementation', relates to the creation of design ideas. Our type of scenario could apply, because HCI scenarios are used to shape design, for example during brainstorming stages [1]. However, the standard does not call for the use of scenarios during this stage. Similarly, an account of the application of 62366 [41] details the use of "...brainstorming, association, [and] role-playing..." during UI design and implementation, but does not specify whether scenarios act as input. It lists scenarios being used for other purposes: to structure usability tests, simulations and support the interpretation of test results. The tension is as follows: the use of scenarios to support design benefits from content that is open to more than one interpretation, therefore supporting creativity, reflection and exploration. The use of scenarios during testing benefits from content that is not open to multiple interpretations, therefore supporting a test process. The same scenario cannot provide for both.

3.2. Challenge: Covering the breadth of uses of infusion device and managing contradictory evidence

The way in which scenarios are applied matters. Even if we did want to use the scenarios to provide an unambiguous statement of use, it is very difficult to provide a single correct view of equipment use. Variations in practice lead to a conflicting or uncertain outlook. We know this is the case from our feedback and a range of studies showing differences between official and actual use [15,42], workarounds [43] and differences across international contexts [44]. Clinical practice varies, as does the level of training [45]. This impacts on interpretation of the scenario content and when it might apply. We found several cases of disagreement between the evidence used to generate the content and subsequent feedback. For example:

> [From one of our sources] "I noted use of yellow cytotoxic tape on a chemotherapy line, fixed below the drip chamber to act as a warning for correct handling."

> [Discussing scenario 1] "So attaching a cytotoxic label to the line, great, not a yellow one though. That's good practice to add a label to the line, but not that." HS-03-01

The scenarios flagged potential for confusion. Differences in nomenclature and terminology were highlighted, as were technical differences relating to (for example) the colour of accessories:

> "he has everything needed to prepare in a blue tray. I take it you mean that's a clean sterile... Well we had blue trays, we've done away with blue trays now you see. But I can understand the phraseology" HS-03-01

This type of discussion was illuminating, but limited the extent to which our scenarios "captured" a single view of health service practice.

3.3. Opportunity: Scenario use beyond design to guide marketing, to inform purchasing and as a resource for training staff

We were therefore interested in the use of scenarios to support a dialogue about the social phenomena relating to healthcare practice, focusing on variations in practice. The reported scenarios (e.g. Fig. 2) were best suited to promoting joint discussion and reflection, rather than unambiguously stating a task. The discussion of scenario content helped to sensitise those involved to the needs of equipment users and provided for two-way exchange.

> "It makes the use of a medical device more personal. So if you're using them, for instance, in training, to get people engaged, then that's definitely a good way" HS-04-01

They benefited from a rich and compelling narrative, rather than a procedural one. Although it is hard to determine whether a task based representation would also provide this, Carroll [1] suggests that this is unlikely e.g.: "detailed analyses of existing tasks tend to be morally inertial: They perpetuate existing conceptions of work; they affirm status quos of various sorts, often, they merely validate normative work descriptions that can be oppressive—the manager's view of the worker's activity."

4. Discussion

We found it feasible to use scenario content to elicit and understand these differences, but recognised that the approach would never provide a complete representation. For example, the checking process revealed differences between the reality of practice in the eyes of different respondents, as well as variability on the ground.

4.1. Integration of scenarios with the design and development process

Although we do not rule out the use of this type of scenario during the early stages of design and development, we suggest a novel use, to explore variations in practice during deployment and subsequent use (stages 2, 3 and 4 in Fig. 1). This could apply to marketing (e.g. facilitating communication between healthcare providers and equipment manufacturers), purchasing (e.g. being aware of how a device might be used beyond statements of intended use) and education/training (exploring such variations in use and better accounting for real use). In all of these cases, the emphasis is less on providing design requirements, and more on revealing the actual practices surrounding device use. The benefit of airing these issues is that although differences may seem superficial, they have the potential to result in the type of mismatch that compromises the safety and usability of equipment.

4.2. Use of scenarios during the different stages of the project life cycle

In these cases, scenarios may be used to illustrate the reason why real use is different from intended use and promote discussion about how equipment may be better integrated. They support the configuration of equipment and provide cases for discussion: i.e. asking a range of health care professionals what is wrong and considering how modifications to the equipment can provide benefit. They sensitise users to equipment issues and can convey how equipment does not provide for user needs, therefore complementing but not substituting for formal reporting systems, such as the FDA MAUDE database.

