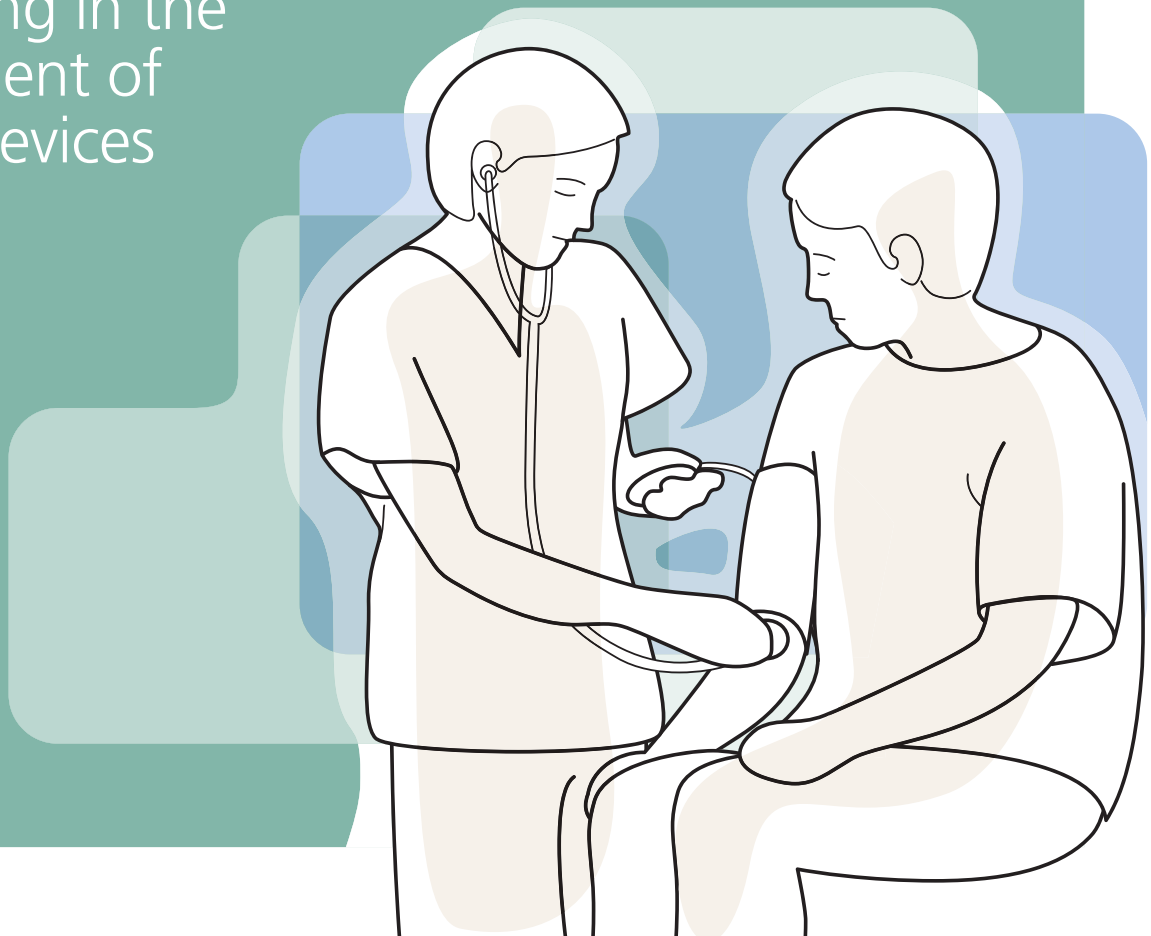
NHS

National Patient Safety Agency

National Reporting and Learning Service

Design for patient safety

User testing in the development of medical devices



About this publication

This guide is based on the publication *MATCH guide to meeting user requirements in medical device development*, produced by The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH; www.match.ac.uk).

This guide is one of a series of design publications produced by the National Patient Safety Agency (NPSA), which are available from www.nrls.npsa.nhs.uk/design

Contents

About this guide

This guide will help you to carry out user testing; a vital step in designing for patient safety. It will tell you what factors to consider when designing user testing; how to interpret the results; and the information that should be available for purchasers or users of the device so that they can understand the testing that has been carried out.

The user testing described in this guide is not a compulsory requirement for new devices; it is advice on how best to conduct the testing that is necessary to comply with existing regulations and standards.

This guide will help you to:

- plan a user testing study;
- identify the safety and usability issues relevant to your specific device;
- specify the design requirements for the safe use of the device;
- make decisions on which users to include in the testing and which methods to use;
- make decisions on what compromises may be necessary – a trade-off will usually have to be made between the benefits of extra user testing and the time and resources available;
- be aware of the ethical, and research and development requirements for user testing studies;
- collect necessary data to meet usability regulations and standards;
- produce documented evidence of your testing.

Who should read this guide

- Developers: This guide is aimed at anyone who is involved with medical device development, including designers, developers, engineers and marketing personnel.
- Procurement: The guide will also be of interest to people involved in the procurement of medical devices and equipment; either to carry out your own evaluations of devices prior to purchase, or to interpret the testing that has been carried out by the developers. It is vital that device developers are able to present the results of the testing that has been carried out in order to demonstrate the safety of the device and, where possible, to inform purchasing decisions.

What it does not do

- This guide does not take the place of the formal risk management approaches that should be adopted during medical device development, such as those specified in *BS EN ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices*[1], or in FDA guidance (see FDA, 2000). It also does not take the place of formal safety methods such as Failure Modes and Effects Analysis (FMEA) or hazard analyses. The methods in this guide are complementary to these approaches and should be used to identify and describe those hazards that would not be identified through such analytic approaches. It should be remembered that not all hazards will be identified by the analysis of incident reports or paper-based methods (FDA, 2000, Section 3.1.3).
- This guide does not provide guidance on how to undertake clinical evaluation, or trials or technical evaluations. Information on conducting clinical trials can be found on the Medicines and Healthcare products Regulatory Agency (MHRA) website (www.mhra.gov.uk).
- This guide does not provide guidance on how to evaluate specific devices. Rather, it provides generic advice that is applicable to a wide range of medical devices and which developers can customise to fit their particular device.
- The testing methods described in this guide do not replace the requirements of medical device regulations and standards. The relevant legal requirements and standards should be checked for your class of device.

1. Introduction

Medical device design and patient safety

The National Patient Safety Agency's (NPSA) Reporting and Learning System (RLS) received 24,207 reports of patient safety incidents involving medical devices between April 2006 and March 2007 (equivalent to three per cent of all incidents reported to have occurred during this time period).[2] Of these reported incidents, 303 incidents were classified by the reporter as resulting in death or severe harm to the patient.[3] Analysis of these incidents found that medical device design issues such as incorrect connections, identification issues and lack of feedback during use could contribute to patient safety incidents.[4]

Examples of design-related patient safety incidents reported to the NPSA

Poor positioning of controls:
'Unable to operate brake on operating table in maternity theatre this morning. Able to override with manual override but manual override is positioned such that it is difficult to access during surgery. Table regularly needs change in position during obstetric surgery'.

Difficulty in identifying and discriminating equipment (possibly due to poor labelling):
'Male patient was complaining of pain in lower abdomen, on investigation the catheter in-situ was a female size catheter length'.

Incompatible equipment:
'Laparoscopic set unsatisfactory 1. Wrong handles on grasping forceps 2. Irrigation handpiece leaking 3. Diathermy hook was not compatible with lead'.

Sizing issues and potential hazards as a result of not anticipating context of use:
'Patient to have an upper airway endoscopy and removal of vallecular cyst. I used a 6.0 MLT endotracheal tube. The surgeon inserted a gag, but it was too large, despite being the smallest adult size. When the surgeon removed it from the mouth, the patient was extubated because the tube had jammed in the slot in the gag'.

1 Introduction

There is an increasing appreciation of the links between the design of medical devices, poor usability, human error and patient safety.[5,6] To reduce the likelihood of error, medical device design must take account of the needs of all users, as well as the range of scenarios and contexts in which the devices may be used.[7] There are a number of human factors principles that can help accomplish this, such as understanding:

- users' expectations of how the device will work, their prior experience, their methods of working, the shortcuts they may take, and the other equipment with which the device will be used;
- the environments in which the device will be used;
- the culture within which the device will be used, such as access to training and maintenance.

Recognising the link between design, human error and patient safety, the regulatory requirements for medical devices are placing an increasing emphasis on usability and other user-related issues. For example, the US Food and Drug Administration (FDA) requires developers to apply the human factors principles that are described in this guide throughout the development of medical devices to identify, understand and address use-related hazards.[8,9]

Increasingly, standards are being used to demonstrate compliance with European medical device regulations and a number of new standards have been developed which specifically deal with usability:

- *IEC 60601-1: General Requirements for Safety of Electrical Medical Equipment* specifies the usability requirements for safety of medical devices;[10]
- The collateral standard requires a 'usability engineering process' to be used during device design. *IEC 60601-1-6* requires developers to keep comprehensive records to show that usability has been considered throughout the design process;[11]
- Another recent standard is *BS EN 62366:2008: Application of usability engineering to medical devices*, which specifies a process for developers to analyse, specify, design, verify and validate usability as it relates to the safety of medical devices.[12]

In light of the move of medical device regulation and standardisation towards improved usability of medical devices, the NPSA has produced this guide to help the developers, manufacturers, purchasers and users of medical devices carry out user testing in the development (or procurement) of medical devices. Including user testing in the design development process has long been shown to contribute to better and safer design, particularly in fields such as drug delivery and anaesthesiology[13,14]. This guide introduces some of the evaluation methods that are specified in the standards and regulations above.

As well as improving safety, user testing can have many additional benefits, such as improved usability, comfort, effectiveness, ease of use, improved learning, reduced training needs, hygiene requirements, maintainability, servicing, storage and labelling. Attention to factors such as comfort, aesthetics and portability will improve the patient experience[15] and may also improve patient compliance with treatment regimes[16]. The methods described in this guide will help you achieve this.

