A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective

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ABSTRACT

The healthcare industry is dependent upon the provision of well designed medical devices. To achieve this it is recommended that user-centred design should begin early, and continue throughout device development. This is a challenge, particularly for smaller companies who may lack the necessary expertise and knowledge. The aim of this study was to conduct a rigorous yet focused investigation into the user requirements for a new medical imaging device. Open-ended semi-structured interviews were conducted with potential clinical users of the device to investigate the clinical need for the device and the potential benefits for patients and clinical users. The study identified a number of new and significant clinical needs that suggested that the concept of the device should be fundamentally changed. The clinical and organisational priorities of the clinical users were identified, as well as a number of factors that would act as barriers to the safe and effective adoption of the device. The developers reported that this focused approach to early requirements elicitation would result in an improved product, reduce the time to market, and save

the time and cost of producing and evaluating an inappropriate prototype.

Keywords

User Requirements, Medical Device, Healthcare

1. INTRODUCTION

To provide high quality care for patients the healthcare industry is dependent upon the provision of well designed medical devices. To be considered 'well-designed' a medical device must firstly be clinically effective and safe, however, it must also meet the needs of the people that will use it and be treated by it. This requires consideration of a number of factors including the capabilities and working patterns of clinical users, the needs and lifestyles of patient users, the environments in which the device will be used, and the system(s) of which it will be part (Martin et al, 2008; Sawyer, 1996). As the healthcare industry is extremely complex this is a challenging requirement; devices are frequently used by multiple user groups for the diagnosis or treatment of different medical conditions in a variety of healthcare (and other) settings. The picture is complicated still further by the fact that the person operating the device is usually not the person who will decide whether to purchase it.

1.1 Medical Devices and User-Centred Design

The last decade has seen an increased appreciation of the importance of user issues in medical device design, with research focusing mainly on the links between device design, poor usability, human error and patient safety (Amoore and Ingram, 2002; Gosbee, 2002; Leape, 1994). The particular role of medical devices in patient safety incidents was recently investigated by the United Kingdom's National Patient Safety Agency. Their review, which looked at all deaths and severe incidents reported to have occurred in the UK National Health Service (NHS) over a one year period (2007), identified many incidents where the design of a medical device had potentially contributed to the incident (Boakes et al. 2008). These included incidents where developers had not correctly understood the context of use of their device and had not anticipated likely error situations, as well as instances where devices had not been designed with users' expectations in mind, with errors occurring when the device did not function as the user had expected.

Ergonomics has made a significant contribution to the improved safety of medical devices, most notably infusion pumps (Garmer et al. 2002; Liljegren et al. 2000; Lin et al. 1998; Obradovich and Woods, 1996). This research has led to industry regulators such as the US Food and Drug Administration requiring developers to apply human factors principles throughout the development process to "identify, understand and address use-related hazards" (FDA, 2002). Usability standards

are increasingly being used to demonstrate compliance with European medical device regulations (BS EN 62366, 2008; IEC 60601-1-6, 2004).

Unfortunately however, the increase in research on the benefits of user-centred design for medical device development has not been matched by an increase in practical guidance and advice on how developers should conduct this work. As Bridgelal Ram et al (2007) state "Although there has been academic research on user engagement, there is a lack of commensurate work on the practicalities of such engagement" (Bridgelal Ram et al, 2007).

It is difficult to know to what extent the published ergonomics research in this area reflects current industrial practice, given the heterogeneous nature of the medical device industry and the understandable reluctance of companies to publicise details of their development processes. It is likely that there is significant good ergonomics practice being carried out in well-established and larger companies. Siemens and Phillips, for example, have strong reputations for adopting good human factors approaches, however, in the UK in particular, a significant proportion of medical device development is undertaken by Small and Medium Enterprises (SMEs) such as small engineering firms and university spin-outs. These types of companies are less likely to have access to in-house or consultant expertise in this area and this is a barrier to adopting user-centred design principles (Martin et al, 2005).

It is our view that the field of ergonomics has an important part to play in assisting developers to apply user-centred design principles more generally in development. As Buckle et al (2006) state, "While pressure can be put on industry to encourage it to focus on user-centred design practice, industry is unlikely to respond to abstract directives or inducements. What is needed, therefore, is a body of exemplar case studies and demonstration projects that show how such an approach can lead to better and more competitive products". This study aims to contribute to such a body of work.

