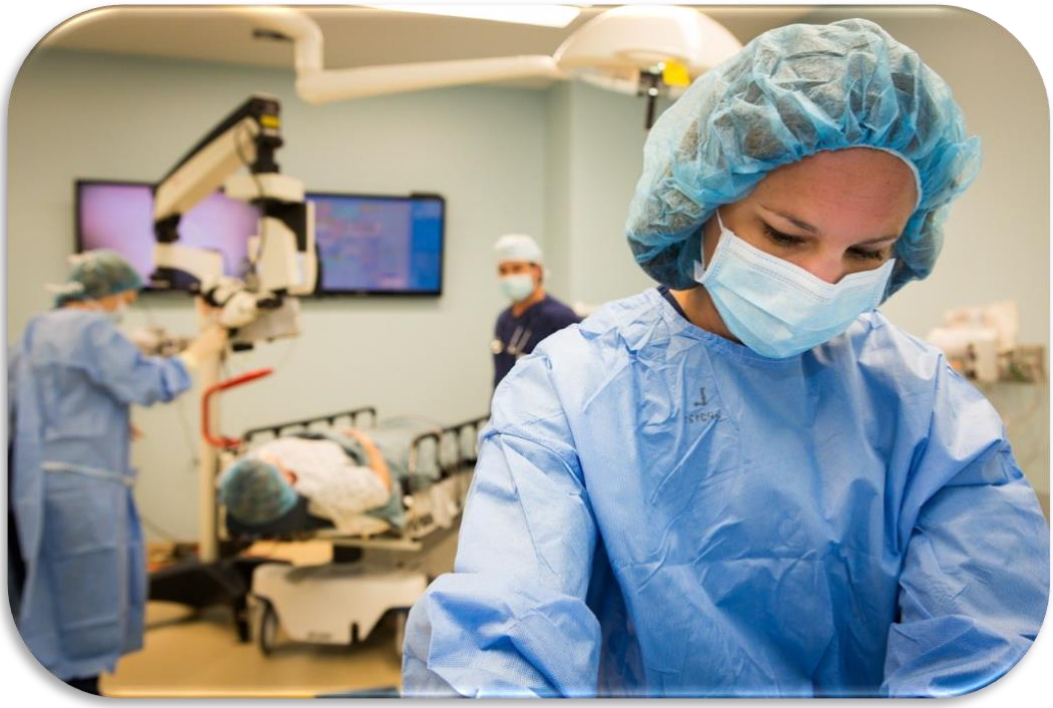
Designing for Healthcare Professionals

- A Human Factors approach to healthcare product development –



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Preface

I (Jeremy) am an Engineer. I completed a bachelor's degree in Mechatronic Engineering and set out into the workforce where I was involved in a number of product developments. After several years in industry, I went back to university to complete a PhD. My PhD topic was to design an interface to control a continuum robot to be used in surgery. My background as an engineer gave me all the skills required to achieve this goal of designing a robust interface and then teaching surgeons how to use it; however, as I started thinking about the limitations of designing for surgery and how surgeons would be using a device they do not fully comprehend I was reminded of the image in Figure 1. This image, or a variation of it, would make its way around engineering offices from time to time. It follows the development of a tree swing as it moves through the various levels of design processes, but the last scene highlights what the user wanted the entire time. I am sharing this comic strip because I realised that by solely relying on my engineering background I would most likely develop an interface that would allow the user to control a continuum robot, but it may not meet the users' expectations and, in the process, not be safe, effective, or efficient, and remove the joy or satisfaction that the user is hoping for from the interaction. In order for the interaction to be desirable and accessible for a surgeon to use, it was imperative that their needs were understood and that the robot and the interface were developed to meet those needs. This could only be achieved by incorporating human factors.

Jeremy Opie, 2021

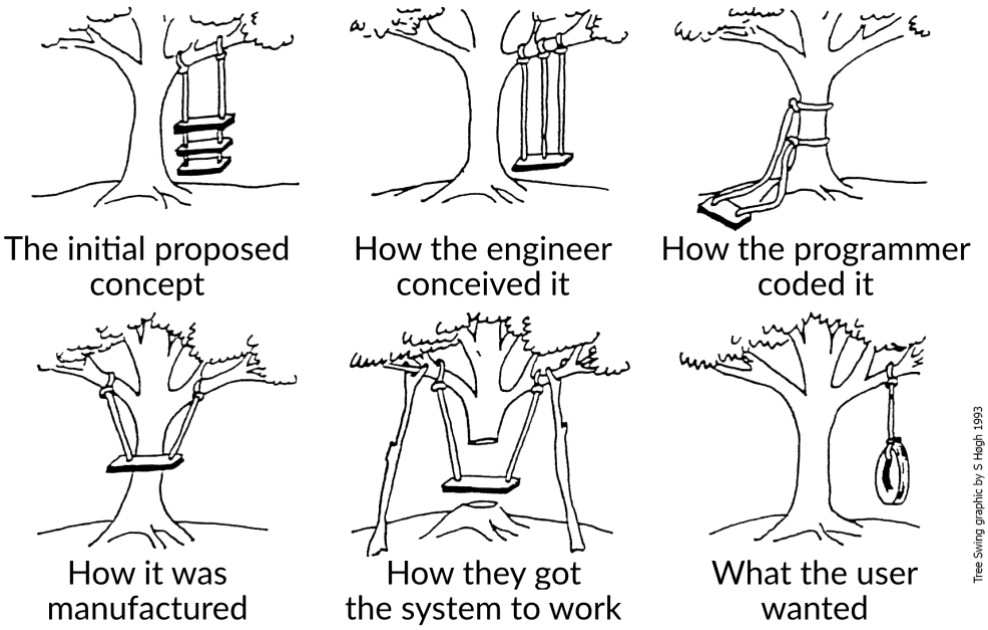

Figure 1 Adaption of the Tree Swing Graphic, S Högh (1993)

Acknowledgements

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This report builds on the hard work of those who have come before, in developing the methods and practices that allow us to better understand user needs. By synthesising the work of others, we have created a guidebook to improve future healthcare products as human factors is used to guide the engineering decision processes.

The authors also thank the engineers, clinicians, and human factors researchers that made the time to review and improve this document through their feedback and suggestions.

Finally, we thank our families for their unconditional support and being sounding boards to help shape this work.

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Introduction

This resource is to assist engineers when developing new technology for healthcare to ensure human factors are incorporated into their design. Including human factors into the product development ensures that usability standards are addressed, the product will be more useful for clinical teams and fit within the intended context, and most importantly, the result will be better patient outcomes.

How Human Factors fit within Engineering?

Engineering and Human Factors research go hand in hand. Engineering deals with the practicality of designing new technology, whereas Human Factors deals with understanding how people will interact with and use new technology. Engineering requirements and user needs, although separate issues, need to be addressed concurrently as they impact each other. The engineering factors investigate how we develop a product or service to solve a problem. Whereas, human factors investigate usability and utility. Usability informs us whether the user is able to perform the task effectively, efficiently, safely, it is easy to learn, and easy to remember how to use all while generating a good experience of using the new technology. Utility informs us whether the product or service provides the correct functionality.