Throughout, scenarios are also providing a quick check of consensus. This provides benefit in terms of illustrating both opportunities for improvement, but also variations in practice. For example, if healthcare practitioners do not agree on a given workflow, there are multiple variants of workflow, or the workflow is unclear or unexpected, there will be implications in terms of the potential for generic technology to provide a solution.

4.3. Limitations of scenarios

Although we observed benefits associated with the use of scenarios, there remain many unanswered questions as to how to get the best out of the technique. For example, there is an opportunity for greater alignment between the phases outlined in Fig. 1, but there is a catch twenty-two situation, in that to create scenarios that are linked to a given product or system, that system has to be deployed. Simulation could provide the means to align such insight with the certification process. Van der Peijl et al. [41] reports on scenarios being created by a clinical expert, and simulation being used so that the lessons learnt could be applied to equipment under development. There are many advantages of getting clinical experts to write scenarios, for example they have domain expertise and will know what is representative of clinical practice. They are likely to create content that suspends disbelief [46]. Outsiders can benefit from tacit knowledge being made explicit, as part of the scenario writing process. However, there are also disadvantages; for example, despite a push to create a standardised and controlled set of clinical terms (e.g. SNOMED CT), the language that medical professionals use is often domain specific and inaccessible to outsiders. The extent to which the scenario can act as a true mediator or boundary object may be compromised. We therefore need to better understand how multiple disciplines can work together to write scenarios, taking into account the need for content that is "plastic enough to adapt to local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites." [47].

5. Conclusion

The aim of this research was to investigate and reflect on the process of using scenarios and, given the challenge of reconciling disparate, possibly incommensurable, views; outline how this type of content can be constructed and usefully applied. One of the recurrent themes encountered during the exercise was the extent to which scenarios could both be used as part of a formal regulatory framework (as mentioned in the introduction), as well as to satisfy wider engagement and sensitisation (e.g. education and training).

This has implications for practice, because although the disciplines of HF/HCI, sales and marketing can be united by the need to understand the context of use, there can also be a divergence in the values and priorities that shape this understanding. On one hand scenarios can be used in a flexible way, where the aim is not to impose a single solution, but to provide the freedom to explore multiple solutions and capture the reasoning behind the chosen solution. In this context, scenarios are being used to support creativity, collaboration and joint reflection. On the other hand, scenarios may also support a standards based development practice or formal risk management process. In this context, the use of scenarios is less flexible. Given that the use for medical device certification differs from user-centred design practice, there

is a need to understand how to integrate the approaches and be mindful of limitations.

For example, if we were to take content of the type we generated, and apply it to a premarket certification activity, there would be many challenges: for example, how to make sure scenarios are valid, manage depth and breadth of investigation, determine a suitable level of detail, and keep the scenarios up to date. Although there are well defined stopping rules for traditional analytical techniques such as task analysis and risk analysis (e.g. FMEA or HFMEA), the looseness and flexibility of this type of scenario makes it hard to transfer principles across. Harmonising the premarket and post market use of scenarios remains a topic for future research. As it stands, the reported scenarios allow for the exploring, discussing, understanding and eliciting of likely equipment usage, as well as revealing differences between actual and intended practice, as well as variations in use. For example, scenarios could be used to articulate otherwise unspoken differences, resulting in a better understanding of how devices will be used once deployed. The results showed that the dialogue created when validating the scenarios was useful. It allowed for mediation across professional perspectives and provided insight concerning the realities of use. The scenarios supported knowledge elicitation and exchange. This is in line with their use in both medical [48–56] and non-medical contexts [3,52,57–65].

In this context, scenarios may be: "heuristic at best"; deliberately underspecified (to promote discussion and exploration); and necessarily incomplete [10]; e.g.: "The main purpose of developing scenarios is to stimulate thinking about possible occurrences, assumptions relating these occurrences, possible opportunities and risks, and courses of action." [66].

Although there is a large volume of literature expressing the benefits of scenario-based design, not much of it recognises processes relating to medical systems. In this context, there is very little advice on how to bridge the gap between usability standards and scenario-based design, as well as practically account for variations in use. The work reported here highlights both challenges and opportunities in bridging this gap.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jbi.2014.11.008.

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