Know your users

All medical devices will have a wide range of users. These are not just the intended operators of a device (for example nurses, as the intended users of an infusion pump), but include all the people that will come into contact with it, either as part of their professional or caring activities, or by receiving treatment or care from the device as a patient. Identifying *all potential users* should be one of the first tasks when developing a device. Users can include:

- healthcare professionals such as doctors, nurses, physiotherapists, Operating Department Practitioners (ODPs), etc;
- other professionals who will come in contact with the device, such as those who maintain it, clean it, transport it, and train people to use it;
- social care staff, carers, parents and other family members;
- patients.

Understanding how and where your device will be used

Devices are never used in isolation, but are part of a complex system of healthcare delivery. A holistic or systems approach to development should be taken where a device is studied in relation to the real context and situations in which it will be used. For instance, the availability of appropriate connectors, consumables and devices being used in hospitals, mobile clinics, ambulances and/or at home will affect how safely they can be used.

Workplace factors such as the physical environment in which the device is used, and the working culture, will affect both usability and safety. Testing should endeavour to investigate how well the design will function under the range of conditions in which it will be used.

This can include assessing the effects of:

- lighting;
- temperature and humidity;
- noise;
- storage;
- the working space around the device;
- how often devices or equipment are moved and how;
- the number of similar devices that may be in use and how these differ in design;
- what tasks are allocated to specific staff and whether devices are used by more than one user at one time;
- whether staff have to multi-task and are subject to interruptions;
- the systems used to order, maintain, clean and store devices;
- access to training, instruction manuals and procedural guidance.

Testing in real, clinical environments and with real patients will often be difficult due to access and ethical issues. Simulation can be an alternative, but it is vital that the key contextual issues for safety are fully represented in the simulated environment.

Example: Involving users to improve device safety (Lin et al, 1998)[17]

One type of medical device that has been associated with risks to patient safety is infusion pumps. This is often due to poorly designed user interfaces which place excessive cognitive (mental) strain on the user during programming[18]. This paper describes a user-focused study that redesigned an infusion pump with the aim of reducing errors with this device, and therefore reducing the risks to patient safety.

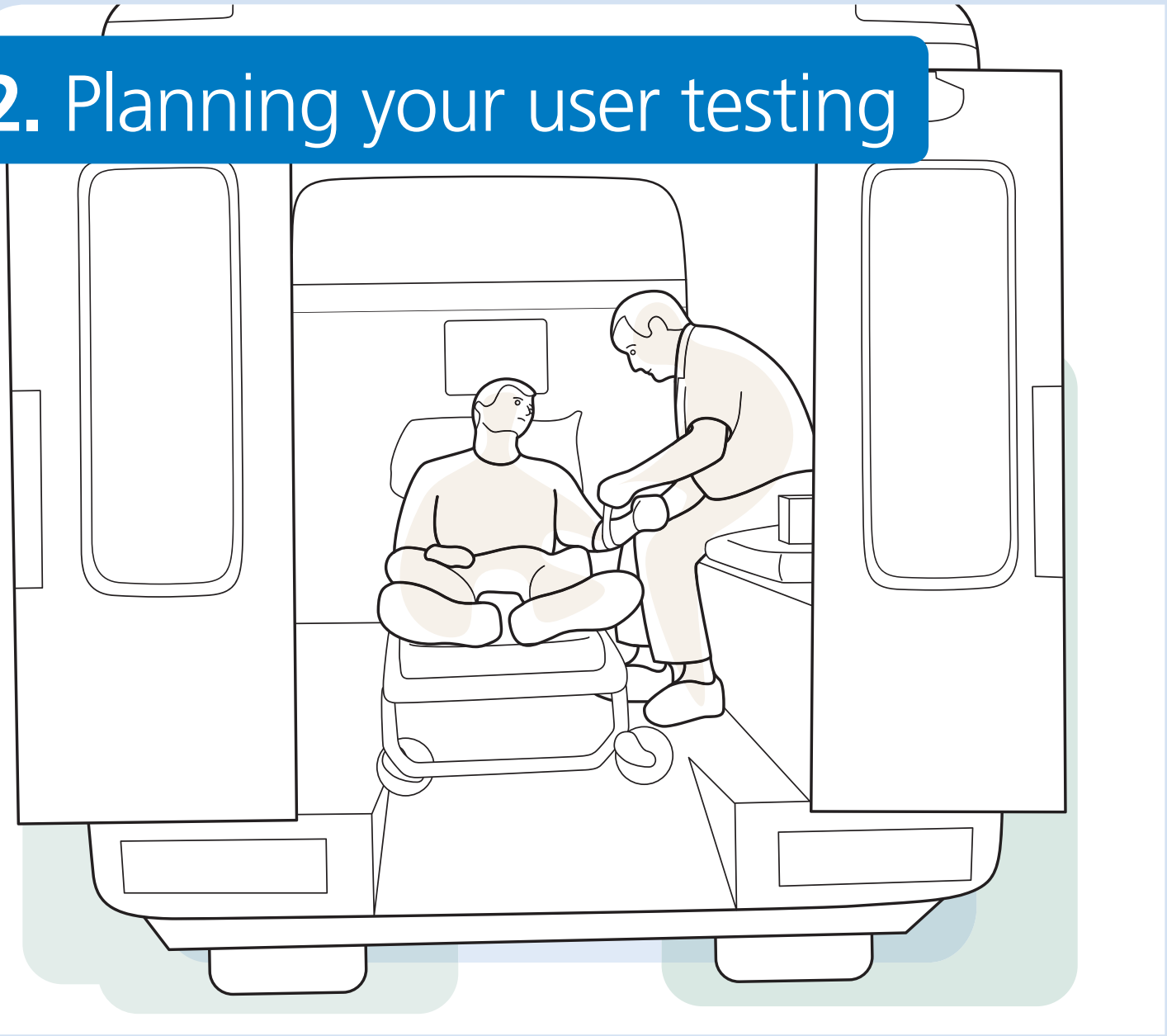
The authors used **Cognitive Task Analysis*** to identify the psychological requirements for programming the infusion device. This involved observations of the device in use during bench tests where expert users used the device to perform certain tasks. They found a number of problems with the user interface which resulted in a high cognitive load being placed on the user. These problems included the fact that no feedback was provided to users during programming, users had to remember what data had been entered and this resulted in errors. In addition, the user interface was found to require complex programming sequences and did not provide users with a way of detecting any errors made whilst inputting data or recovering from such errors. The authors concluded that using this device in a high pressure working environment such as an intensive care unit could result in errors which could have significant implications for the safety of patients.

The device interface was re-designed to address the faults and the human factors approach was continued in the evaluation of the new interface. In order to evaluate whether the Cognitive Task Analysis and subsequent re-design had been successful, **Usability tests** were performed to compare the new and old interfaces. A number of users who had no direct experience of either interface were asked to perform a programming task. The new interface was found to be faster to program (improved efficiency) and it also resulted in lower mental workload ratings and fewer errors (improved safety).

This study illustrates the importance of considering the environment in which the device will be used; the authors recognised that operating the device in a stressful environment such as an intensive care unit would increase the likelihood of errors. It provides an effective rationale for identifying the points in the task where the user required extra support and providing this in the design of the new device.

*See 'User testing methods lab' on pages 38 to 59 for discussion of terms in bold.

2. Planning your user testing



This section describes the key steps in planning your user testing. Working through the following list of questions can also help (a checklist of these questions can be found in the Appendix on page 60).

1. What do we want to find out? e.g.

- Which errors are likely?
- What contributes to the error?
- When will they occur (start of the task, calculations, disposal, during transfers)?
- Will they be detected? Can they be recovered?

2. Why do we want to know this information? e.g.

- To demonstrate safety and minimise the likelihood of errors occurring
- To identify which users are likely to make errors and will need extra support or training
- To identify what warnings and instructions are needed, if the risks cannot be removed or mitigated

3. Who are the best people to provide this information and take part in the testing?

- How many people should take part in the test?
- What is the optimum mix of participants and how do you ensure a representative sample?
- If they are not available, who are the next best?
- Are there any patient or professional groups that could collaborate in this study?
- Is any of this information available already (e.g. from within the NHS, from published literature or from anthropometric/ergonomics guidelines)?

4. When is the information needed?

- If the next step of development has to begin in 12 months, it will be difficult to conduct the research in the NHS because of the need to obtain ethical and R&D approval.

5. **How much** money is available to conduct this testing and who will fund it?

6 . **Where** should the research be performed?

- Does it have to be performed in the clinical environment?
- Or could it be conducted outside: in the community, a simulated environment, over the internet?

7. **How** do I do the testing?

- The answers to the above questions will help to pick the most appropriate methods and users.

Decide on the aims of the study

It is important to have clear aims for the testing. There may be a number of objectives in any one study. When interpreting the results, it is important to acknowledge that decisions and compromises may need to be made about competing criteria, for example, in some cases, improving the safety of a device may increase cost.

Examples of study objectives

- Identify 'target users' or those users most likely to need support
- Define 'normal' and 'abnormal' use
- Test the scope, clarity and effectiveness of a user manual
- Reduce human error/improve safety
- Decide what support users will need and identify training needs
- Identify compatibility issues with other equipment
- Measure clinical performance of a device
- Improve usability

Identify the users that should be included in the testing

Identifying the different groups of users for a device is known as 'defining the user population'. Different groups will have different needs and requirements as well as different levels of expertise and experience. Depending on the aims of the work, it may be necessary or appropriate to study representatives of all, or only some, of these potential groups. The following will help you decide on the people that should be included in your user testing:

1. Ensure a representative sample of each user group

Care should be taken not to view any one user group as a collection of similar individuals with the same needs, lifestyles or requirements. Within each user group (patients, clinicians, etc), there will be significant variations between individuals according to skills, age, ethnicity, type and degree of illness, physical and mental characteristics, etc. It is not enough for instance to identify the users of a device as diabetic patients or nurses, and assume that all of these individuals behave in a similar way. But how do you decide what a representative sample is?

Examples of user characteristics

- Age
- Gender
- Ethnicity
- Socio-economic status
- Clinical speciality
- Educational background
- Amount and type of training
- Physical characteristics
- Religion/cultural background
- Competencies
- Training
- IT skills

The answer is to identify the **key** characteristics that will affect how the device is used. For example, if the device being designed will aid the process of taking blood, it will be ideal to include representatives from all of the groups that perform this task, i.e. phlebotomists, nurses and doctors, and then to

consider their skills, training and support in this task, and where it will be performed. But different characteristics will be relevant for different cases. For example, IT skills are unlikely to be relevant for this device. However if the device being developed had an interactive interface, it would be important to study a group of users with different levels of general experience and expertise in IT and specific experience with devices with similar interfaces.