To assist in ensuring that health technologies are designed so that they are effective, efficient, and satisfying for users there are three usability standards: ANSI HE75 (*Human Factors Engineering – Design of Medical Devices*), IEC 60601-1-6 (*General requirements for basic safety and essential performance*), and IEC 62366 (*Application of usability engineering to medical devices*). Applying these standards should ensure that the product is used as intended, and that potential patient and user safety risks are properly identified and mitigated. Also, incorporating human factors into the design process ensures that these standards are addressed during development and not as an afterthought too late in the product development, which may result in high cost to change the product in order to meet these standards or developing a product that is not useful.

To design technology that provides the user with a product or service that is beneficial to them it is important that we understand the needs and practices of the user in the context where that product or service will be used. There are a number of classic Human Factors methods we can apply to achieve this in a healthcare setting: e.g., surveys, focus groups, interviews, observations, contextual inquiries, and task analysis. Once the user needs are understood, the technology can be designed to ensure it is delivering a good solution to the users' problem, which can be conducted in collaboration with users through workshops, user investigations, informal scenarios, and focus groups to develop and evaluate prototypes. In some cases, foundational engineering research is needed to develop innovative technologies that better address the problem. Once developed to a suitable level, the evaluation of the technology can commence to ensure that the product or service is usable, useful, and safe to the user, including cognitive walkthroughs, heuristic evaluation, usability studies, and user experience (UX) evaluations. These evaluations will indicate

whether the new technology has successfully met the users' needs or whether further iterations of design and evaluation are required. Finally, when the system has undergone basic evaluation testing and gone through as many iterations of design as are required to deliver a safe and usable product, it can be tested 'In the Wild', that is to say, evaluated by users in the environment it was designed for.

The methods and the evaluations can produce both *quantitative* and *qualitative* results. *Quantitative results* indicate whether the technology achieves its intended goal, and provide an indication of utility; whereas *qualitative results* indicate whether the technology is engaging, effective, efficient, safe, and satisfying from the user's perspective. As quantitative analysis is widely used in engineering it is not addressed in this document; rather, we focus on methods for gathering and analysing qualitative data, which are rarely used in engineering.

When to incorporate Human Factors

Within the field of engineering there is a commonly used model to develop products, which comprises the following steps: identify or be informed of a problem, investigate technologies that can be used to overcome the problem, develop a design concept, identify design requirements, develop a design and prototype, refine the technology, test the technology, prepare for mass production, and then test for scalability. This process can be seen in Figure 2.

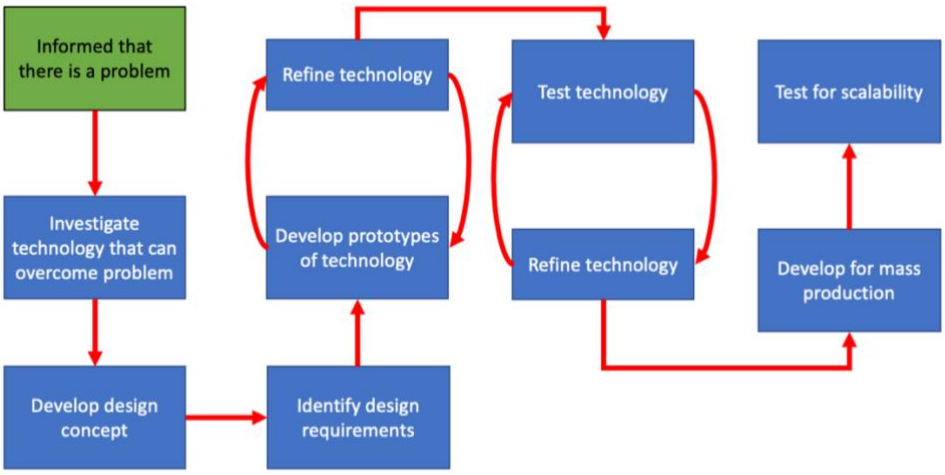


Figure 2 Engineering process model (linear)

The human factors approach is similar, but it incorporates four additional stages: understanding user needs, designing the product, testing and refining the product, and then testing in the wild when possible.

Incorporating the human factors approach with the engineering development model generates the process model in Figure 3. This allows us to identify when in the engineering process the human factors methods and evaluations are best undertaken.

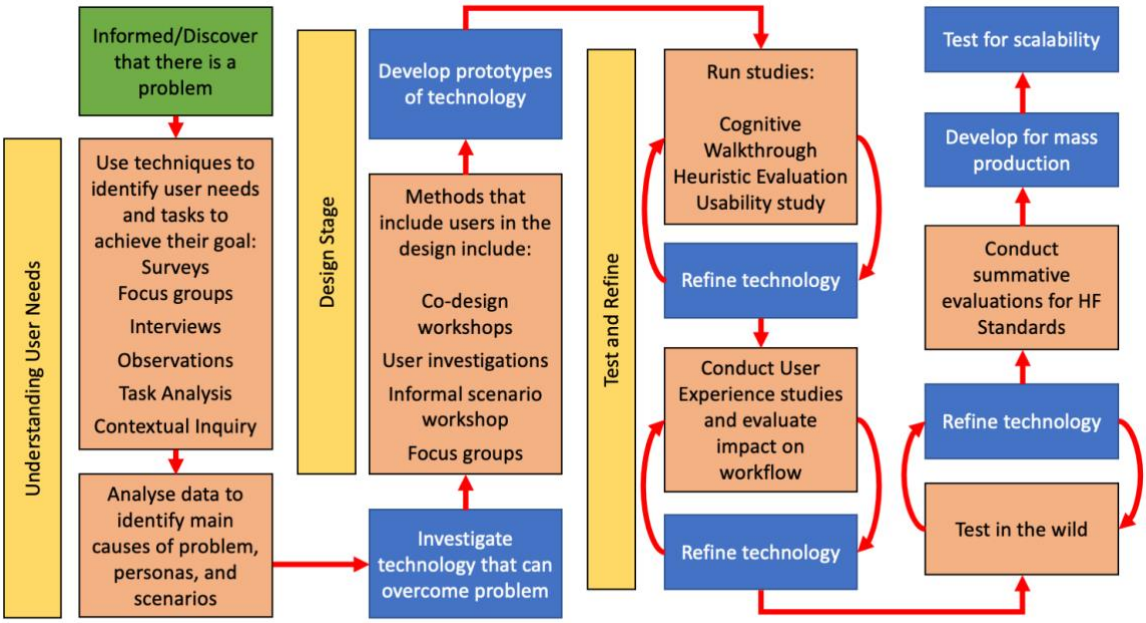


Figure 3 Engineering and Human Factors process models integrated

Examples of the need for Human Factors

People have a conceptual model of how they expect a system to work, based on prior experience with similar systems. When something does not work as expected, mistakes can occur or less reliable processes may be undertaken that the designers did not account for. Errors in a system can also be the result of poor design, such as a complex user interface or using iconography on buttons that do not easily portray the intended action. The following examples are medical devices that reached market without sufficient human factors input. In some cases, they had not been properly tested resulting in the loss of life; in others, the impact that the medical device would have on the surgical team was not discovered until used in practice.