1.2 Requirements Specification

The published ergonomics literature on medical devices has concentrated largely on the later stages of development, notably prototype evaluation. Little research has been conducted on how to conduct the earlier user research that is necessary for developers to 'understand and specify the context of use' and 'specify the user and organisational requirements' (ISO 13407), and this has been identified as an industry-wide problem. As Martin et al (2008) state, "Currently, users are generally not brought into the developmental process until after the design brief for a new product has been produced. This may be because medical devices are frequently technology driven rather than resulting from an identified un-met need" (Martin et al 2008). There are a number of possible reasons why developers may wait until they have a prototype before consulting users, most notably time and financial constraints. However, failing to adequately study the potential users of a device at the beginning of development may result in assumptions being made about them including basic and essential information such as who they are, and what their needs, capabilities and

characteristics are. Assumptions may soon become accepted and unquestioned, and if these are false or incomplete then the device will be developed and evaluated based on incorrect information. Developers may then unknowingly spend the rest of the project attempting to identify and recover from these wrong assumptions. This has serious implications not just for the safety of the new device, but also for the commercial success of the device as the aim of the early stages of product development should be to "identify and prioritise potentially lucrative ideas" (Cooper et al 1998).

1.3 Research Methods for Requirements Specification.

To date, the most notable study on methods for collecting medical device user requirements was conducted by Garmer et al (2004), who found a combination of focus groups and usability tests to be effective for defining requirements for a new design of ventilator. Usability tests were found to be effective for identifying detailed requirements for the user interface and focus groups were then used to prioritise the requirements and to identify important contextual information. The authors found that carrying out close user engagement within the clinical environment was a "powerful tool… to develop an understanding of and acknowledging the importance of user problems" (Garmer et al, 2004). However, this study investigated an existing device, with the aim of developing an improved version. There has not yet been any published research on collecting user requirements during the development of a completely novel medical device.

This paper describes a user-centred approach to the early stages of development of a novel medical device being developed by a small medical device company. The aim of the user research was to validate and refine the concept for the new device, as well as to collect user information, experiences and preferences. A secondary aim was to investigate, from the perspectives of a small medical device company, the process of involving users early in the development of a medical device, to determine the value of the information collected and the impact of this on the product development pathway.

2. METHODS

This study consisted of two parts. The aim of the first part was to specify the requirements for a new blood vessel imaging device. A brain-storming session was performed with the development team to identify all potential clinical users of the device, followed by an interview study with a sample of these user groups. The study was designed to be scientifically rigorous yet also practical and therefore achievable for small medical device companies in terms of the time and cost involved. The aim of the second part of the study was to evaluate the quality and utility of the data from the perspective of a small medical device company, to study how the user data was incorporated into development and how it affected development.

2.1 The Medical Device

The device described in this study produces images with the aim of providing an inexpensive, portable device that will enable clinicians to perform common procedures more successfully and efficiently and with less pain and discomfort to patients. One reason for the lack of published research on medical device development is the understandable reluctance of companies to disclose commercially sensitive information about a device under development. This project is no different, and as a result we are not able to describe the exact technical details of the new device or detailed information about the potential market.

2.2 Requirements Specification

2.2.1 Brainstorming Session

A brainstorming session was conducted with all members of the device development team. The team consisted of individuals from a number of disciplines: engineering (5), nursing (1), medical physics (1) and clinical physiology (1). Before beginning, the ergonomics researcher (JM) explained the aim of the brainstorming sessions, which was to identify all potential clinical applications and users of the proposed new device. The developers were asked to adopt a broad definition of user, defined here as 'any healthcare worker who may be required, either regularly or occasionally, to locate, examine or access the blood vessels of patients, or to assist with these tasks'. The researcher provided prompts when necessary to encourage the development team to consider the full range of applications and users for the devices, even ones that appeared unlikely.

The development team was then asked to specify their *Research Objectives* for the user requirements study. They were asked to discuss and decide: why they were carrying out this work, what sort of information they wished to collect from users, and what they would do with the data collected. The aim was to ensure that the planned study was focussed on the needs of the developers and that the data collected would be understandable and *actionable*. In other words, we wanted to ensure that the research investigated the right topics, asked the right questions, and produced data that could be easily understood and implemented into development.