Identifying users

In the case of a new wheelchair design, potential users will include patients (wheelchair users), carers, relatives and hospital staff. If the aim of the user testing is to investigate chair comfort, only the wheelchair users themselves need to be involved. However, if the aim is to look at how easily the chair can be manoeuvred, in addition to the wheelchair users themselves, testing should also include family members and carers, hospital staff such as nurses, porters and ambulance staff, and anyone else who may interact with the wheelchair.

2. Balancing the views of different users

Bias is an important consideration when carrying out user testing. Including too many of one group of users and not enough of another means the results will be overly inf uenced by one group. This can also happen if one group of users feels more comfortable expressing their views. It is important to consider this if talking to multiple users at one time (e.g. in focus groups); the professional boundaries and hierarchies that can exist for healthcare staff may mean some staff groups, or junior staff, may feel unable to speak up.

3. How many users should be included?

The number of users to include will differ depending on the type of study. Studying too small a number of users will mean that it is unlikely the data collected will be representative of the user group as a whole. Although the general view is the more the better, there will also come a point when studying more users will not result in any new information or will not increase the comprehensiveness or representativeness of the data.

In most instances there will be constraints on the amount of money and time that can be spent on user testing, and a compromise will have to be made between including more users and minimising the cost and time spent on the testing.

The number of users that you study will depend on the aim of the testing and the methods used. For **Usability tests** (where users perform typical tasks with a new device whilst being observed and listened

to, see page 46 for further information), research in the area of human-computer interaction suggests a rough guide of five users for collecting initial or general opinions of users[19]. If the aim is to collect more specific or critical information however (e.g. when looking at safety), 10 users is the minimum number for informal testing (when statistical significance will not be measured). For formal testing where statistical significance will be measured, the minimum number is 15 to 20[20, 21, 22].

It is important to note that these guidelines on sample sizes do not apply for clinical trials when statistical advice should be taken on the number of participants necessary to demonstrate eff cacy of new device.

In addition, user testing for safety should not take the place of appropriate risk analysis as it may not identify errors that may be uncommon but potentially signif cant.

It is important to remember that these minimum numbers are for each *specific group* of users e.g. nurses, patients. In the example of developing a new aid for general orthopaedic surgery, there would be a number of user characteristics that may affect how this device would be used, e.g. clinical experience and clinical specialty. It may be helpful to construct a matrix to help formalise the thinking behind this. Figure 1 shows that in this case the researchers decided that the body area operated on by the surgeons may affect the way this device is used. They wanted, therefore, to include users who dealt with each of the four major types of orthopaedic surgery: hips, knees, shoulders and spine. Experience was another factor that the developers believed may affect the needs and opinions of the users, and therefore they sought to include equal numbers of 'experienced' and 'less experienced' users, defined in this case as more or less than five years' experience of performing orthopaedic surgery.

It can be seen that in this situation the total number of participants would be 40. If another user characteristic was added to this, such as the type of hospital that the users work in (large versus small for example) then the matrix could be expanded to include this and the sample would increase from 40 to 80.

Figure 1: Example matrix for calculating sample size

	Clinical experience	
Type of orthopaedic surgery	> 5 years	< 5 years
Hips	5	5
Knees	5	5
Shoulders	5	5
Spine	5	5

For methods such as **Questionnaires**, which are less resource-intensive, larger groups can be included at relatively little additional cost.

4. Use 'real' users or 'proxies'?

Whenever possible, the 'real' users of a device should be included in user testing, i.e. the people that will either use the device or have it used to treat them. There may be situations, however, when it is not possible to include real users, for example certain types of patients such as children, vulnerable adults or very sick patients. In these cases a suitable proxy (sometimes known as surrogate) may be used instead. Proxies should be people who are likely to be able to provide the most accurate information on users' opinions. This may be a parent or other relative, a carer or a healthcare professional.

Developers should be aware of both the usefulness and limitations of using proxies to capture user data. For instance, whilst it may be attractive to keep testing in-house if a device is commercially sensitive, there are validity issues associated with involving people who do not have the characteristics, experience or knowledge of the ultimate users of the device, or may have a vested interest in the development of the device.

Potential pitfalls of proxies:

Using a clinician to obtain the requirements of their patients

This can be an attractive option in many ways as clinicians tend to deal with a large number and wide range of patients, and therefore can give an opinion on the clinical situation, needs and lifestyles of these patients. However, they may see their patients infrequently and for very short periods of time and focus mainly on clinical issues. As a result, although they will be able to provide a detailed and accurate account of their patients' clinical details, they will be much less qualified to report on issues such as the lifestyles of patients, their feelings about their condition or how it affects their everyday life. If it is these types of issues that are of interest, it will be more appropriate to use other proxies such as relatives, carers or perhaps individuals who have suffered from a condition previously but have now recovered.

Using a senior user to obtain the requirements of all users

Asking a senior member of a user group to comment on requirements may appeal as they are likely to have extensive experience of working in a number of different environments. For example, when designing a device to be used by nurses, a group of senior nurses could be seen as being the best people to survey. However, senior users may find it difficult to report on the requirements and opinions of less senior staff or newly-qualified staff. They may not be able to accurately predict the frequency or type of error they make or the sort of training they require. They may also base their opinions on how things happened in the past rather than on current clinical situations.

A good practice example of using proxies

Zhang et al (2003) [23] successfully involved proxy users during an evaluation of an infusion pump. The aim of the evaluation was the early identification of initial usability issues, so that these could be fixed before the device was put through a more rigorous evaluation with a sample of real users. The device was tested against a number of usability rules or heuristics, which included issues such as, 'users should be informed about what is going on with the system through appropriate feedback and display of information'.

Rather than using the real clinical end users in this early testing, which would have been time consuming and expensive, the evaluators were experts in designing human-computer interfaces. The evaluators performed a 'walk-through' of the interface by performing a number of tasks with the device with the usability heuristics in mind. Each evaluator recorded which heuristics had been violated and how severe the violation was.

The authors decided to use proxies at this stage as the issues and problems they were looking to identify were likely to be common to many types of user interfaces. Fixing these types of problems at this stage would mean that when the device was evaluated by a sample of the target clinical users they would not be distracted by these and instead could concentrate more on issues such as whether it was easy and safe to use, in a real-use context.

5. How to identify and recruit participants

Finding participants for user testing can be difficult. Broadly speaking, there are three main routes to accessing participants: from within the NHS, from organisations outside of the NHS such as patient groups or professional bodies; or lay people.

From within the NHS

One of the primary benefits of accessing participants from within the NHS is that a wide range of different users can be accessed. For example, if interested in surveying diabetic patients about a current device, involving a hospital diabetes clinic will allow all patients attending that clinic to be approached. This type of approach makes it easier to include a wide range of participants who are likely to vary according to age, ethnicity, educational background, socio-economic group, physical characteristics, etc.

Access to NHS staff can vary considerably between and within trusts, depending on the interest in the research project. Some clinic managers may be keen to participate in research and will allow their staff to participate in studies during working hours, which may mean that more people are willing to take part. Conversely, many others may be unwilling or unable to release NHS staff from work because of operational requirements; therefore if staff wish to participate then they have to do so in breaks or in their spare time.

Before any NHS staff or patients can be approached to take part in any research, Ethical and Research and Development (R&D) permission must be obtained from

the relevant authorities, and this can be a lengthy and time consuming process (see page 24).

Patient groups

Patients can also be accessed through a patient group that looks after the interests of people suffering from a particular illness or condition. In the UK there is a network of Patient Participation Groups (PPGs) which look after the needs and interests of the local community. Most of these are situated within primary healthcare, specifically GP surgeries and health centres. All of these PPGs come under the umbrella of The National Association for Patient Participation (www.napp.org.uk). Although ethical approval from the NHS will not usually be required to conduct this type of research, all studies involving human participants should be conducted in accordance with basic ethical principles such as informed consent and respect for the confidentiality of participants. It is also essential to comply with the *Data Protection Act 2000* and the Caldicott Principles when processing identifiable data.

Lay users

In some cases the only people available to developers for user testing may be lay people; individuals who cannot be classed as *trained* or *expert* as either a patient with a particular condition, a carer or healthcare professional. There are significant risks associated with including such people in the development of a medical device as they will often lack the unique experience, characteristics or knowledge of the potential users of the device.

There may be some occasions when it is appropriate to involve members of the public in user requirements research, for example:

A company is developing a new design of asthma inhaler and wants to identify the shortcomings of designs currently supplied by the health service. As these types of devices are used by a very large number of people, conducting a survey of people from outside of the NHS or a patient group may be acceptable. Although, if repeated access to people with asthma were required, for evaluations of prototypes for example, then it may be appropriate to approach a group such as Asthma UK to collaborate.

Applying for Ethical and Research and Development (R&D) approval

Before beginning any research that involves NHS patients or staff it is essential to obtain approval from the appropriate authorities. Ethical and R&D approval must be obtained before conducting any research that involves any of the following:

- NHS patients/service users (including NHS patients treated under contracts with private sector institutions);
- relatives/carers of patients and users of the NHS;
- use of/access to NHS premises or facilities;
- NHS staff, recruited due to their professional role;
- healthy volunteers, where a drug or device is being tested within the NHS.

In some circumstances, ethical approval is a legal requirement even where the research is conducted outside the NHS. This includes any clinical investigation of a medical device subject to the Medical Devices Regulations. Detailed guidance on legal/policy requirements for ethical approval can be found on the National Research Ethics Service (NRES) website at www.nres.npsa.nhs.uk/applications/apply/

Under the Department of Health's Research Governance Framework for Health and Social Care, management permission ('R&D approval') is required from each NHS organisation which will be involved in the research, prior to starting the research in that organisation. If the person who will conduct the research is not an NHS employee, they will usually have to have an honorary contract with the NHS trust before they can begin the study to allow them onto NHS estate. R&D approval usually involves the NHS trust agreeing to undertake the costs of using NHS resources and providing indemnity for negligent harm.