Example of the infusion pump

In 2006 Denise Melanson, who was receiving chemotherapy treatment, went to hospital to get more medication for her infusion pump. She subsequently died from an overdose of fluorouracil and cisplatin, a drug used to treat her tumour, because the quantity to deliver per hour was miscalculated by not taking into account the number of hours per day, so instead of receiving 1.2ml per hour, she received 28.8ml per hour. She returned to the hospital four hours later with an empty medication bag, instead of four days later, but there was no way to mitigate the already administered lethal dose of fluorouracil and cisplatin. A local news article reported that investigators had concluded that the fatality was a result of an overdose of fluorouracil, poor design of the chemotherapy protocol, and the inability to rectify the situation after the lethal dose was administered. However, a human factors investigation (pg 57-63) replicated the scenario with five nurses from the

same hospital using the same pump; three entered incorrect data, all of them were confused by the setup or selection of mL/hr, two were confused by the programming of the device, and three were confused with the placement of the decimal point. It was also discovered that there had been eight similar incidents prior to Denis Melanson's, but the lessons learned from these incidents were either difficult to find or unavailable resulting in them not having a global impact as per this investigation. A human factors study should have been carried out prior to the device being approved or marketed, and the device and/or clinical protocol should have been designed to minimise the risk.

Example of Therac-25

The Therac-25 was a medical device used to destroy remaining tumour growth, after patients had had the majority removed through manual surgery, by firing electrons or x-rays at a targeted location. This machine was computer controlled and remotely operated. For shallow growths a low rad mode 'e' was used; for deep growths a high rad mode 'x' was used in conjunction with a metal plate to transform the electrons into x-rays. The Therac-25 also automated more of the safety features, which in previous models had been manually operated. In 1986, Ray Cox went in for one of his follow-up treatments, of which he had already had some. The operator accidently set the machine to 'x', but immediately realised his error and changed the setting from 'x' to 'e'. Due to this quick change in settings, the metal plate used to change the electrons to x-rays retracted; however, the machine was still set to high rad mode. The operator, in another room, delivered a dose to the patient, but due to the setup the computer responded with an error. The operator, going off prior knowledge, believed this to mean that the machine did not deliver the dose, so they delivered it again. A second time the error message came up, and so the operator delivered another dose. At this point, Ray Cox removed himself from the machine after receiving three painful blasts. Due to untested software, no human-based safety checks, and no hardware interlocks Ray Cox died 4 months later due to major radiation burns. This was just one of many cases in which fatal levels of radiation were delivered to patients over the lifespan of the machine. Had a human factors study been carried out the risk involved with an operator quickly changing from one mode to another and putting the machine into an unknown state should have been discovered, which would have prevented the accidental loss of lives.

Example of da Vinci Robot

The da Vinci robot is a minimally invasive surgical system that can support a number of surgical procedures. The complete system comprises three main parts, the patient cart, the surgeon console, and the vision cart. The patient cart contains the moving arms of the robot, which can have multiple joints moving at any given time as the surgeon controls them via the surgeon console, which is tethered to the system. The surgeon console is a fully immersive system, providing better vision for the surgeon and control of the robotic arms. However, this setup has unintentionally created barriers between the surgeon and the rest of their surgical team, as the team is no

longer co-located beside the patient, which has resulted in communication challenges as well as a change in the distribution of tasks. In one example, the surgeon had provided instructions to the scrub nurse, but they were getting frustrated that it wasn't being carried out. However, the nurse had performed the action, but not considered a need for a verbal confirmation that the task had been completed as prior to the presence of the robot this was not required. In this instance a gulf of frustration developed between the two. It has also been noted that with the introduction of the da Vinci robot, scrub nurses are no longer aware of the actions surgeons are carrying out as they control the robot. This causes those situated by the robot to ‘dance’ with the robot to ensure they aren't accidentally struck by a swinging arm. Conducting an ‘in the wild’ evaluation could have highlighted the communication issues that the surgical team now face with the introduction of the robot. Discovering this issue early would have allowed the development team to mitigate or resolve the problem, producing an uninhibited workflow between team members.

Understanding user needs

There are a number of methods that can be utilised to understand the needs of users; however, depending on the method we use we may only understand the surface layer of what users think they want, rather than pushing into the deeper understanding of what users really need, as illustrated in the Figure 4. This section will delve into a number of methods, listing them from surface gathering methods to gaining deeper understanding, that can be used in healthcare. Each method highlights what the method is, and why, when, and how you could use each during the development process.

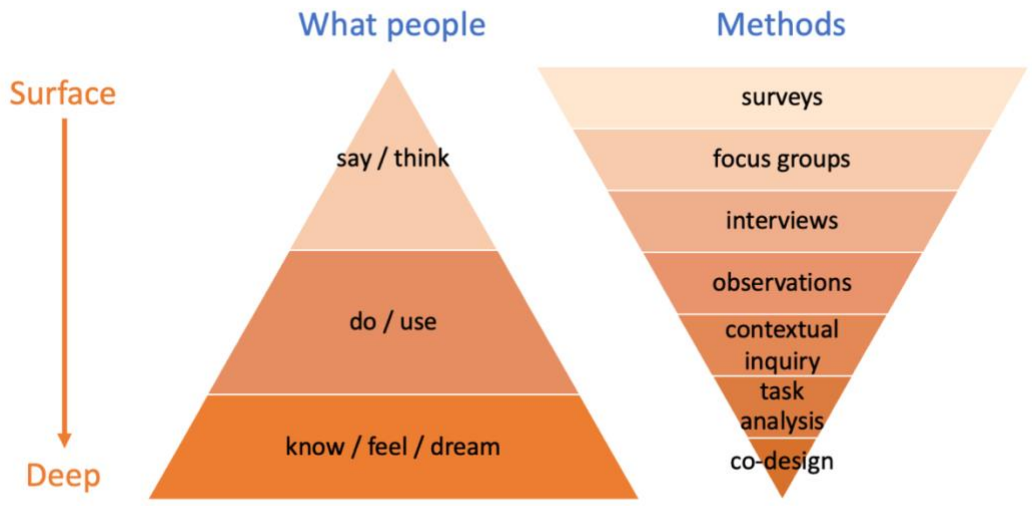


Figure 4 Participatory design methods adapted from Sanders, 2012

Surveys

Gain people's thoughts, feelings, and opinions based on their responses to a list of questions.

What and Why

Surveys are a means to gather data from a chosen population (which might be more or less precisely defined) of people based on a list of questions. There are two types of surveys questions, which produce different types of answers. The first are closed questions, which offer a predefined list of responses, typically using a 5-point Likert scale. These questions produce quantitative results, that is, results that are measurable and require statistical analysis. The second are open questions where the participant can provide whatever information they think is relevant to the question. These questions produce qualitative data. Most surveys will incorporate a mixture of both open and closed questions, depending on what response the

researchers think will provide the information necessary to help them improve the system.

When

Surveys can be used at various times throughout the course of product development. They can be used at the beginning of a project to gain an understanding of users' perceptions on a topic or after running an evaluation to assess the users' experience when using the system.