The *Research Objectives* of the development team were to:

- Refine and validate the concept for the new device
- Identify the target clinical and patient users
- Identify any barriers to safe and effective adoption
- Collect user opinions on possible design features

2.2.2 Interviews with Potential Users

The results of the brain-storming session were used to inform the design of the user consultation

exercise. A total of 47 individual semi-structured face-to-face interviews were conducted with a variety of healthcare staff from two UK hospitals. A purposive sample was used; participants were drawn from the clinical departments identified in the brainstorming exercise described in section 2.1.1. The clinics included were: renal, phlebotomy, clinical research, neonatal and intensive care (see table 1). Based on the data from the initial interviews, an additional clinical (Clinical Haematology) was added to the study. Clinic managers were consulted before beginning to explain the aims of the study and the likely time commitment for each participant, and permission was obtained to conduct the interviews during working hours. Each interview lasted between 16 and 44 minutes and was recorded using a digital voice recorder. Ethical permission to perform the interviews was obtained from the UK National Health Service and informed consent was taken from each participant. Prior to beginning each interview the aims of the interviews were clearly defined before commencing the study. These were to investigate:

- How the clinical procedures under investigation were currently performed[1].
- The problems that the participants currently encountered. Why and how often they occurred, and the consequences for patients, clinicians and the hospital
- Whether there was a felt need for the proposed device.
- The type of data required from the new device.
- The design of the proposed device.
- Any factors that may affect the safe and effective uptake of the device within the clinical environment.

During the interviews the researcher adopted a careful approach to ensure that the participants were encouraged to talk as freely as possible about the issues around vascular access that they felt were the most relevant and important. Prompts were used when necessary to encourage the participants to provide more detail or to expand on issues. Additional questions were used to clarify the themes that emerged during the interviews. At the end of each interview the researcher brought up any topics that had not already been covered and the participants were also asked if there was anything else that they wished to discuss. Immediately after each interview the researcher wrote brief field notes under each of the pre-determined *Research Objectives* to record the main points raised during the interview, a technique which has been shown to improve the accuracy of analysing recorded interviews (Fasick, 2001; Wengraf, 2001)

2.2.3 Data Analysis

In keeping with the objective of this research which was to conduct a user specification study that was practical and achievable for a small medical device company, data analysis was a targeted process that aimed to produce results that were closely linked to the aims of the developers.

[1] For reasons of commercial confidentiality the clinical procedures investigated in this study cannot be described in detail

The interviews were transcribed based on three categories: Clinical Need; Barriers; and Design. These key organising concepts were based upon the *Research Objectives* identified by the development team in the brainstorming session (section 2.2.1.) and were also informed by the researcher's field notes. Data from the interviews were analysed and informally coded in line with grounded theory method (Glaser and Strauss, 1967; Charmaz, 2000). The researcher identified portions of the data that represented common themes and issues and ascribed a keyword, or code, to each of these. The categories and examples of the codes used in the analysis can be seen in Table 2. A number of these codes were directly related to the clinical need and market for the proposed new device and as such are commercially sensitive information and cannot be presented here.

The coded data was analysed in relation to the research questions specified by the developers. Common and conflicting ideas, experiences and opinions were identified in relation to the following factors:

- The difficulties that the participants encountered during the clinical procedures under investigation and how these varied according to patient and type and clinical department.
- How often these difficulties occurred and the consequences for patients, clinicians and the hospital.
- How the proposed new device would fit into existing patient care pathways.
- The barriers that may prevent the device being used effectively in clinical practice
- The anticipated benefits of the new device for clinicians and patients as well as the hospital or healthcare provider.
- Design preferences for the new device.

2.2.4 Feedback to Development Team

The data was fed back to the wider development team in a number of ways. The aim was to communicate the data in a concise and accessible way, whilst also conveying the range and depth of the information. The results were presented during a development team meeting by the ergonomics researcher (JM) with a written report circulated beforehand. The report consisted of two sections: an executive summary providing a concise overview of the data from each clinical area presented under headings that represented the objectives of the research, and a main report which presented detailed description of the procedure and results. A number of direct quotations from participants were used to communicate the extent and range of the requirements, experiences and emotions expressed by the participants.

2.3 Interviews with Development Team

A secondary aim of the study was to study how user requirements elicitation can be effectively conducted by small medical device companies and evaluate the approach used in this study. To investigate this, the ergonomics researcher conducted two qualitative semi-structured interviews with the two senior members of the development team, both of whom were engineers. The first interview was conducted before the user requirements research began to determine what user research had already been conducted and the results of this. The developers were asked who they thought would be the main users of the device and what their requirements were. They were also asked to describe what they wanted to find out from the user research and how they intended to use the data.