Applications to Research Ethics Committees and NHS R&D offices should be completed using the Integrated Research Application System (IRAS). More information and advice can be found on the IRAS website: www.myresearchproject.org.uk/

If the research project involves a clinical investigation of a non-CE marked medical device, or a CE-marked device that has been modified or is being used for a new purpose, then the Medicines and Healthcare products Regulatory Agency (MHRA) must also be notified and Notice of No Objection obtained. The MHRA is the UK government agency responsible for ensuring that medical devices are safe and effective, and comply with Medical Device Regulations. Their website should be checked for updates on medical

device regulations: www.mhra.gov.uk. Applications to MHRA Devices Division can also be generated using IRAS.

Applications for ethical approval, R&D approval and, where applicable, MHRA Notice of No Objection, may all be made in parallel.

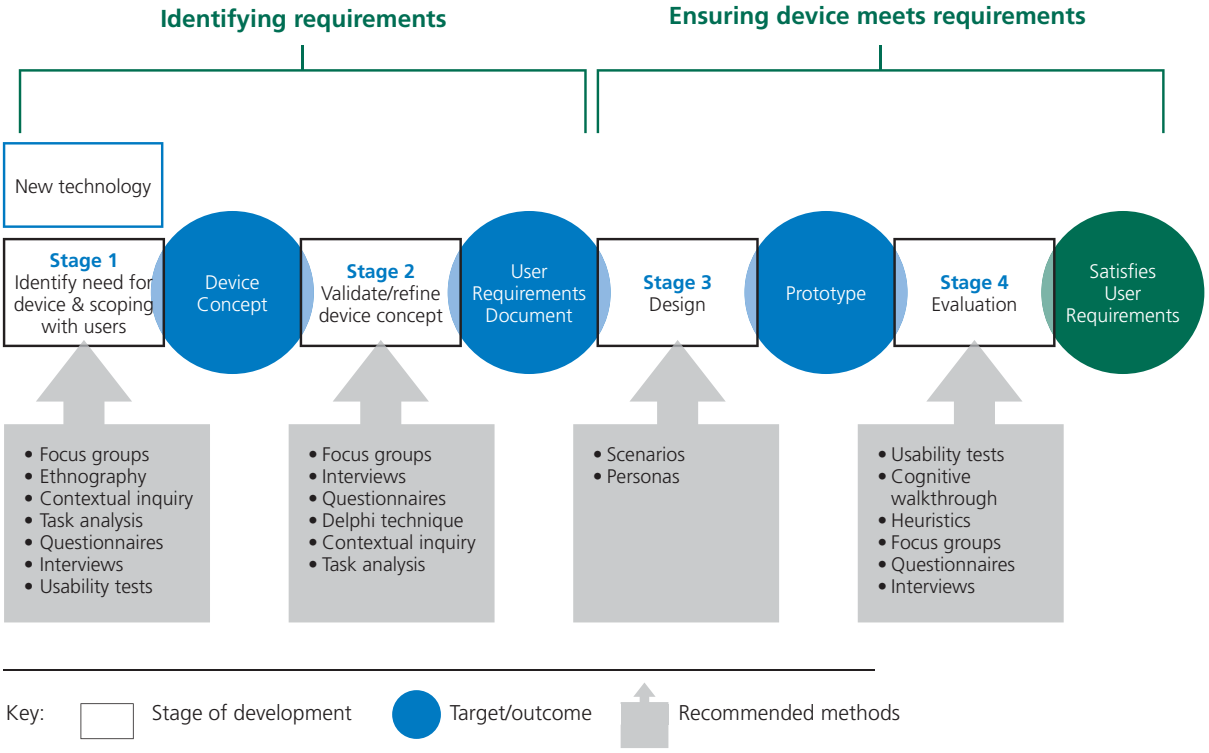
3. User testing inputs into the device development pathway

This section covers how to incorporate user testing into the pathway of device development. The issues that should be considered at each stage are identified here, as well as the methods that could be used.

Figure 2 illustrates a typical device developmental pathway; this suggests the stages of device development and how user testing can map onto each stage. Broadly speaking, the first two stages can be seen as identifying the requirements for the device, and the second two stages as ensuring that the device meets those requirements.

The entry point into this pathway will vary. For example, the need for a new or improved device may already be known and development may move directly to the validation stage, but most of the steps and processes in this figure will be relevant at some point during development.

Figure 2: User testing inputs into the device development pathway



STAGE 1

Identifying the need for the device and scoping with users

The aim of user testing at this stage is to establish first of all whether there is a need for a device or a revised design. There are many reasons for initiating the development of a new device, including: improved patient outcomes; making a task quicker, easier or more cost effective; improved service quality or safety.

This work will normally be small-scale involving a relatively small number of users. Testing at this stage should be open-ended in nature and may involve studying:

- an entire work environment including multiple users (e.g. an operating theatre);
- the working pattern of particular clinicians (e.g. shadowing particular groups throughout their working day);
- the experiences of a particular patient group as they progress through the healthcare system.

If some information is already known about the potential device, a more focused study may be appropriate. For example, a surgeon may have reported a problem with a particular procedure and identified a need for a device to solve it. In this case, a detailed study of that procedure would be required, ideally including a range of different users.

Methods

A variety of different research methods can be used during this stage of development. For example, **Ethnography*** may be used for scoping, open-ended research; **Task analysis** and **Usability tests** for more focused studies; **Contextual inquiry, Focus groups, Interviews** and **Questionnaires** may be used in both types of study (see 'User testing methods lab' from page 38 for a discussion of these methods). As with all user research, ideally more than one method should be used in order to gather different types of data. For example, an observational technique such as contextual inquiry may identify a number of issues which can then be investigated further, validated and refined via a discussion method such as a focus group.

Possible outcomes

Possible outcomes are the identification of a safety issue, or how a new or improved device could make a positive contribution to the healthcare system. For example, a clinical procedure that is currently very time-consuming or has been identified as a high-risk with potential impacts on patient safety.

*See 'User testing methods lab' on pages 38 to 59 for discussion of terms in bold.

Identifying a need for a new or improved device: An example of good practice

Coble, Karat and Kahn, 1997[24]
This paper describes an ergonomics approach to the development of a new medical IT system. The authors reported that previous systems had not been widely adopted by the target users; therefore the aim of this study was to identify what the users' requirements were so that a system could be designed that would meet these.

To identify the requirements for the system, a **Contextual inquiry (CI)** was performed. This consisted of approximately 300 hours of observations of the target users in a variety of clinical situations. Specifically, the authors wanted to understand exactly what information the users required at each point in their work tasks and to identify the optimum way of accessing this information. Once the data had been analysed and the User Requirements Document had been produced, users were consulted again to review and prioritise more than 500 requirements that had been identified and also to check that the developers had correctly interpreted their requirements. The authors report that this process was crucial in developing an accurate User Requirements Document that could be successfully translated into the functional specification required to develop a prototype device. The ergonomics approach was continued throughout the development of this device with usability tests being used to evaluate a number of prototype iterations.

For many development projects it would not be possible to conduct a research project as extensive as this because of the time and money required. However, the general principles of this approach can be adopted by medical device developers wishing to identify areas of unmet need but on a smaller scale. Observing users as they perform tasks whilst in the context of use can be extremely useful at identifying tasks that are currently performed in an inefficient, dangerous or otherwise sub-optimal manner. Listening to users describe what they're doing, and asking them questions about the reasons why, can identify ways in which a new or improved device could improve the task.

Naturally the more time spent observing (different) users, the more likely it will be that the conclusions drawn will be representative. However, it is possible to get an understanding of tasks from just a small number of observations, although care should be taken to validate any assumptions with a larger group of users before basing design decisions on them.

Validate/refine device concept

User involvement at this stage is critical in order to ensure that the device produced is clinically effective and safe. Additional benefits include a well-conceived and well-designed device that will help healthcare professionals carry out their work effectively and efficiently as well as improve health outcomes where patients have a better quality of life and retain independence and dignity.

The aims of user testing at this stage in development are to gather information on:

- The attributes of the potential users. This will include the mental models that users have of how they think the device will work; how they use instructions; patterns of errors; and the type of support they may need. This will help decisions to be made on the training requirements for the device. When considering who the users are, this should include not only the 'target users' (who the device is actively designed for) but also any other individuals who may also happen to use the device, and in particular should identify those users most at risk of making errors.
- The working patterns of the potential users. As well as potential errors, this will identify the factors that may prevent uptake of the device; such as the need for a device to be a particular size or weight, to be portable, to be compatible with certain other devices or to include certain accessories.
- The clinical pathways and the healthcare system that the device will be part of. This will be required to identify the situations that will constitute 'normal intended use'.
- Importantly for safety, the ways in which the device will be used outside the 'intended' use must also be identified. It must be recognised that users will regularly adapt the way they operate devices to create shortcuts (which they may see as ways to save time or increase efficiency or effectiveness) and anticipating these is a vital component in designing for safety. These 'off label' ways of operating devices are often easy to predict and should be accounted for by the design.
- User opinions on device design. As well as providing opinions on designs that developers have suggested, users may also come up with innovative and useful ideas on device design and should be encouraged to do so.

What constitutes and can be defined as *normal* use and the risks associated with this are important issues when seeking regulatory approval for a medical device. Documenting these in the *usability engineering file* is required by the standard *IEC 60601-1-6.*[11] Devices that have a user interface may require additional research at this stage to elicit specific information on this aspect of design.

Testing at this stage will allow developers to identify the factors that will contribute to a successful device. These are often called user requirements. Once the critical issues have been identified, this will allow the developers to decide on the methods to use during the evaluation stage. Examples of these criteria could include:

- Programming the device must take no more than 90 seconds;
- The device will need to be easy to learn to use for a wide range of users including those with no professional training;
- The device must be compatible with devices x and y;
- The device must be usable by people with severe arthritis.

Methods

The choice of methods to be used at this stage will be influenced by whether you are interested in capturing the views of individuals or the views of a group.

The interaction that results from a group can result in a large number of opinions and experiences, as participants bounce ideas off each other. However, in these situations an individual may find it difficult to express an opinion that conflicts with the rest of the group.