How

When developing a survey it is important that the objective of the survey is well understood to help focus the questions. Decide which questions are best given as closed questions and those that should be open questions. With closed questions ensure that the question is not biased towards a particular answer, and that responses are consistent between similar questions. Surveys should also be as short as possible; this reduces the risk of participants not finishing the survey, or getting frustrated with it and answering questions without reading them. Once the survey is created it should be rigorously tested, to ensure that participants provide the correct type of answers and that the questions are easy to understand. In some situations, there are existing validated questionnaires such as the System Usability Scale (SUS), or the NASA Task Load Index (TLX); these can be very useful if they address the questions that matter in the study. The method by which the survey results are analysed should also be well understood and tested.

Pros

Can be used in a variety of ways and are not onerous on the participants.

Cons

Surveys are deceptively easy to create, but it is difficult to create a good survey that is able to gather insightful data. They only gather information on the participant's opinions and not on what they actually do. If not properly designed the survey will not generate any informative results. Difficult to get participants to complete the survey completely, especially when there are lots of questions (particularly open questions).

Points to Ponder

Are the questions appropriate?

Is the survey too long?

Is the survey too repetitious?

For closed questions, are the questions (or possible responses) biased?

Resources

For further information on creating great qualitative surveys, click here (25 min read including videos). For useful questions to improve feedback surveys, click here (4 min read).

Focus Groups

Bring together a group of people to understand general perceptions, beliefs, and attitudes.

What and Why

Focus groups are used to establish a consensus from a large group of users through discussing together an issue or task to understand how they would like to see it improved, and identify the barriers they currently face or broad opinions on a subject or product. In healthcare, focus groups could include various groups, such as clinicians, patients, nurses, etc. when exploring issues that relate to multiple users. However, in some cases a single user group may be all that is required (e.g. understanding nursing issues at the bedside may only necessitate talking with nurses). Therefore, the participants should be recruited based on their interaction with the problem space.

When

Focus groups can be run either during the '*understanding user needs*' section or during the '*design stage*', depending on what information you are trying to elicit from the participants. When observations may be difficult to conduct in a timely manner and you are seeking to identify general concerns and barriers for users, then conducting a focus group during '*understanding the user needs*' can provide information to move forward on the project. If the purpose of the focus group is to gauge the sentiments from users about initial prototypes, then the focus group would be undertaken during the '*design stage*' once a prototype for evaluation has been developed.

How

These sessions should be pre-planned and moderated by the researcher to guide discussion whose job it is to manage and guide the discussion without manipulating the course of a discussion towards a particular opinion. To prepare for running a focus group the following points should be covered:

- Define the objective you wish to achieve
- Select which users are required to attend
- Determine the number of participants per session, how many sessions, and the location of the focus groups
- Recruit participants based on defined criteria
- Develop questions used to guide the discussion using open-ended questions
- Run the session

The session itself is run in a similar manner to Interviews, with the main difference being that you are interviewing a group of individuals simultaneously, and encouraging conversation between them as well as with you.

Pros

Gather a lot of information quickly, provide good insight into an issue as it is being explored from multiple perspectives at the same time.

Cons

Difficult to organise due to busy schedules. Sometimes difficult to get participants involved in the conversation. Like interviews, only give a perception on what people think happens rather than what actually happens. The opinions of some may be drowned out by more vocal participants, or participants may not feel comfortable sharing opposing views to others in a group discussion. Requires a good moderator to achieve ensure everyone's voice is heard.

Points to Ponder

What is the purpose of the focus group?

Who should be included in the focus group?

How many participants will be in each focus group?

Do the participants best encapsulate the demographic of potential users?

Have you gathered enough information or should you run another focus group?

Resources

For further information on how to run a focus group, click here (12 min read).

Interviews

Provide insight into user needs and help establish context of the user's environment. They also help to identify or clarify key points of frustration.

What and Why

Interviews are perceived as an easy method to perform, but in actuality can be difficult to conduct well; however, they can produce good insights into the needs of users. They are used to explore issues and hear individuals' stories. Interviews are versatile, as they can be conducted in person, over the telephone, or by video link. Interviews can also range from unstructured, which involves going in with no clear focus and letting the questions come naturally, to semi-structured, where the interview is guided by a script but allows the interviewer to explore issues in more detail by adding follow-on questions, to structured, where the interviewer cannot deviate from the questions they have created. In relation to human factors, semi-structured interviews are the most common as they provide guidance to the interviewer as to what they are going to ask, but provide the flexibility to delve into topics that warrant further exploration.

When

Interviews can be conducted at various times during the '*understanding user needs*' phase. If the researcher is unfamiliar with the environment they are examining, then an interview prior to conducting observations could provide them with the necessary context. Interviews post-observations help to gain further insight from the users with identified issues when contextual inquiries are not possible. When used in healthcare, interviews should have a clear objective and the duration should be taken into account (keep it short).

To enrich data collected from interviews, probes can be used to help guide discussion or to uncover information specific to what issues you are exploring. Probes can take on various shapes and sizes, from graphs of data, screenshots or video of observations, or cards that promote new thoughts.

How

Introduction:	Introduce yourself, explain the intention of the interview, reassure them about ethical issues and data management, gain signed consent, ask to record.
Warm-up:	Ask general non-threatening questions.
Main body:	Present questions in a logical order and start with broad questions and then narrow down. Avoid closed questions.
A cool-off period:	Include a few easy questions to wind down. Give the interviewee the chance to add anything else they feel is important, or to ask any questions in return.
Closure:	Thank the interviewee, make it obvious that the interview has ended, and switch off the recording device.

Pros

Delivers insights into users' perceptions of a task. Ability to gain insights from a range of different perspectives, such as healthcare professionals, patients, technicians, etc.

Cons

Only provide a user's perspective on what they think they accomplish, and in some cases are idealised perspectives on the situation. Interviews can also be very time consuming and, within healthcare, may be difficult to arrange as healthcare professionals are already time poor.

Points to Ponder

What is the purpose of the interview?

What relationship does the interviewee have to what you are trying to understand?

Do you have a good understanding of the users' needs?

Have you properly understood situations the participant has described?

Have you uncovered the information you are looking for?

Resources

For further information on the pros and cons of conducting user interviews, click here (48 min read including videos). Additional tips for conducting qualitative interviews, click here (10 min read).

Observations

Used to observe and understand user's behaviours and workflows to identify current issues and uncover opportunities to improve user experiences.

What and Why

When observing people interacting with technology, we are able to see how that technology works within the context of their workflow. This allows us to see what people actually do, as opposed to what they say they do. Observers in healthcare settings typically take on the role of outside observation; that is, the observer is not participating in the environment they are observing. It is also important that when observing healthcare settings multiple perspectives may be required as professionals move around patients. Through observations we want to understand what people are doing, how they are doing it, and with whom they are doing it. We

also should be observing the moments that bring satisfaction to those whose work we are observing, and their moments of frustration. Identifying these key points help us to understand when technology can be helpful or a hindrance to the users.

When

Observations are an important method used to identify user needs. Depending on the researcher's familiarity with the environment and the users, observations may be carried out prior to interviews. They provide a good first step to familiarise oneself with the context the user works in, and understanding the users' needs in context. Observations may also highlight other areas, previously unknown to the researcher, that require further exploration. For example, if you are observing pain medication delivery at the bedside, you may find that the issue of late delivery is not at the bedside, but at the drug station where bedside nurses get access to the medication.

How

The AEIOU framework can help identify what you need to focus on when conducting observations.