The second interview was conducted after the results of the user research had been presented to the whole development team. The same two developers were interviewed in a similar semi-structured format. The aim was to investigate the utility of the research and how the developers planned to use the results in the next stages of development. This interview covered the same topics as the first, but also asked whether the user research had affected their beliefs about the clinical need, the potential clinical and patient users of the device or the possible barriers to safe and effective adoption.

Table 1. Participant Characteristics

Gender	Clinical Role	Hospital	Department
Female - 35	Nurse – 21	Nottingham – 28	Phlebotomy – 17
Male – 12	Phlebotomist – 17	Exeter - 19	Renal – 10
	Doctor – 5		Clin. Haematology - 8
	Support Nurse – 2		Neonatal - 6
	Healthcare Assistant -2		Intensive Care -3
			Clin. Research – 3

3. RESULTS

The results from this study were presented to the developers in the three categories that emerged

from their *Research Objectives*. The results were presented according to how they confirmed or contradicted the existing plans and views of the developers. Areas of consensus and variation between the participants were clearly identified as well as the apparent reasons for the variation.

3.1 Clinical Need

The interviews with the development team, performed before the user requirements research, found that they had a strong idea of what the clinical need for the device was, who the target users would be and which patient groups would potentially benefit from the device. This concept was based upon informal discussions with a small number of healthcare professionals from a local NHS hospital.

The application for the proposed device was that it would be an aid to regularly performed clinical procedures. The main benefits of this would be that clinicians would be able to work more efficiently and patients would be treated more quickly and with less pain and discomfort. The development team reported that it was their belief that there was a large clinical need for the proposed new device and it would be used routinely in the majority of hospital clinics to treat a wide variety of in and out-patients. They anticipated that the users would include a wide range of clinicians, with the target users being phlebotomists. They estimated that each user would use the device up to 20 times each day.

3.1.1 Results from User Requirements Study

A high level of consensus was found between the participants with regard to whether there was a clinical need for the proposed new device. Similar patterns of experiences, opinions and requirements were reported by participants working in the same clinical departments and these were independent of their specific clinical role within the department.

The most striking theme that emerged from the interviews was 'Patient Distress' as a result of delayed or failed attempts to perform the clinical procedures that the device would potentially assist with. This theme was mentioned by all of the clinical participants, most commonly with regard to the theme of 'Delays to Treatment' and the worry that patients experience with regard to this. When the clinicians were asked about the problems they encountered and the consequences of these, every participant began by talking about their patients and the impact on their treatment and state of mind.

"Some of them (patients) get really distressed at the thought of us giving up. Some say, 'oh please keep on trying'"

Phlebotomist, 17 years experience

"Failure is just awful 'cos the patient gets nervous and wound up. So it is a big bugbear, they so want you to get it first time and you want to get it first time for them. So to go through all that and then possibly not to be able to get your treatment... because that does happen"

Haematology Staff Nurse (17 years experience)

Of the 47 clinical participants, only 2 mentioned unprompted that failing to successfully perform the clinical procedures had a negative impact on themselves. When the other participants were specifically asked about this the general response was that difficulties and delays were seen as just part of the job. One theme that did consistently emerge, however, was 'Pressure'.

"*We know that the patient's treatment depends on what you're doing and they'll say 'please get it because this depends on it' and if you're under a lot of pressure it can be difficult*."

Renal Support Nurse, 4 years experience

Both of these themes were related to the main clinical need for the new device, namely: that it would enable patients to receive important, in some cases life-saving, treatment more quickly than was currently the case. There was less agreement between the participants when they were asked how many patients could potentially benefit from such a device, for example:

"Probably 1 in 20 is really difficult, you've just got to get over it and get used to dealing with difficult patients."

Junior Charge Nurse – Haematology (16 years experience)

"Maybe a third are problematic where you have to try a good few times or go and get somebody else."

Staff Nurse - Haematology (19 years experience)

There was a high level of agreement with regard to the types of patients that could potentially benefit from the device. These were patients in certain clinical departments such as oncology, renal and haematology. The elderly was also a group mentioned by a number of respondents. The participants reported that the delays in treatment for these patients could lead to serious health problems or even death. The participants that treated these patients reported that they would use the device regularly, in general at least once or twice a day. Those that dealt with a general hospital population reported that they would have less use for the device, with many of these

participants anticipating that they would never use the device.