Studying individuals may be more appropriate in circumstances where a delicate or personal topic is being discussed, or when there are practical problems with getting a group of users together at the same time. Methods such as **Focus groups** and **Delphi technique** are useful in obtaining a consensus opinion from a group and the Delphi technique does not require the participants to have face-to-face contact. Techniques such as **Interviews** and **Questionnaires** can gather opinions of individuals. Developers may wish to complement this type of investigation by performing a **Task analysis** or some type of observational study of the task or environment in order to access information and contextual factors about the use of the device that users may not be able or willing to articulate. **Contextual inquiry** is an effective method for identifying information about dangerous or inefficient practice that users may have become so familiar with that they aren't consciously aware of them.

Outcomes

The outcome of the research at this stage in development should be a *User Requirements Document*. This will include the information necessary to produce one or more prototype designs, as well as details of potential errors that may result from using the device. Developers will be able to draw conclusions such as: the device will need to be no bigger than x; operable by y and z groups of users without training; and will need to be compatible with devices a, b and c.

At this point, some difficult design decisions may have to be made. For many devices the potential users will be a wide variety of people, potentially including both professional and lay users and with differing specialties, skills and abilities. Even within user groups that appear to be more homogenous, individuals will have differing work patterns and habits, not to mention attitudes, opinions and preferences. Once the requirements of all users have been identified therefore, conflicts will have to be resolved. This will require decisions to be made on who the *primary users* should be and those who may be more vulnerable to error: in other words, those users whose needs should be prioritised during design. However, designers must also be mindful that this is not at the expense of the other clinical and non-clinical people who will also use the device.

Validating a concept for a new device: an example of good practice (unpublished)

A company developed a concept for a new medical device using a new technology that they have developed in house. Following discussions with a small number of clinical contacts from a local hospital, a concept for the device was developed. This was that the device would provide an image of patients' blood vessels and would be an aid for taking blood samples and delivering intravenous drugs, making these procedures more successful, quicker and less painful. The primary target clinical users of the device were thought to be phlebotomists, and the target patients to be the general population attending a hospital or their GP surgery for a blood test or for a drug to be administered intravenously.

To validate the concept for the device, a brainstorming session was conducted to identify all potential user groups of the device. Face-to-face, semi-structured interviews were then conducted with representatives of each of these at two NHS hospitals. The objectives of the interviews were to investigate:

- what difficulties are currently encountered during vascular access;
- how often these difficulties occur and the consequences for patients, clinicians and the hospitals;
- how a device for locating blood vessels might contribute to patient care;
- the barriers that may prevent such a device being used in clinical practice;
- design preferences for the new device.

The results of the interviews significantly changed the concept for the device. Previously, the developers thought that the primary users would be phlebotomists, but the interviews found they did not require an aid for locating and accessing blood vessels.

This group reported that they encountered very few problems and the problems that did occur did not have serious consequences for either the patient or themselves. Other groups however, who were previously thought of as being likely to be just occasional users of the device, expressed a significant need for the potential new device. The interviews revealed that they encountered a large number of problems when locating blood vessels and that these often had serious implications, including delays to essential treatment (and increased costs as a result of this), as well as significant distress and pain to patients.

The developers reported that consulting users in this way at an early stage in development was invaluable in helping them to refine the concept for their device and potentially saved them the cost (and time) of developing and evaluating an inappropriate prototype.

Design

Device design should be based upon the *User Requirements Document* produced in Stage 2 of development and will result in the production of one or more prototype devices which can then be tested in an iterative manner. In each cycle the prototype is refined and improved and then tested. The testing results are then used to further refine the design, which is then subjected to further testing until it meets a certain pre-determined standard.

There are numerous examples of how the design of medical devices can lead to potential use errors (adapted from: *BS EN 62366: 2008 Medical devices – Application of usability engineering to medical devices*[12]):

Example of design issue	Possible resultant use error
Two push-buttons on a control panel are too closely spaced	The user inadvertently presses the wrong button
Two icons on a device control panel look too similar	The user misinterprets the icon and selects the wrong function
A user interface requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion	The user enters an incorrect sequence and fails to initiate infusion
An infusion pump displays a misleading 'Open Door – Reset' message when there is air in the infusion line	The user repeatedly opens the door and presses the reset key instead of clearing air from the infusion line
The user-adjusted high and low alarm limits on a heart-rate monitor are not continuously displayed	The user fails to detect a dangerous increase in heart rate because alarm limit is set too high, it is not displayed and the user is over reliant on the alarm system
The typical force that is used to secure connectors exceeds the breaking strength of a catheter connector	The user cracks the catheter connector when tightening

There are also a number of simple design principles which can be followed to ensure improved usability (see box on this page).

The type of prototype produced in each cycle of design will depend upon the type of evaluation to be done. In the early stages a low-fidelity, or even a virtual, prototype should be considered to test the basic concept for the device. This approach has the benefit of being quick and inexpensive, and also allows multiple designs to be evaluated at the same time. As the device moves through the cycles the design will develop into a fully functional, high-fidelity prototype.

Further reading

- Department of Health. *Design for Patient Safety: A system-wide design-led approach to tackling patient safety in the NHS*. 2003. Available at: www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59881
- Sawyer, D. *Do it by design – an introduction to human factors in medical devices.* US Food and Drug Administration. (1996).

Design rules of thumb for improved medical device safety (adapted from Sawyer, 1996):[7]

- Make design as consistent with user expectations as possible.
- Design work environments, controls and displays around the basic capabilities of the user, such as strength, dexterity, memory, reach, vision and hearing.
- Design well-organised and uncluttered control and display arrangements.
- Ensure that the association between controls and displays is obvious. This reduces the user's memory load.
- Make labels and displays so that they can be easily read from typical viewing angles and distances.
- Design control knobs and switches so that they correspond to the conventions of the user population (as determined by user studies and existing medical device standards), e.g. turning a dial to the right = increase/high.
- Use colour and shape coding, where appropriate, to facilitate the rapid identification of controls and displays.
- Colours and codes should not conf ict with universal industry conventions.

- Make sure that controls provide tactile feedback.
- Be consistent and unambiguous in the use and design of headings, abbreviations, symbols and formats.
- Always keep users informed about current device status.
- Provide immediate and clear feedback following user entries.
- Design procedures that entail easy-to-remember steps.
- Give users recourse in the case of an error.
- Do not over use software when a simple hardware solution is available, e.g., a stand-alone push button for a high priority, time-driven function.
- Consider using dedicated displays or display sectors for highly critical information. In such cases, do not display other data in these locations.
- Cables, tubing, connectors, levers and other hardware should be designed for easy installation and connection. If properly designed, incorrect installation should be impossible, extremely difficult, or so obvious that they can be easily detected and remedied.
- User instructions should be understandable, and warnings conspicuous.
- Positive locking mechanisms are desirable whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.
- Consider the wide spectrum of operating environments when designing and testing alarms, including other equipment in simultaneous use.
- Make sure that both brightness contrast and colour contrast are sufficient for legibility under a variety of lighting conditions.
- Design alarms to activate immediately following the onset of a critical problem. It is important that alarms identify the source of the problem.
- Design alarms so that when they are silenced, they remain silent temporarily. They ideally will have visual indicators to indicate status and a mechanism for querying the reason for the alarm.

STAGE 4

Evaluation

The evaluation of a new device should be iterative and involve a number of cycles of evaluation, re-design and further evaluation. Evaluation of a prototype device will not only involve safety and usability issues, but will also include critical factors such as functionality, clinical efficacy and cost viability. It may be tempting to delay user testing of a prototype until a high-quality, fully-functional prototype has been developed. However, leaving user evaluation until late in the development process can lead to problems. For example, if a device has already been CE marked or met other regulations, changing seemingly 'small' issues such as the shape of a device or moving buttons on the user interface, will require re-certification and therefore may become too expensive or time-consuming to implement. It is also possible that without a mechanism for collecting user feedback during early stages of development (whether formal or informal), important information on issues such as usability, context of use or possible hazardous situations may be lost.

User evaluation, therefore, should be conducted *alongside* the functional evaluation of a product so that changes based on user feedback can be made at the same time.

Evaluation should be based on the *user requirements* that were developed at stages 1 and 2. The criteria against which the device will be tested can be defined based on these requirements. Examples of criteria for success are:

- Using the new device will improve the safety of patients because of fewer errors;
- More users will be able to use the device safely without training;
- The new device effectively supports the working practice of the users by x, y, z;
- The device can be used in x, y and z settings without additional support.

As well as safety, success criteria can also include clinical, functional, organisational and economic aspects:

- Using the device will allow procedure x to be performed an average of 15 minutes quicker than the current practice;
- The new device enables patients to live more independently by providing them with an effective method of treating themselves.

Substantial improvements in terms of cost, efficiency, clinical and service quality or satisfaction as well as safety are often required to convince individuals/ hospitals to invest in a device over an existing device which may be less safe.

Evaluate in isolation or comparison?
Evaluating a prototype device in a comparative way can be extremely useful, particularly in the later stages of evaluation when seeking to demonstrate the performance of a device against current practice or against the gold standard. A comparison could be with an existing device, perhaps a device that is currently deficient, which the new device is seeking to replace. A comparison could also be made between a particular task or clinical procedure performed with the aid of the new device and without. However, just demonstrating that a device is an improvement on the existing situation does not necessarily mean that the device is either safe or that it meets the requirements of its users. Healthcare purchasers will usually require *evidence* that a new device will result in financial savings or significant benefits to patient safety before they will agree to purchase the device.

Methods
Methods that are particularly useful for the evaluation of prototype devices include:

- usability tests;
- cognitive walkthrough;
- heuristics;
- focus groups;
- surveys;
- interviews.

Outcomes
In the early stages of prototype evaluation the likely outcome will be the identification of a number of issues that require improvement. In addition to functionality problems, other issues may include:

- Screen should be bigger;
- Device should also measure blood pressure;
- More detailed instructions are required;
- Alarm tone should be changed – similar to that of other device in the clinic;
- Feedback on the entered parameters should be provided to the user;
- Device is too heavy.

It is necessary to set the goals of evaluation before beginning so that the performance of the device can be measured against this: '*How will we know when we have developed a device that meets the needs of its users?*' As with all stages of device development, there is unlikely to be complete agreement between users as to whether their requirements are being met, and therefore decisions will have to be made on which of these will have to be sacrificed.