Activities	What are the actions that the people are performing?
Environments	Where do the activities take place? What resources are available to them? What is the environment like (noise, temperature, lighting)? Where are people standing and other objects in the room positioned?
Interactions	How are people interacting (verbally, mannerisms, through technology)? Who are they interacting with? What are the interactions about?
Objects and Tech	What objects and technology are present? How are they being used? How are people using particular objects to perform their tasks (gripping, manipulating, typing, touching)?
Users	Who is present? What is their role? How are they involved in the activity?

Pros

Provide an unbiased glimpse into the practices of users, able to uncover issues that users are unaware of.

Cons

Time consuming, small sample size, huge data set, Hawthorne effect (people alter behaviour in response to being observed). Often hard to interpret data when the work is unfamiliar to the observer.

Points to Ponder

Who are the main users you want to focus on?

How do the key users perform the given task(s)?

What aspects of the task are frustrating to the user?

Does anyone else interact with the task / activities you are investigating?

Are you able to capture all of the data you require?

What area of the observed environment is of most interest to you?

What routines do the participants undertake?

What are they doing that you didn't expect them to do?

Resources

For additional information on observations, specifically how to prepare and conduct, click here (10 min read).

Contextual Inquiry

Are a combination of interviews and observations, providing opportunities for the researcher to inquire of the user additional information to improve understanding.

What and Why

Contextual Inquiry is a method that combines observations and interviews. It allows the researcher to be observing the practices of the participants, and provides the freedom for inquiry into why they are performing the actions they are performing at the time and how they understand their work. This allows for a great deal of information and context to be understood quickly based on the user's experience performing the task, and acknowledges the user as an expert at performing their tasks. Contextual Inquiry can also provide important details to models relating to communication, roles and relationships of those being observed, sequence of events, impact of the environment, and reasons behind the structure of the system.

When

When possible, contextual inquiries should be conducted as one of the first methods of understanding the user's needs as it allows the researcher to probe the user for details they do not understand. In some scenarios they can be performed instead of observations, as the interactions of the users may be minimal and easily captured during the inquiry. However, in some healthcare settings contextual inquiry is impractical due to patients being present, the cognitive effort already required for healthcare professionals to perform their tasks, and the ability to record both sound and vision when people are working within sterile conditions and patient privacy needs to be maintained.

How

Contextual inquiry begins with observation and then from what is being observed querying users to gain further understanding. For example: Why did you ask the patient to roll over? What information is helping you to make that decision? How do you know how much medication to give the patient? Therefore, contextual inquiries should use a combination of observation and interview techniques. Optionally, the insights from contextual inquiry can be represented in a set of work models that describe the flow of communication between people, the physical environment that shapes work, the design of key artefacts that support the work, the task structure (called a "sequence model") and an overview of the culture and policies that shape work.

Pros

Quick to perform and provide a lot of additional context that cannot be gathered from observations alone. Promotes that the user is an expert and that the researcher is trying to understand how they perform their tasks.

Cons

Not always achievable due to the constraints of healthcare. Large data set, and prone to the Hawthorne effect (observation alters behaviour). Often hard to interpret data when the work is unfamiliar to the observer.

Points to Ponder

Where is the user receiving their information?

Why do they perform the actions they do?

What is the result of the action?

How do they know when to take an action?

Resources

For additional information on contextual inquiries, click here (3 min read). For additional information on using contextual design work models, click here (20 min read).

Task Analysis

Understand the tasks users perform to reach their goal/s.

What and Why

Task Analysis is about understanding the tasks required by participants to achieve their goal(s). This is important as it allows the researcher to understand the entire workflow for individuals or a team working together to perform a task (e.g. surgery), and highlight the tasks that cause the most frustration for the user(s). Task analysis allows the researcher to understand how the participants progress towards their goal and what is required for them to achieve along the path towards their goal.

There are several types of task analysis that can be completed, depending on the situation; however, in the case of healthcare, there are two main task analysis that can be performed: physical and cognitive. Physical task analysis is the process of identifying the actions that users perform to achieve their goal within their environment and includes capturing any subtasks. A cognitive task analysis is focused on the “thinking” tasks where decision-making, problem-solving, and judgements relating to the goal are taking place.

Performing a task analysis allows for the users’ process flow to be captured and identifies the means by which they interact with the environment around them and can highlight when and how they make decisions to progress towards their goal. It provides insight into opportunities for improvement that may not otherwise be obvious. Completing a task analysis provides essential information to understand where new technology will be situated within the process flow, identifies what other aspects of the process will be affected, and how the cognitive load of the user can be reduced.

When

Task analysis should be conducted as early as possible and, in most instances, can be completed alongside an observational or contextual inquiry study. Identification of the tasks that cause the most physical and cognitive effort for users at the beginning of the design process allows for more appropriate prototypes to be generated in later development phases, which will have the most impact on improving performance of the user. Additionally, a second task analysis can be carried out when conducting ‘in the wild’ testing, to ensure that the technology is being used when expected and to

see how users integrate the technology into their workflow and identify how it improves their decision making.

Pros

Identify key tasks that require attention, can be produced in line with other methods, provides the researcher with a clear understanding of what is involved to achieve a set task.

Cons

Having reliable observational, contextual inquiry, and interview data that can be structured into a valid task analysis.

Points to Ponder

What are the goal(s)?

Does the task contribute to achieving the goal?

How do the tasks relate to each other?

Are there any tasks that are unnecessarily repeated?

Who does the task affect?

What decisions are being made during each task?

Resources

For a more in-depth review of task analysis, click here (15 min read).

Design Stage

The design stage showcases methods that can assist engineers in developing prototypes of healthcare products that meet the needs of their intended users. These methods include various types of workshops, prototyping, personas, and scenarios. Workshops allow engineers to engage with users, thus allowing their immediate thoughts and insights to be integrated and explored; however, although workshops are beneficial, they are not essential, as there are other methods of engagement. Prototyping allows engineers to work with and trial early low-fidelity concepts with users. Personas help in ensuring that the healthcare product is being developed for the correct users, and scenarios can help to identify key moments where technology could be helpful or allow engineers to convey to users potential scenarios in which new technology can help improve current systems and practices.

“Understanding the user’s needs” provided a list of methods to help to understand what users say, think, do, and use. Figure 4 indicates that through these methods we can work towards developing technology that will make a positive difference. Through the design stage we try to ground the needs and aspirations of users in relation to performing their work.

The design stage allows users to explore new ways of approaching their tasks to achieve their goals using low fidelity and exploratory means. Within healthcare this could be exploring interfaces for surgeons, developing improved visualisation or data for bedside nurses, or investigating devices for home use.

In this section we will expand on each of the design stage methods and highlight what the method is, and why, when, and how they can be used.

Workshops (Co-design)

Engage with users in developing technology fit for purpose.

What and Why

Workshops are a way to engage with users to understand their desires on how they would like to see their practices improved with technology. Recently, most workshops have been labelled as co-design, meaning that the users are part of the decision-making process. However, there are a number of different types of workshops that can be conducted with users, which generate different outputs. These workshops may be co-design, in the sense that you are generating prototype ideas; user investigations, as you work with users to evaluate prototypes and roleplay potential scenarios; and informal scenario workshops, which envisage how they would like to see the task improved by generating speculative scenarios. For this introduction, all types of workshops will just be referred to as workshops.