It would be less useful in outpatients but around the wards would be very useful, in some wards you wouldn't use it but in some wards like oncology I think you'd use it a number of times per day.

Phlebotomist, 18 years experience

I think it could help for the very difficult cases would probably be more beneficial to the people that don't do it as often as we do, like GP surgeries but when you do it all day long like we do then you don't really need help.

Phlebotomist, 8 years experience

3.2 Barriers and Design Preferences

Before the user requirements research began, the developers believed that the main barriers to effective use would be the size and weight of the new device. This was because they anticipated that users would regularly carry the device around the clinical environment.

3.2.1 Results from User Requirements Study

The most frequently mentioned barrier to regular use of the device was 'Time', which was mentioned by the majority of the participants. Certain clinical roles, specifically phlebotomists, reported the most time pressures and there was strong agreement that the time that would be required to set up and use the new device would be a major barrier to its use. Participants from other departments also expressed concern that the new device would take too much time to use:

"I think something like that would be too time-consuming, time is of the essence for us in our job. If it's going to add more time to our working day, then I would tell you not to make it because you're just wasting your money because we simply wouldn't use it"

Phlebotomist (6 years experience)

Speed is a key thing, I want to get patients sorted within ten minutes so it needs to be very quick"

Haematology Manager (22 years experience)

Weight was not identified as a specific issue, however, a number of participants mentioned 'Portability' and stressed that it would be important that the device could be easily taken to a

patient's bedside. A common response was that the device should be "easy to use". Further probing of this term discovered that participants meant that it should be simple to set up and operate and not require extensive training or maintenance. Other potential barriers identified by the participants were the presence of existing medical equipment which may make it difficult to get the device close enough to the patient as well as issues such as access to sufficient electrical sockets. There was a high level of consensus among the participants about the importance of hygiene; any equipment that made contact with patients would need to be sterile. The interviews also revealed that the device should be free standing as healthcare staff would need to have both hands free.

There was less agreement on how the device should be designed with participants giving a number of different suggestions. For example, some participants thought that the data from the device should be displayed on a screen whereas other believed that it should be displayed directly onto the patient. Some participants requested that the device should be on a stand that could be wheeled around the clinic whilst others preferred the idea of being able to carry the device and then to fix it onto the patient's bed or chair. Differences in opinion on design were not related to clinical role, clinical department, or level of experience.

3.3 Interview with Development Team: Follow-up

The developers reported that the most significant result of the user research was the discovery that there was not a widespread need for the new imaging device within a general hospital population. The results of the research challenged their fundamental concept for the device and this was an unexpected outcome as they had believed their original concept was accurate. The discovery of a number of additional clinical applications for the new device, however, was a significant finding.

"After the interviews it seems that that application is quite limited so the fact that it identified different markets is a big positive part (of the research)"

Developer 1 (Biomedical Engineer / Project Manager)

The developers had anticipated that the user research would establish a consensus from the users on how the new device should look and feel and that in this respect the research had not met their objectives and they would have to conduct more work would be needed on this issue. However, they reported that the interviews had identified a number of previously unknown factors that were going to be key factors in developing a device that met the needs of the users, the most notable of these being the time required to set up and operate the device:

"They (results) show that speed is going to be the key thing and that's a new challenge that we didn't know about before. That's going to be the priority of the hardware and software development"

Developer 2 (Biomedical Engineer)

The developers reported that this user research study was substantially different to the approach they normally would take at this stage of development which was the initial consultation they had conducted with a small number (<5) of clinicians from the same department in a local hospital. When asked whether the more rigorous approach had resulted in benefits, the developers stated that they believed it had prevented them from developing and testing an inappropriate prototype and as a result would potentially result in the device making it to market more quickly. Furthermore, they felt that the device had a better chance of being successfully adopted without any post-market changes having to be made.

"We usually focus just on the technology so we wouldn't look at the applications. So this is quite different from the way we normally do it. We would introduce it into the market and then make changes if we got opinions back that the design wasn't ideal"

Developer 2 (Biomedical Engineer)

Table 2 Analysis: Categories and Examples of Codes

Categories	Codes
Clinical Need	Patient Distress
	Delays to Treatment
	Pain
	Time pressures
	Areas of the body
	Elderly
	Chemotherapy
	Dialysis
	Expertise
	healthcare resources
	Impact on health
	Frustration
Barriers	Time
	Training/Instructions
	Mobility
	Electrical sockets
	Work space
	Other equipment
	Availability of equipment
	Safety
Design	Short start-up time
	Hands free
	Hygiene
	Manoeuvrability
	Portability
	Weight
	Dimensions