Presenting your results
It is important that the methods and results of any user testing are made available for potential purchasers and users of the devices (this is a

requirement of usability standards such as *BS EN 62366: 2008 Medical devices - Application of usability engineering to medical devices*[12]).

A documented process will provide users with an understanding of the assumptions that have been made by the manufacturers about the potential users of the device, the conditions in which the device can be safely used and safe work practices. For instance, if the testing has had to be carried out in a simulated clinical environment, it is important purchasers are aware of this and the restrictions to the validity of the testing that this may entail. Similarly, if testing has not included the possible use of the device by patients, then this will affect the restrictions that are put on use of the product by patients as the errors they could make will not have been accounted for. The American standard AAMI/ANSI HE74-2001 (Human Factors Design Process for Medical Devices)[9] provides guidance on the sort of documentation that should be included in demonstrating conformance to that standard.

Typical information that should be included in a user testing file:

- A description and pictorial representation of the device, its interface, ancillary equipment and any connectors or consumables that will be used;
- Instructions for use;
- A profile of those users that have been considered in the design of the device and their characteristics;
- The methods that were used for the testing, a justification for their use and the results;
- Exclusions to the testing, and assumptions that have been made about either the users or the conditions of use;
- A description of the intended operating conditions for which the device has been developed and tested;
- The potential hazards, including reasonably foreseeable use errors that have been considered in the development of the device and its testing;
- The design considerations that have been incorporated to address those errors;
- A description of any the residual risks that have been considered acceptable, and how these have been mitigated.

4. User testing methods lab

This section introduces some of the methods that can be used during your user testing process. Recommended further reading on each method is also included. The methods lab consists of:

- User-centred design (UCD)
- Cognitive walkthrough (CW)
- Delphi technique
- Ethnography
- Contextual inquiry (CI)
- Usability tests
- Heuristic evaluation
- Personas
- Scenarios
- Task analysis
  a. Procedural Task Analysis
  b. Cognitive Task Analysis
- Focus groups
- Interviews
- Questionnaires

User-centred design (UCD)

UCD is an ergonomics approach which focuses on users throughout planning, design and evaluation. It is recommended that UCD should begin at the earliest stage possible, ideally at concept, and continue through an iterative design and evaluation process. A user-centred design approach will use a variety of research methods depending upon factors such as the stage of product development, the type of users to be studied and the type of data required. The major methods used during UCD are briefly presented in this methods lab section.

Further reading

Stanton N.A., Salmon P.M., et al. *Human Factors Methods: A Practical Guide for Engineering and Design*. 2005.

Cognitive walkthrough (CW)

A technique that attempts to measure usability of a device without including true end-users is the cognitive walkthrough. CW is performed by expert evaluators, usually members of the development team or usability specialists, rather than actual end-users. In a CW the focus is on learning through exploration; the evaluator specifies the sequence of actions required to perform a certain task and then works through that sequence to identify potential usability problems. The main focus is often upon how easy a system would be to learn for a novice user.

The main disadvantage of the cognitive walkthrough is that it is difficult for designers to truly think and act like users, particularly novice users. In addition, some authors report that, as a consequence of evaluators' lack of domain and contextual knowledge, some of their suggestions may be inappropriate or make other tasks difficult or impossible[25]. However, CW is a low investment technique ideally suited to the early identification of design problems and is relatively cheap and quick to perform. It can be used to refine preliminary designs by identifying obvious usability problems in-house before testing with real end-users is performed on a later prototype.

Further reading

Wharton C. The cognitive walkthrough method: a practitioner's guide. In J. Nielsen & R. Mack. *Usability Inspection Methods* 1994. pp. 105-140.

Key features of cognitive walkthrough:

- Used during prototype evaluation to identify usability problems with a device.
- Often performed by members of design team 'thinking as users'.
- Depends upon ability of evaluators to think and act like users.
- May miss significant contextual issues.

Particularly useful for: A quick and cheap in-house method for identifying major problems before more extensive usability testing with real users.

Delphi technique

During medical device development it is essential not only to identify user requirements but to *prioritise* these. The large number of different users and stakeholders that must be considered can make this particularly complex. The Delphi technique, which seeks to obtain a *consensus* of opinion from a group of people, can be useful for achieving this. This method asks 'experts' to provide opinions or ratings. These opinions and ratings are then used to formulate another round of questions during which the experts are made aware of how their responses compared with those of the other respondents. In the case of medical devices, experts may include recipients (patients), operators (carers, patients, staff), procurement, maintenance, trainers or all of these groups, and the success of this method will be dependent upon the correct choice of stakeholders.

The Delphi technique normally consists of a number of rounds of questions to progressively identify, clarify and expand on issues and ideas. The first round usually consist of general questions to gain a broad understanding of the views, opinions or needs of the range of experts. The responses from this round are collated and summarised and form the basis of the next round of questions to investigate further or clarify the issues raised in round 1. Again the results are collated and used to formulate a third (and usually final) set of questions which will generally consist of obtaining a consensus on the relative importance of the factors identified in the previous rounds. A key aspect of Delphi is the anonymised feedback that the experts receive between each round of questioning; general feedback is provided to the experts between rounds and individuals are given the opportunity to revise judgements as a result of the feedback.

An example of the use of the Delphi technique in medical device development is provided by Batavia and Hammer[26] who used the technique (in conjunction with focus groups) to identify needs and requirements for new assistive devices. Focus groups were performed with a large number of users of existing assistive devices to identify areas where these were deficient. This resulted in a list of possible features for inclusion in new devices. A panel of experts, which consisted of a sample of long-term assistive device users, then underwent a number of rounds of questioning to prioritise the requirements. The authors reported that this approach was successful in obtaining user requirements and resulted in a number of important recommendations for device design such as the importance to users of a long battery life for powered wheelchairs.

The Delphi technique may be a useful option when wanting to obtain a consensus of opinion on a

complex issue. Since it can be performed electronically, via email or a webpage, it may also be useful when a face-to-face meeting may not be appropriate, for example in situations where publicly voicing a contrary or critical opinion may be unlikely due to a particular group dynamic or the type of users involved. The lack of face-to-face meeting means that Delphi may be useful when it is difficult to get many users together at the same time, and with increasing use of email this method is becoming quicker, cheaper and easier to perform

Further reading:

Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing* 2008; 32(4): 1008-1015

Key features of the Delphi technique:

- Used to establish a consensus between a number of people.
- A number of rounds of questions are used.
- Following each round, anonymised responses are sent to all participants allowing them to re-consider their responses.
- Useful for obtaining an 'expert' opinion on issues where there is little or no reliable data.
- May be inappropriate to establish a consensus – the variation between people may be more interesting or relevant.

Particularly useful for: Establishing the extent and consequences of a problem, for example asking a group of consultants: "if we could provide you with a device that could do x, how would this benefit your patients and how many of them would benefit?".

Ethnography

Ethnography is an observational research method, originating from the social sciences, that emphasises the importance of discovery. Traditionally ethnography involves the researcher spending a significant amount of time, sometimes as long as a number of years, observing an environment. In addition to observation of the environment, the researcher may also undertake other data collection techniques such as interviews with key personnel.

When performing ethnography, researchers attempt to minimise the impact of their pre-conceived ideas and avoid letting their actions, opinions or values affect the situation under investigation; rather they adopt the role of learner. An example of an ethnographic approach to medical device development could be a researcher spending a number of weeks with a patient, with the aim of understanding all aspects of how they live and manage their condition, or spending a prolonged period of time in a clinical environment to study the culture and behaviour and feelings of the people within it. In a true ethnographic approach the researcher would have no predetermined ideas of ways in which the patient or clinic may be helped (e.g. assuming beforehand it is likely that the patient would benefit most from an improved wheelchair/ home dialysis machine).

Ethnography is extremely time-consuming. Researchers require considerable training and will spend a considerable amount of time observing the environment under investigation. For this reason it is unlikely to be a practical method to be used in commercial product development. **Contextual inquiry** developed as a shortened, more focused form of ethnography that is more suited to product development.

Further reading:

Atkinson P, Hammersley M. 'Ethnography and participant observation'. In: Denzin N, Lincoln Y, editors. *Handbook of qualitative research*. 1994. p. 248–61.

Savage J. Ethnography and health care. *BMJ* 2000; 321: 1400-02

Key features of ethnography;

- Long-term observation of an environment.
- Focus is on learning without pre-conceived ideas or questions.
- Provides qualitative, descriptive data.
- Very expensive and time-consuming.

Particularly useful for: identifying unmet needs or potential for error by providing a thorough understanding of an environment.

Contextual inquiry (CI)

Contextual inquiry, with its roots in ethnography, is also a method of capturing contextual data by observing users in their own working or living environment. This method developed as a form of ethnography that was more suited to product development and is sometimes referred to as 'shortened ethnography'. CI is based upon the theory that good design begins with a good understanding of how people work or live, and that this understanding can be obtained by focused observations and interviews. People are adaptable and resourceful and are constantly inventing ways of fixing and adapting to problems that they encounter at work or at home. CI aims to obtain this information; information which may be implicit in the user's mind but may remain undiscovered otherwise.

CI is performed by conducting contextual interviews with users. The researcher shadows the user whilst they complete their work, or perform everyday tasks, and elicits information by asking questions about what is happening, why it's happening and how particular tasks could be made easier. The developer/designer may notice tasks which appear unnecessarily complex or inefficient and can probe the user for the reasons behind these, asking questions such as 'why do you have to do that task in that way, when you could do it this way?' This aims to identify areas where tasks could be made easier, safer or more efficient, whilst the fact that crucial contextual information is also collected means that the factors that may prevent this can also be recognised. For example, there may be tasks which appear unnecessarily repetitive but are important safety checks, and shortening or automating these may compromise patient or use safety.

Further reading:

Beyer H. & Holtzblatt, K. *Contextual Design: Defining Customer-Centered Systems*. 1998.
Coble, J.M., Karat, J. & Kahn, M.G.'Maintaining a focus on user requirements throughout the development of clinical workstation software.' Proceedings of the 1997 Conference on Human Factors in Computing Systems, CHI, Mar 22-27 1997.