Workshops provide means for the participants to explore the problem space and identify opportunities for improvement and barriers that currently hinder their ability to perform a task. However, the aim of a workshop is not to establish a final solution,

instead they are used to develop concepts to inform design for an established user. Workshops are a means to bring multidisciplinary teams together to leverage the expertise from one another to generate concepts that explore different facets of knowledge. Workshops that involve engineers, clinicians, and human factors provide a balanced discussion. The engineers are able to provide expertise in what technology is available and how it can be integrated into practice. Clinicians can provide details on the scenario, task, and the environment in which it will be incorporated. The human factors help to determine the points of human interaction and incorporate users' needs into the design.

To get the most out of your workshop there are different methods that can be used to help generate creativity. These include collages, paper prototyping, sketching, mind mapping, storyboards, inspirational cards, video-based card sorting, modelling, and others. For more details on each of these methods, what they are and how to use them, click here (10 min read).

When

Workshops are, in most cases, best run once you have a clear understanding of user needs, and are looking at developing initial concepts with the users. Apart from design workshops, other types of workshops (click here for more examples) may be run in order to get different information from users or to critique the design as it gets closer to its final concept. This allows you to ensure that it still meets the users' needs before moving into any formal evaluation.

How

There are many ways in which a workshop can be run, but using the following plan will help get the most out of a workshop.

- Explain the purpose of the workshop and what you will be doing during the workshop and how it will be structured so that participants know what to expect
- Encourage creativity and remind people that everyone can be creative and contribute to the workshop
- Divide people into teams when working with a large number of participants, (in some cases ensuring that each group has an individual from each discipline can be helpful as they can learn from each other e.g., engineers and clinicians working together as the engineer has the technical understanding while the clinician has the contextual understanding)
- Describe what you expect to get out of the workshop so that participants can properly contribute to the outcome
- Run the workshop using the method you chose earlier
- Re-group. This is a time for the individual groups to explore how others have contributed and provide feedback to help generate the best possible outcomes

- Debrief with the group to discuss standout features, issues, opportunities, and barriers

Pros

Generate good ideas that take on board user needs, allow unprofitable designs to be rejected early during the design stage, empower users in the decision-making process.

Cons

Time consuming, difficult to recruit participants, huge data set.

Points to Ponder

What do you plan to achieve from the workshops?

What are the main user needs that the workshop is focused on?

Who should you invite to the workshops?

What method will allow you to best help participants explore ideas?

Resources

For additional methods that can be incorporated into your workshops, click here (5 min read). A pocket guide for different insights into preparing and running your workshop, click here (9 min read).

Prototypes

Test and explore design concepts using low-fidelity methods.

What and Why

Prototyping is a method that allows ideas to be quickly tested to illustrate a concept and look for areas of improvement. Doing so can provide early insight into the design process and allow for various concepts to be explored before investing a lot of time and money into a project. The prototypes themselves also can be low fidelity, that is they are made up of basic elements to represent the idea, and be either physical or digital. Physical prototypes could be comprised, but not limited to, hand drawings, modelling clay, cardboard mock-ups, 3D printed mock-ups or anything that allows you to investigate and experiment with ideas. Digital prototypes could be plug and play electronic components and simple digital sketches.

When

Prototypes can be generated from the initial idea of a product, through to validation, with the only difference being the level of fidelity in the design. For example, when developing a new health application for a mobile phone, a low-fidelity prototype, made of wireframe sketches, can be useful. It could provide the layout of pages, information you want users to have, and how the pages interact allowing yourself and others to test ideas and find solutions to problems. However, some evaluations, such as validating software or mechanical behaviour in a system, require a much higher fidelity system to be developed. For example, when developing a new instrument for surgery the ergonomics may only be able to be understood once you have a high-fidelity 3D printed part with components inside to test for balance, stability, and usability.

How

Prototyping is about doing, rather than pondering on how to do something. There are no rules as to how to prototype or what materials you should use. However, the level of fidelity of the prototype should continue to increase as requirements are met and further and more robust evaluation is undertaken.

Pros

Prototypes are generally quick to build and evaluate. They allow for ideas to be made and tested.

Cons

Can be difficult to demonstrate ideas (especially for low fidelity prototypes) to other team members.

Points to Ponder

Can you test this feature easily with a low-fidelity prototype?

Does this prototype provide enough detail to test my ideas?

Resources

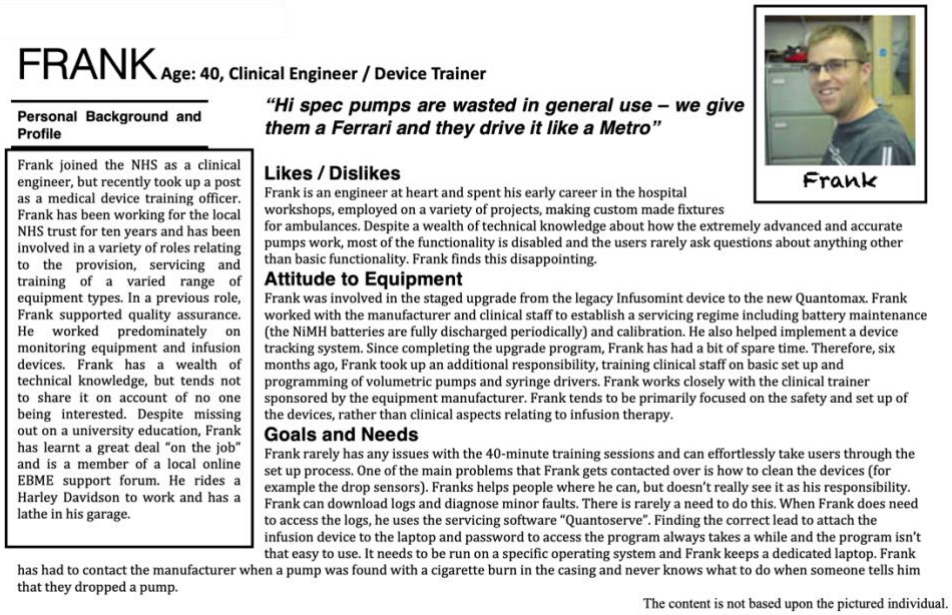
For additional information on developing prototypes, click here (12 min read). For more information on the difference between low and high fidelity, click here (2 min read).

Personas

Develop a representative profile based on evidence captured from observations, interviews, and other sources of data of users.

What and Why

The development of a persona allows researchers to have a clear image in their mind of who they are developing a product for. A persona provides a snapshot of a generic user and provides information such as: their job title and/or responsibilities, demographics, goals and tasks they need to complete, the environment they work in, with supporting quotes from the data. An example of a persona used to highlight a clinical engineer can be seen in Figure 5.



FRANK Age: 40, Clinical Engineer / Device Trainer

"Hi spec pumps are wasted in general use – we give them a Ferrari and they drive it like a Metro"

Frank

Personal Background and Profile

Frank joined the NHS as a clinical engineer, but recently took up a post as a medical device training officer. Frank has been working for the local NHS trust for ten years and has been involved in a variety of roles relating to the provision, servicing and training of a varied range of equipment types. In a previous role, Frank supported quality assurance. He worked predominately on monitoring equipment and infusion devices. Frank has a wealth of technical knowledge, but tends not to share it on account of no one being interested. Despite missing out on a university education, Frank has learnt a great deal "on the job" and is a member of a local online EBME support forum. He rides a Harley Davidson to work and has a lathe in his garage.