4. DISCUSSION

The main aim of this study was to refine and validate the clinical need for a new medical imaging device. The results of the interviews strongly suggested that there was a clinical need for the new device but that the need was markedly different to the one envisaged by the developers. It was unlikely that the new imaging device would significantly benefit the general hospital population but that there may be benefits to particular groups including patients with renal failure and cancer, and the device had the potential to have a significant impact on these groups. This led to the developers reporting that they would be changing the concept from 'high-volume, low impact' to a 'low-volume, high impact' device, a change they anticipated would result in the device being a more attractive proposition for the NHS.

Key to the success of this part of the study was including participants from all clinical departments identified as potentially benefiting from the device and not restricting the work to those that had already been identified as the likely target users. This was the result of the team being encouraged to broaden their research aims at this early stage of development. Rather than focusing solely on the original clinical need for the device, the aim was to identify as many problems, needs and difficulties as possible. Using semi-structured and open-ended questions was crucial to this as it enabled participants to talk freely about their work and all of the issues that they and their patients faced. The focus was on learning about the problems and difficulties that clinical staff encountered and the implications of these for patients. An example of the success of this open-ended approach was the fact that one of the participants recommended to the researcher that they should extend the study to include clinicians from the Clinical Haematology department. This clinical area had not been identified by the development team as potentially benefitting from the device yet it was found to be one of the clinics that could potentially benefit the most from the new device.

Clearly defining the study research questions at the beginning of the study brought a focus to data collection and analysis that was an important factor in the success of this industry-led study. The company developing the new device was a relatively small enterprise and therefore there were limited resources available for data collection and analysis. Focusing the analysis on the developers' *Research Objectives* allowed the results to be presented in a way that was easily understandable for the developers and also in a way that was actionable. Particular care was taken to describe areas of consensus and variation between the participants and to clearly identify the target clinicians who would use the device most often as well as the patients that would likely benefit the most from the device. Using direct quotations, which often included powerful and emotive language, appeared to be effective way of conveying to the development team the serious implications of the problems reported by the clinical participants.

When developing a new medical device it is important that the clinical applications and the clinical and patient users are correctly identified early in development. This will allow the correct user requirements and capabilities to be collected as well as accurate information about the context of

use and how the device will be used in practice. This information is crucial when designing for safety and effectiveness as devices that have not been designed to adequately take account of these factors have been shown to contribute to patient safety incidents (Boakes et al, 2008).

This study show the value of conducting early user research during medical device development and provides an example of how this research can be conducted in a way that is rigorous, yet also meets the practical needs of small developers. When choosing appropriate methods for data collection developers have a number of options available to them (Martin et al, 2006), and previous work by Garmer et al (2004) has shown that focus groups can be an effective discursive method. However, this approach was not appropriate for this study for two reasons. First, the operational requirements of the hospitals meant that it was not possible to bring a group of users together at the same time, and secondly, we wanted to ensure that participants felt able to freely discuss any negative aspects of their own or their colleagues' negative practice and felt that the participants may be reluctant to raise these types of issues in a group environment. Although different methods were used in these two studies, they both demonstrate how active involvement of users enables a broad range of requirements to be collected. We can conclude from this that a variety of research methods may be appropriate for early requirements elicitation but that whichever methods are used, researchers should ensure that users are able to talk freely and openly about the issues that affect them to ensure that as wide a range of issues as possible are identified.

This research demonstrates the value of performing user research early in the development process. Early elicitation of user views ensures that the findings can be incorporated into prototype design more easily and with less cost. In this case the developers believed that the research would save them the time and money of developing and testing an inadequate prototype.

From this research a number of observations can be made about the practicalities of performing user research within the field of healthcare. The most notable observation was that the well-being of their patients was the primary concern of all of the health professionals interviewed, with any difficulties or inconveniences they experienced being seen as very much of secondary importance. This goal-driven culture that is characteristic of the healthcare industry has important implications for device developers. For example, as clinical users will find ways to meet their goals even in the face of poor design, for example by the use of workarounds to increase efficiency and effectiveness, it may be difficult to accurately evaluate the performance of a device.