Key features of contextual inquiry:

- Focused observation of users within the environment of use.
- Observer shadows and questions the user whilst they perform tasks.
- Requires close observation of users: may not be appropriate in some clinical situations.
- Involves prompts like:
  "Let me see if I understand. I think you are doing that because... is that right?"
  "Can you stop a minute? I'm not sure I really understand what you are doing. Can you explain it to me?"
  "Let's stop and talk more about why you do that."

Particularly useful for: developing a clear understanding of an unmet need from the perspective of a particular patient, clinician or carer.

Usability tests

Usability is defined in ISO 9241-11 as 'the extent to which a product can be used by specific users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use'. Usability testing involves users performing a number of typical tasks using the device under investigation in order to evaluate how effective the device is. Different types of data collection methods may be used during a usability test depending upon the device and the aims of the test. If the device being tested aims to improve the efficiency of the user, it may be appropriate to use 'time taken to perform the test' as the measure for device performance. However, if improved safety is the primary objective, the number of errors made during the course of a task may be a more appropriate measure and, if the test is concerned with how the users feel about the device, user opinions can be collected by means of interviews, questionnaires or focus groups.

Usability testing forms a key part of user-centred design as it can be used numerous times during development. For example, testing an existing device to identify its problems or shortcomings may be an effective starting point for the design of a new device.

Later on, once a prototype device has been developed, usability testing can be used again to evaluate it. Usability testing may involve comparing two devices, for example comparing a new device with an existing one to demonstrate the improvement or it can just involve one device. Ideally, a number of rounds of usability tests will be performed, with the results of the tests being used to refine the prototype device, which can then be tested again either to identify more problems or to demonstrate the improvement of the device.

Further reading:

Dumas J, Redish J. *A practical guide to usability testing*. 1999.

Key features of usability tests:

- May be used a number of times during development to:
  - identify problems with an existing device;
  - evaluate a prototype design or earlier prototype;
  - demonstrate the improvement of a new design over an existing device.
- Users are asked to perform typical tasks.
- Data may be collected in a variety of ways e.g.:
  - post-task interviews;
  - informal opinions of users;
  - time taken to complete task;
  - number of errors made during task.

Particularly useful for: evaluating prototype devices to determine their performance and safety.

Heuristic evaluation

Heuristic evaluation is a discount (shortened) form of usability testing which uses evaluators to test a device rather than real end-users. Heuristics can be used in some circumstances when real users cannot be involved for practical or confidentiality reasons, and can be extremely useful in the early stages of evaluation to identify major usability problems with a device. This method involves a systematic evaluation of a device by assessing its compliance with a pre-determined 'heuristics'; principles or 'rules of thumb' that a device should meet. The list of heuristics for any device will be informed by the user requirements collected during early device development and will reflect the factors that have been identified as a priority for the safety of the device. These may include factors such as:

- The device should provide feedback to the user at each stage of data input;
- The device should provide a summary of inputted parameters to the user at the time of prompting them to proceed with operation;
- Instructions for use of the device should be visible or easily retrievable whenever needed;
- Users should be informed about what is going on with the system through appropriate feedback and display of information[23].

The evaluators evaluate the device against the list and decide whether or not it complies with each of the heuristics.

Heuristic evaluation developed in the field of human-computer interaction research, and is most suited to the evaluation of computer-based medical devices and their user interfaces. Heuristic evaluation does not seek to replace a full evaluation with a representative sample of 'real' target users, rather it is best used early on in evaluation to identify major, or more obvious usability problems. Identifying and fixing these types of problems early on means that a full user evaluation can then be performed on a better quality prototype where the focus can be on more subtle usability issues. For example, if a full user evaluation is being conducted on a device with a small number of glaring usability issues, it is likely that the users will focus on these during the evaluation and may not notice the less obvious problems; problems that may be more important.

When considering this method developers should question whether it is appropriate to use evaluators without the medical experience (either as a patient or healthcare professional) of the target users. However, this technique can contribute to medical device development as an initial usability test performed in-house early on to identify and fix initial problems

before performing an extensive usability test on a later prototype.

Further reading:
Nielsen J. *Usability inspection methods*. 1994.

Key features of heuristics:
- Shortened version of usability testing carried out in-house.
- Evaluates the performance of a device against pre-determined 'rules of thumb'.
- Dependent upon the availability of relevant and well-established heuristics for the particular device.

Particularly useful for: A quick and inexpensive initial evaluation of computer-based medical devices.

Personas

A persona is a fictitious character that represents a user of a device. Personas are frequently used in website and software design as a way of building up a picture of the people that will use the product. Each persona represents a distinct and important pattern of user behaviour that has been observed in the environment in which the device will be used. Such behaviours may include: a tendency to throw an asthma inhaler into the bottom of a schoolbag; an unwillingness to read the instruction manual for a drug infusion device; or the fact that someone will keep leaving a particular task because of frequent interruptions. Knowing there are users out there who behave this way gives you a solid basis for making design decisions to support them. A good persona is not a list of tasks or duties; it is a narrative that describes the flow of someone's day, as well as their skills, attitudes, environment and goals.

This method is particularly useful when there is a team of people working on a product as it enables the team to keep a picture of the type of people that will use the device. Using personas can aid communication: presenting information about potential users as lists makes it harder to absorb, but most people have the ability to relate to other people (or representations of people). This format helps ensure that everyone on the team knows who they are developing the product for.

It is important to ensure that personas are not based on stereotypes but are developed as a result of careful study into potential users of a device. Care should also be taken to create as wide a group of personas as possible to ensure that the different users are not represented as a homogenous group of people with similar needs, opinions and experiences.

Further reading:
Pruitt J & Adlin T. *The Persona Lifecycle: Keeping People in Mind throughout Product Design*. 2005.

Key features of personas:

- Fictitious characters that represent the users of a device.
- A rich narrative that describes the flow of a user's day and their skills, attitudes and goals.
- Not a dull list of tasks.
- Care should be taken not to create stereotypes but to include the full range of users' characteristics.

Particularly useful for: Giving a real identify to otherwise faceless 'users' and then communicating this to a team throughout device development.

Scenarios

Scenarios are typical examples of how a user will interact with a device or system. They can be used in a similar way to personas: to help the development team build up a picture of how users will use and interact with a device. As with personas, care should be taken when developing scenarios that they are based on real observations and/or discussions with a wide range of users and also take into consideration the context of use.

Scenarios can be useful tools during the early evaluation of a device, especially as the basis for creating tasks for methods such as **Cognitive walkthrough** and **Heuristics**. Scenarios should be validated or checked with users before being used as a basis for design decisions or evaluation.

Further reading:
Carroll J. *Scenario-based design.* 1995.

Key features of scenarios:
- A typical example of how a device will be used.
- Developed following observations and/or discussions with a variety of users.

Particularly useful for: Early stage in-house testing of a device as part of a cognitive walkthrough or heuristic evaluation.

Task analysis

Task analysis seeks to examine a particular task and to break it down into the actions, decisions and/or cognitive processes that are necessary to complete it. This helps to identify task sequences, dependencies, information requirements and opportunities for error. Studying a task in detail helps to identify areas that are inefficient, unsafe or unsatisfactory. There are two types of task analysis that may be particularly useful during medical device development:

Procedural Task Analysis

Procedural Task Analysis breaks a task down into each of the individual steps and decisions that are required to achieve it, allowing the identification of the information, devices and clinical staff involved in each task. This is useful for identifying the points within a task which are challenging, time-consuming, result in errors, or are in other ways inefficient or hazardous. This type of analysis may be useful for identifying tasks which are sub-optimal and would benefit from either the provision of a new device or the improvement of an existing one.

For example, when analysing hip replacements, an observer noticed that in a number of the operations a significant amount of time was taken up with the surgeon assessing the alignment of the joint and then keeping this steady and re-checking it throughout the operation. This increase in operation time had a number of implications, including the increased risk associated with longer anaesthetic times as well as significant cost implications of the added staff and theatre time. Further investigation with the surgeon also indicated that this issue lead to long-term problems for the patient in terms of mobility. The analyst came to the conclusion that a device that could calculate the optimum alignment for the joint and then monitor this throughout the operation could make a contribution to a more successful procedure, whilst at the same time reducing the operation time.

In this example, one particular step was identified that was affecting the time taken to complete the task and also the success of the task itself. This shows that analysing a task in detail allows issues such as the time taken to perform a task, the roles of the staff involved and the consumables used to be collected. This information can also be used to calculate the potential reductions in cost or resources associated with the new device or design; information which may be extremely useful when demonstrating the benefits of a new device to purchasers.

Cognitive Task Analysis

Cognitive Task Analysis (CTA) was developed in response to an increase in the number of tasks and systems that are dependent on cognitive processes. This method aims to identify sources of high *cognitive*

strain as these are potential sources of error. Once these have been identified, devices can be developed that support the user by reducing the mental burden caused by a task. This method has been used successfully in safety-critical industries such as rail and nuclear, and it could have a similar impact on healthcare. Put simply, when people are working under pressure and have a number of things on their minds, leading to high mental workload, errors are more likely to occur and go undetected. Cognitive task analysis is used to investigate tasks that are primarily dependent on cognitive processes. It documents each of the thought processes and decisions that are required to complete a task.

Examples of ways that devices can support the user's cognitive work include:

- Providing a screen that displays all of the information entered into a device so that the user does not have to remember it;
- Informing users about what the system is doing through appropriate feedback and display of information;
- Allow the easy identification of, and recovery from, errors.

A relevant example that is often cited when discussing medical device applications is that of infusion pumps. In order to administer a particular dose of a medication to a patient, a clinician will program an infusion pump to automatically deliver the drug.

Programming the user-interface often involves navigating through a number of different screens and entering data into these, and a common problem with these types of devices is the lack of feedback given to the user as they progress. The user has to remember everything that they have previously entered, which increases the load on the *working memory* and increases the *cognitive strain*. These are potential sources of error that would be identified during a CTA.[27]

Although potentially very useful for studying healthcare practices, there are barriers to performing task analysis in a medical setting, including the time needed to perform the analysis. In addition, to obtain a comprehensive picture of how tasks are carried out, it is essential that a representative group of users are studied. This is particularly important in healthcare as the same task is likely to be performed differently depending upon the patient involved, the individual performing the task (different clinicians, carer, etc) and the healthcare environment where the task is being carried out. Obtaining access to the clinical environment may also be difficult and, in some cases, it may not be appropriate to directly observe the treatment of patients.