Likes / Dislikes

Frank is an engineer at heart and spent his early career in the hospital workshops, employed on a variety of projects, making custom made fixtures for ambulances. Despite a wealth of technical knowledge about how the extremely advanced and accurate pumps work, most of the functionality is disabled and the users rarely ask questions about anything other than basic functionality. Frank finds this disappointing.

Attitude to Equipment

Frank was involved in the staged upgrade from the legacy Infusomint device to the new Quantomax. Frank worked with the manufacturer and clinical staff to establish a servicing regime including battery maintenance (the NiMH batteries are fully discharged periodically) and calibration. He also helped implement a device tracking system. Since completing the upgrade program, Frank has had a bit of spare time. Therefore, six months ago, Frank took up an additional responsibility, training clinical staff on basic set up and programming of volumetric pumps and syringe drivers. Frank works closely with the clinical trainer sponsored by the equipment manufacturer. Frank tends to be primarily focused on the safety and set up of the devices, rather than clinical aspects relating to infusion therapy.

Goals and Needs

Frank rarely has any issues with the 40-minute training sessions and can effortlessly take users through the set up process. One of the main problems that Frank gets contacted over is how to clean the devices (for example the drop sensors). Franks helps people where he can, but doesn't really see it as his responsibility. Frank can download logs and diagnose minor faults. There is rarely a need to do this. When Frank does need to access the logs, he uses the servicing software "Quantoserve". Finding the correct lead to attach the infusion device to the laptop and password to access the program always takes a while and the program isn't that easy to use. It needs to be run on a specific operating system and Frank keeps a dedicated laptop. Frank has had to contact the manufacturer when a pump was found with a cigarette burn in the casing and never knows what to do when someone tells him that they dropped a pump.

The content is not based upon the pictured individual.

Figure 5 Example of a persona (from Vincent, 2014)

When

A persona should be developed at the end of the understanding user needs phase, after all the data has been obtained and analysed.

How

From the data, group similar participants together to generate a single profile that represents that user group. Each profile should contain information obtained from observations, interviews, contextual inquiries, etc., about each identified user. The information in the persona should detail the major goals and needs identified, but should be broad enough that it describes a group of participants, and not a specific individual.

Pros

Help focus the design ideation to ensure that it meets the requirements of the prescribed user; can be created quite quickly from the data.

Cons

Can become outdated quite quickly, depending on the method used to generate the persona they may be based on users' opinions rather than reality.

Points to Ponder

How does the data support the persona?

What motivates your persona to achieve their tasks?

What are the needs of your persona?

Does this persona interact with other personas, and what relationship exists between them?

Resources

For further understanding on developing personas, click here (9 min read time).

Scenarios

Capture instances of users detailing their tasks, descriptions of how technology could be used within a given context.

What and Why

Scenarios provide context behind the users' intentions to perform their task. There are two types of scenarios that are commonly developed, current or speculative. A current scenario is used to depict in detail how a task is currently carried out. It can be used to highlight key points of frustration within the given context. Speculative scenarios, which are more common, depict how users' needs can be addressed with the adoption of technology. Although these are fictional, they allow researchers to envisage how technology can be incorporated and utilised within the users' context. Each scenario should list the goals that could be accomplished from their design, and how they relate to the observations and interviews from which they were conceived.

When

Scenarios are best developed during the phase of establishing which technology provides the best outcome for users. Doing so allows them to be implemented into workshops as a way for users to investigate possibilities, and for users to provide additional contextual implications the researchers may be unaware of.

How

Scenarios are written using descriptive language to portray the story and context of how technology can be used in a given situation. When developing a scenario there are three main points to consider. Who is the user? What is the context of the scenario? What goal is the user trying to accomplish?

Pros

Quick to develop, helps others to envisage how the technology can be used.

Cons

Fictional, good on paper but difficult to implement.

Points to Ponder

Is the scenario realistic?

Is the scenario achievable within the available time?

What challenges may arise from this scenario?

Resources

For further understanding on developing scenarios, click here (6 min read time).

Test and Refine

Once a product has been prototyped it is important that it is rigorously tested and evaluated prior to going into production to ensure that it can accomplish the task it is designed to perform. This process is a refining process, as in most cases, multiple versions need to be developed to improve performance, reliability, and repeatability. Within this phase there are a number of human factors methods that can help identify potential errors and usability concerns, including cognitive walkthroughs, heuristic evaluations, usability studies, user experience evaluations, and 'in the wild' testing. Cognitive walkthroughs and heuristic evaluations are expert evaluations, meaning, they are conducted by human factors experts within the domain of healthcare to provide feedback and solutions for potential user errors. Usability, user experience, and 'in the wild' evaluations allow for evaluation on the user's ability to perform tasks and understand if the healthcare product is usable, useful, and safe to the user as well as satisfying. The test and refine stage is an iterative phase, allowing for changes in the design to continue until the new technology meets the user's needs.

In this section each of the test and refine methods are expanded upon, highlighting what the method is, and why, when, and how they can be used.

Cognitive Walkthrough

Conducted by a human factors expert to review the system to identify potential use errors.

What and Why

A cognitive walkthrough is an evaluation method to identify how easily tasks can be performed by users. However, unlike usability studies, a cognitive walkthrough is best conducted by a human factors expert rather than observing participants perform tasks. If the person conducting the cognitive walkthrough is too familiar with the product, they may potentially miss significant issues. Essentially, it requires the evaluator to put themselves in the shoes of the potential user. Using personas will greatly assist to achieve this.

When

The cognitive walkthrough is best conducted during the early design stage, prior to user testing and can even be conducted based on sketches of the product. This allows the expert to identify key issues that still require attention before conducting formal testing with participants.

How

A set of tasks for the user to examine are required to conduct a cognitive walkthrough. The tasks can be grouped to focus on a specific high-level task. For example: setting up the product, using it to capture information, retrieving information from it, etc. For each task, the evaluator works through the steps of the task, asking four questions (see below) about the likely user thinking for that step and the feedback they receive from the product. The evaluator identifies potential user difficulties and errors through this process.

Pros

Cost effective, quick to run, and no recruitment required for the process.

Cons

Sometimes difficult to put yourself in the shoes of your participants.

Points to Ponder (the four questions)

Will the user try and achieve the right outcome based on the information you have?

Is it apparent what the next step is based on the last action?

Is there a correlation between the action you are performing and the outcome you expect to achieve?

When a correct action is taken, is there some indication that the user is heading towards achieving their goal?

Resources

For further understanding on conducting a cognitive walkthrough, click here (10 min read time).

Heuristic Evaluation

An evaluation conducted by human factors experts to identify potential usability issues that intended users may encounter when interacting with a product's user interface.