Asking health professionals about their clinical practice is a delicate issue. In complex work environments such as healthcare, workers are often required to make tradeoffs between thoroughness and efficiency to achieve their clinical goals and accessing this type of information can be challenging for two reasons. Firstly, the research has to be performed in a way that allows users to access and retrieve the necessary information and secondly, the respondent has to feel safe enough to disclose information that they may not normally acknowledge or discuss with management or other outsiders. Our experience was that care was needed at the beginning of each

interview to reassure the participant that the information collected would only be used to inform design of the new device and would not be passed on to anyone within the hospital. Once participants had been reassured however, they were generally open and willing to talk about the problems that they encountered. In addition, the simple process of conducting interviews outside of the clinical environment seemed to relax the participants allowing them to be more focused on the interview.

4.1 Study limitations

In this study, requirements elicitation was a one-off process that was performed to collect the information required to develop a prototype device. However, viewing the elicitation process as such a discrete task may be problematic. It is extremely difficult for prospective users or manufacturers to predict how a new product will be used in practice as the tasks involved will naturally evolve due to the presence of the device, a phenomenon that is known as the task artefact cycle (Carroll et al 1991). It should be acknowledged that needs elicitation should not stop when prototype production begins but should continue through an ongoing cycle of elicitation and re-design.

Another limitation of this study is the reliance entirely on interview data. Data generated through discursive methods such as interviews and focus groups will inevitably be restricted to what participants are aware of and what they can recall and articulate. However, in many cases users may not be aware of the deficiencies in their work environment or may not be able to articulate the details of the tasks they complete and the workarounds they employ and it requires specialist skills in interviewing techniques to elicit this type of information effectively (Sorrell and Redmond, 1995). Ideally the interviews would have been complemented by observation of the users completing tasks within the clinical context of use.

This study did not effectively establish user preferences for the design of the device, which was one of the objectives of the development team. This is likely to be due to the fact that the research was conducted in the very early stages of development. As the proposed new device was completely novel, the users did not have a prototype or similar device to stimulate ideas. It has been previously suggested that users find it difficult to suggest design ideas when unprompted (Hayes and Abernathy, 1980; Hamel and Prahalad, 1994) and that this is particularly true when considering novel and highly technology innovations (Veryzer, 1998; O'Connor and Veryzer, 2001). Defining design preferences may have been an unrealistic objective for user research at such an early stage of development. This suggests that, whilst medical device developers may understand the theoretical argument for user involvement, a greater awareness is required of precisely what sort of contribution users can realistically be expected to make at each stage of development.

5. CONCLUSION

This case study provides evidence of the value of conducting extensive user research during the early stages of medical device development. A broad and wide-ranging approach to data collection, followed by a focused analysis and reporting process produced data that the developers found accessible and actionable. We have demonstrated that user research can be performed in a way that is rigorous whilst also meeting the practical constraints of small medical device enterprises. As Buckle et al (2006) have identified, publication of this type of research is necessary if we are to persuade developers of the benefits of adopting user-centred principles.

Consulting potential users of the new device early on meant that a clear clinical need for the device was identified, the target populations defined and their requirements collected. This information made a clear and positive contribution to product development. When developing any new medical device the user and organisational requirements must be correctly specified. This will increase the likelihood of producing a device that is not only safe and clinically effective but is also easy and satisfying to use. However, these processes are also critical from a business perspective. Developing a new medical device is an expensive and high-risk undertaking. It is essential therefore that the correct device is developed, a device that is safe, meets the needs of users, fulfils a clear clinical need and, most importantly, improves the health of patients.

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REFERENCES

Amoore, J.N. and Ingram, P., 2002. Learning from adverse incidents involving medical devices. BMJ. 325, 272-275.

Boakes, E., Norris, B. and Scobie, S., 2008. The role of design and human factors in medical device patient safety incidents, in: S. Hignett, B. Norris, K. Catchpole, A. Hutchinson, S. Tapley (Eds.), Proceedings of Improving Patient Safety conference ‘From safe design to safe practice’, the Ergonomics Society, Loughborough, 2008, pp 185-189.

Bridgelal Ram, M., Grocott, P.R. and Weir, H.C.M, 2007. Issues and challenges of involving users in medical device development. Health Expectations. 11, 63–71.

BS EN 62366: 2008 Medical devices - Application of usability engineering to medical devices.

Buckle, P., Clarkson, P.J., Coleman, R., Ward, J. and Anderson, J., 2006. Patient safety, systems design and ergonomics. Appl. Ergon. 37, 491-500.