Further reading:
Kirwan B, Ainsworth LK. *A guide to task analysis.* 1992.

Key features of task analysis:

- Breaks down a task into individual actions, decisions and processes.
- Cognitive Task Analysis can be used to identify areas of high cognitive strain, which are potential sources of error.
- Can be time-consuming to perform.

Particularly useful for: Identifying points in a task that are currently difficult, inefficient or may result in errors with a view to improving them.

Focus groups

Focus groups are used in a wide variety of industries and their popularity reflects the relatively low cost and time commitment involved. Often used within a user-centred design approach, focus groups may be employed at a number of stages during product development: to identify unmet needs at the concept stage; to investigate the features and characteristics required by users and their relative importance; and to obtain feedback on prototype designs as part of usability testing. It has also been suggested that focus groups allow deeper issues to be investigated, such as emotional bonding of users with products and cultural perceptions of products.

Data generated through methods such as focus groups will be restricted to what the participants are aware of and what they can recall and articulate. This may be problematic as, in some cases, users may not notice the deficiencies in the devices that they use, or may not be able to identify areas where improvements to the device could benefit them. As Holtzblatt and Beyer[28] state, 'people are adaptable and resourceful creatures - they invent many workarounds and quick fixes to problems and then forget they invented the workaround. Even the details of everyday work become second nature and invisible.'

The dynamics of a focus group discussion may also affect the responses of certain participants, for example making it more likely for some participants to conform to the views of others or expressing opinions and behaviours that are socially acceptable. As a result, ideally focus groups should be complemented by some type of observation of the situation or device under investigation in order to access information and contextual factors about the use of the device that users may not be able or willing to articulate.

Further reading:
Langford J and McDonagh D (eds.) *Focus Groups: Supporting Effective Product Development*.

Key features of focus groups:

- Group discussion with 8-10 users.
- Provides the opinion of a group, not a number of individual opinions.
- Can be used at many points throughout development to:
  - identify un-met or ill-met need;
  - obtain specific ideas for a new device;
  - obtain user opinions on a prototype device.
- Requires a moderator to guide discussion.
- Ideally should be supplemented by observational data.
- Unlikely to be suitable for discussing sensitive issues.

Particularly useful for: identifying full range of issues and needs through group discussion.

Interviews

Interviewing potential users of a new device is one of the most common approaches to user research. They are relatively easy and cheap to perform, can be employed at all points of the product development pathway and are highly flexible in terms of their length, structure and scope as well as where and when they are conducted.

Interviews enable a topic to be investigated broadly and deeply. For example, investigating how a patient feels about their condition, how it impacts on all aspects of their life and how that has changed over time. However, as with focus groups, interviews are dependent upon what the participants are consciously aware of, as well as what they can recall and articulate at that moment in time; therefore, ideally they should be complemented with some kind of observational study.

The success of an interview will be somewhat dependent on the rapport that the interviewer develops with the participant, especially when sensitive issues are being discussed. Interviewers will often need to adapt their approach according to the type of person being interviewed and therefore some

training should be considered before embarking on an interview study.

Interviews can be conducted in many different ways. As well as the traditional face-to-face method, interviews can also be conducted over the phone or over the internet. Conducting interviews over the phone or the internet is likely to be a cheaper option and may allow more participants to be contacted. However, without face-to-face contact it may be more difficult to discuss sensitive issues or for props, such as existing or prototype devices, to be presented which can be useful for prompting discussion.

The type of interview chosen will depend upon the time and money available. A balance must be struck between how many interviews are conducted and the depth in which the topic can be investigated with each participant. A useful rule of thumb is that the earlier in product development, the less structured the interview should be. At the beginning of development the important issues are unknown and therefore users should not be guided too much, but allowed to freely describe their thoughts and feelings: what is important to them; what do they need; what would make their jobs or lives easier, what would help their patients or the person that they care for? Later on in development when the important issues have been identified, the interviews can become more focused, for example, prioritising requirements or evaluating to what extent a prototype device meets these requirements.

As with all user research, a combination of different research methods should be considered. For example, if the aim is to uncover problems that occur in diabetic clinics, a possible approach could be to firstly survey a number of diabetic nurses asking them to describe the range of problems that they encounter in their clinical practice, followed by a smaller number of in-depth interviews to more thoroughly investigate the most common or relevant issues.

Further reading:
Sawyer D. *Do it by design – an introduction to human factors in medical devices.* US Food and Drug Administration. 1996.

Key features of task interviews:
- Time and resource intensive.
- Can be used at all points of the product development cycle.
- Should be unstructured at the beginning of development and become more focused as the product develops.
- Well-suited to discussing sensitive or personal issues.
- Care should be taken by the interviewer to put respondent at their ease.
- Can complement other methods, e.g. to discuss in detail issues identified by a survey or observed during a usability test.

Particularly useful for: obtaining a detailed understanding of how an error could compromise patient safety or how a particular clinical condition affects a patient's life. Useful for discussing sensitive issues such as human error.

Questionnaires

Questionnaires are a popular research method due to the belief that they provide a quick and inexpensive way of collecting the opinions and thoughts of a large number of people. However, producing an effective questionnaire requires considerable thought and skill. As Boynton and Greenhalgh[29] state, 'anybody can write down a list of questions and photocopy it, but producing worthwhile and generalisable data from questionnaires needs careful planning and imaginative design'.

A major strength of a questionnaire is that each participant is provided with exactly the same information, thereby removing the potential for bias that may result from varying the way questions are asked during interviews. However, this also means that no clarification can be given to the respondents whilst they're completing the questionnaire, and so it is imperative that questions are written simply and unambiguously so that they are interpreted in the same way by all respondents. Another advantage of this technique is that people can usually choose when and where they complete a questionnaire and therefore may be more relaxed and provide more considered responses.

Two basic types of questions can be used: closed or open (or a combination of both). Closed questions are where the participant is provided with a list of responses to pick from, for example: yes – no; strongly agree – agree – neutral – disagree - strongly disagree. Open questions are when the respondent is provided with space in which to answer in their own words.

Closed questions have the benefit of being quick and easy to administer and analyse. However, they do force respondents to pick a pre-determined response when it may be the case that none of the options truly reflects what they feel or believe. They also do not allow new issues to be raised and therefore will not identify any issues that the researcher is not already aware of.

Open questions tend to take more time and effort to administer and analyse. However, they do result in much richer data; respondents are not restricted in the responses that they can give and this can result in the identification of issues that were not previously known. Answering open questions requires more of respondents and some people may be unwilling or unable to take the time or effort to write a long full answer and may instead just leave the question blank.

As a general rule, open questions should be used in the earlier stages of development, when the aim is to develop an understanding of the full range of feelings or experiences a group of people have. A common approach is the use of open questions to identify all possible responses to an issue and then to use

these responses to explore these in more detail (e.g. frequency, relative importance) with closed questions.

Further reading:
Boynton PM and Greenhalgh T. 'Selecting, designing and developing your questionnaire'. *BMJ* 2004; 328: 1312–1315

Key features of task interviews:

- Inexpensive way of contacting a large number of people.
- The same information and questions are presented to each respondent.
- Further information or explanations cannot be given to participants.
- Unclear responses cannot be clarified.
- Open questions are useful for identifying a full range of views and experiences.
- Closed questions can then be used to explore the extent of a problem / need or the priorities of a group.
- Response rates can be very low.
- Can be used to collect quantitative data suitable for statistical analysis

Particularly useful for: Identifying the unmet needs of a group of people with a view to developing new devices, e.g. surveying a range of patients with a particular condition to discover what their needs are and which of these are most important.

Appendix

Checklist: Planning your user testing

Description of device			
Current stage of development			
All possible user groups including regular, occasional and patients (even if not operators)			

All potential environments of use			
Likely purchaser			
What current practice is this device trying to change? Any competitors?			

What?	**What do we want to f nd out?** • What are your research questions? • Aims and objectives e.g. – Which errors are likely? – What contributes to the error? – When will they occur (start of the task, calculations, disposal, during transfers, etc.)? – Will they be detected? – Can they be recovered?	

Why?	**Why do we want this information?** • To demonstrate safety and minimise the risk of error? • To identify which users are likely to make errors and will need extra support or training? • To identify what warnings and instructions are needed, if the risks cannot be removed or mitigated?	

Who?	**Who are the best people to provide this information?** • How many people should take part in the test? • Which user groups should take part in the testing (all users? those most at risk of error?) • Which staff groups? – Patients? – Support staff (maintenance, porters, admin. staff)? – Carers, family?	

Who?	• Are they representative of all users in each group (e.g. age, gender, experience, language)? • Are there any patient or professional groups that could collaborate? • If they are not available then who are the next best group? • Is any of this information available already (e.g. from within the NHS, from published literature or from anthropometric/ergonomics guidelines)?	

When?	**When is the information needed by?** • Does the study need ethical, R&D and/or MHRA approval? • Is there time to get approval?	

How much?	**What is the budget for this research?**	

Where?	**Where should the study be carried out?** • Does it need to be in the context of use or can it be carried out in a lab? • Does it have to be performed in a clinical environment? • Or outside, in the community, a simulated environment, over the internet?	
How?	**How should the testing be carried out?** • What type of data should be collected? e.g. – Numbers of errors – Time to complete task – Costs – Opinions – Experiences – Contextual information	
	What is the best way to collect this data? • Observation • Recall of participant • Measurements • Ratings/ranking • Is any of this info already known? • Comparison with an existing situation or device? • Internet-based method?	
	Group or individual method? • If the project deal with any sensitive or personal issues group methods such as focus groups may be inappropriate	

How?	**What expertise do we have?**	
	Is a prototype required for this study? • High fidelity working prototype • Low fidelity working prototype • Non-working • Virtual (computer generated?) • Paper representation	
	Appropriate research methods: • User centred design • Cognitive walkthrough • Delphi technique • Ethnography • Usability tests • Heuristic evaluation • Personas • Scenarios • Task analysis – Procedural Task Analysis – Cognitive Task Analysis • Focus groups • Interviews • Questionnaires	

This checklist is available in Word format from www.nrls.npsa.nhs.uk/design

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