Carroll, J.M., Kellog, W.A. and Rosson, M.B. 1991. The Task-Artifact Cycle. In: JM Carroll (ed),

Designing Interaction: Psychology at the Human-Computer Interface, Cambridge University

Press, London.

Charmaz, K., 2000. Grounded theory. Objectivist and constructivist method. In: Denzin, N., Lincoln, Y. (Eds.), Handbook of Qualitative Research. Sage, California, pp. 509–536

Cooper, R. and Wootton, A.B., et al, 1998. Requirement capture: theory and practice. Technovation, 18, 497–511.,

Fasick, F. A., 2001. Some uses of untranscribed tape recordings in survey research. Public Opinion Quarterly, 41, 549–552.

FDA 2000, Guidance for Industry and FDA Premarket and Design Control Reviewers - Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, US Food and Drug Agency, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094461.pdf (Accessed Jan 2011)

Garmer, K., Liljegren, E., Osvalder, A. L. and Dahlman, S., 2002. Arguing for the need of triangulation and iteration when designing medical equipment, J. Clin. Monitor. Comp. 17, 105-114.

Garmer, K., Ylvlen, J. and Karlsson, I, C, M., 2004. User participation in requirements elicitation comparing focus group interviews and usability tests for eliciting usability requirements for medical equipment: a case study. Int. J. Ind. Ergonom. 33, 85–98.

Glaser, B., Strauss, A., 1967. The Discovery of Grounded Theory: Strategies for Qualitative Research. Aldine Cop, New York

Gosbee, J., 2002. Human factors engineering and patient safety. Qual Saf Health Care. 11, 352-354.

Hamel, G. and Prahalad, C.K., 1994. Competing For the Future. Boston, MA: Harvard Business School Press.

Hayes, R.H. and Abernathy, W.J., 1980. Managing our way to economic decline. Harvard Business Review. 58, 59–82.

IEC 60601-1-6: 2004. General Requirements for Safety of Electrical Medical Equipment Collateral Standard: Usability.

ISO 13407 1999 Human-centred design processes for interactive systems

Leape, L.L., 1994. Error in medicine, JAMA : J. Am. Med. Assoc. 272, 1851-1857

Liljegren, E., Osvalder, A. and Dahlman, S., 2000. Setting the requirements for a user-friendly infusion pump, in: Proceedings of the XIVth Triennial Congress of the International Ergonomics

Association and 44th Annual Meeting of the Human Factors and Ergonomics Association, 'Ergonomics for the New Millennium', Jul 29-Aug 4 2000. Human Factors and Ergonomics Society, San Diego, CA, United States, 132.

Lin, L., Isla, R., Doniz, K., Harkness, H., Vicente, K. J. and Doyle, D.J., 1998. Applying human factors to the design of medical equipment: Patient-controlled analgesia. J. Clin. Monitor. Comp. 14, 253-263.

Martin J. L., Murphy E, Crowe J. A and Norris B. J., 2006. Capturing user requirements in medical device development: the role of ergonomics. Physiological Measurement. 27, R49 -R62.

Martin, J. L., Norris, B. J., Murphy, E. and Crowe, J. A., 2008. Medical Device Development: The Challenge for Ergonomics. Appl. Ergon. 39, 271 – 283.

Martin, J L, Craven, M P and Norris, B J., 2005. MATCH: A new industry-focused approach to medical device development. In: Tartaglia et al, ed. Healthcare Systems Ergonomics and Patient Safety: Human factors, a bridge between care and cure, Florence, Italy. Taylor & Francis Ltd, London, pp. 294-297

Obradovich, J.H. and Woods, D.D., 1996. Users as designers: how people cope with poor HCI design in computer-based medical devices. Hum. Factors. 38, 574-592.

O'Connor, G.C. and Veryzer, R., 2001. The nature of market visioning for technology-based radical innovation. J Prod Innov Manag. 18, 231–246.

Sawyer D., 1996. Do it by design: an introduction to human factors in medical devices. US Department of Health and Human Services Food and Drug Administration (Center for Devices and Radiological Health)

Sorrell, J.M. and Redmond, G.M., 1995. Interviews in qualitative nursing research: differing approaches for ethnographic and phenomenological studies. J. Adv. Nurs. 21, 117–122.

Veryzer, R., 1998. Key factors affecting customer evaluation of discontinuous new products. The J Prod Innov Manag, 15, 136–150.

Wengraf, T. (2001). Qualitative research interviewing: Biographic narrative and semi-structured methods. London7 Sage Publications