What and Why

Heuristic evaluation is a method that allows human factor experts to measure the usability of a user interface based on a predefined list of rules of thumb (the

heuristics). There are a number of heuristics that can be used to evaluate a user interface including Nielsen's, Shneiderman's, Gerhardt-Powals', and Connell and Hammond's. The heuristics have been designed to cover the areas that users typically have the most difficulty with; evaluating the product's user interface against a set of known areas of concern during the design phase can help improve the user's experience with the product. Nielsen's 10 usability heuristics are a good guideline when developing user interfaces and cover: visibility of the system; match between system and the real world; user control and freedom; consistency and standards; error prevention; recognition rather than recall; flexibility and efficiency of use; aesthetic and minimalist design; recognise, diagnose, and recover from errors; and help and documentation. More detail on these 10 heuristics can be found on the NN/g website (10 min read).

When

Like Cognitive Walkthrough, a heuristic evaluation can be conducted at multiple times during the course of development, and as early as sketch prototypes of the user interface. This allows obvious issues to be discovered from low-fidelity prototypes to more nuanced issues that can only be found with a high-fidelity user interface.

How

A heuristic evaluation can be conducted using the following seven steps.

1. Decide on which set of heuristics best suits your user interface. Additional heuristics may also be included, depending on the product being developed.
2. Work with healthcare usability experts and not potential users. It is recommended that multiple experts, ideally five, are used to ensure that all aspects of the user interface are properly evaluated.
3. Briefing session. Ensure that those evaluating the user interface know what is required of them and which aspects of the user interface you want them to evaluate. The information provided to each evaluator should be the same so as not to introduce bias into the evaluation.
4. Begin the first phase. This phase is exploratory, allowing the evaluators time to understand the interactions and scope of the product. Then, as experts, they can decide on which elements of the heuristic they want to focus on. Ideally each evaluator will work independently of the other evaluators during this phase.
5. Begin the second phase. This phase is for the evaluators to apply the heuristics to the user interface they are evaluating.
6. Record the findings. This can be done in one of two ways; firstly, an observer may be used to take notes and possibly record the interactions of the evaluator. Secondly, the evaluator can be left to make their own notes. Having an observer present requires coordination between parties; however, an

observer reduces the time required to analyse the data as this can be done on the fly with no need to interpret the evaluator's decisions.

7. Debriefing session. This time is for the evaluators to come together and synthesise their findings to create a complete list of problems. This phase also demonstrates why using usability experts, rather than potential users, is important as the evaluators are not only asked to define usability issues, but also recommendations on how to address the usability concerns. The report should list all identified problems, explain why they are an issue, depict the heuristic that each problem relates too, and provide suggestions to improve the usability of the product.

Pros

Evaluators have the freedom to focus on heuristics they are familiar with. The evaluation can be conducted at the early stages of development. Not only are usability concerns identified, but potential solutions are also provided from healthcare usability experts.

Cons

It can be difficult to find enough domain specific usability experts to evaluate and cover all areas of the heuristics. Some evaluators, who may not be familiar with healthcare, may overshoot the mark and identify issues that would not usability issues for the intended users (e.g., terminology).

Points to Ponder

What aspect of the user interface should be evaluated?

Do the heuristics you are using cover all elements of usability for your user interface?

Are the evaluators familiar with healthcare products and user interfaces?

When in the project is the best time to conduct a heuristic evaluation?

Resources

For further information on understanding heuristic evaluation and additional tips, click here (5 min read plus 8 min video). For more details on how to conduct a heuristic evaluation, click here (12 min read).

Usability study

Identify problems with your product; Discover opportunities to improve the product.

What and Why

A usability study evaluates a participant's ability to use a product or service by observing them. The participants should be representative of those who would normally use the product to determine how effective and efficient it is to use, how easy it was to learn to use the product, and to identify key areas of concerns that participants have with the product. Doing so provides strong evidence of how close the product is to being ready for deployment, and can also identify whether the product is providing the right service to the user to establish its utility. The output of a usability study includes both qualitative (the users' opinions of the product including likes, dislikes, and desired features) and quantitative results (successful tasks, completion times, error rates, etc.).

When

Conducting a usability study early on during the development stage allows for issues to be identified and solutions to resolve them to be applied while the cost of implementation is low. In Figure 3, the usability study is shown as being conducted as soon as a working prototype is developed, and in some cases the prototype can be very low fidelity. For example, if you were developing a health application on a mobile device, a wireframe model (basic sketches of the skeletal framework of a website) evaluation could identify the same issues as a completed app, but the cost to adjust a wireframe is must less than having to reconfigure a completed application. For some products, multiple usability studies might be required to be run at different points along the product development path to evaluate different aspects of the product.

How

The format to conduct a usability study should be well structured, and planned well in advance to allow for piloting the study. This ensures you are able to capture the information that is most important for you to progress in the development of the product. A set of tasks you wish the participant to complete should be constructed, as well as a task scenario to accompany each task. The tasks could be independent of each other or sequential in nature; either way, the tasks used should be those that have been identified as being most common, critical or important, or having been previously conducted incorrectly.

Understanding the users' thought processes during the usability test is paramount in identifying points of frustration, misinterpretation, and opportunities for improvement. To achieve this a '*Think Aloud*' method is commonly adopted. This method invites the users to provide a continuous verbalisation of their thought processes, detailing what they are thinking, and describing difficulties they may be having when performing the task (e.g., not knowing where to click to submit a form on a website). Thing Aloud can be conducted concurrently with the task or retrospectively. A retrospective Think Aloud may be best suited in particular healthcare settings when

observing the user perform an action in a setting where they cannot verbalise their thoughts at the time; such as interacting with a patient or performing a task that requires a significant amount of cognitive effort. In these instances, having the user conduct a retrospective think aloud while watching a video playback can deliver similar results. However, the shorter the time between the recording and the playback the higher the accuracy. Alongside Think Aloud, '*Probing'* is another technique that can be carried out, where the researcher may ask follow-up questions when they identify something they have not seen before or based on something the participant expresses that they would like to explore further. Again, probing can occur either concurrently with the task or retrospectively.

The method by which you wish to capture the users' actions should also be considered, these could include: sound recording, screen recording, participant recording, action tracking, gesture tracking, gaze tracking, or any combination of these.

A usability test should consist of the following basic plan:

1. Welcome the participant and explain the purpose of the usability study.
2. Explain to the user how you are going to capture their thought processes (Think Aloud and/or probes, and either concurrent or retrospectively).
3. Remind the participant that you are testing the product not them.
4. Give them a task scenario and have them start the task (take good notes during the study as it is easier to take notes, rather than trying to recall the study at a later time).
5. Continue the tasks until either they are all completed, or the allotted time has ended, as this can also indicate the difficulty of the tasks.
6. At the end of the session you may want to provide an exit survey (such as a System Usability Scale (SUS)), to identify users' initial perceptions of the device, thank the participant and provide any agreed incentive.

It is important when conducting a usability study that as a researcher you remain neutral, that is, do not provide opinions during the study and try to avoid providing assistance to the participant when they are getting frustrated. If the participant decides to give up or asks for assistance you can either end the scenario or provide minimum assistance. The reason you may wish to provide assistance is when the following task scenario is dependent on the participant completing the current task scenario or they are only on step 2 of 10 and you want to assess whether all steps are as hard as this particular step.

Pros

Good insight into product usability, engage with representative users, ability to identify issues early on in the product development.

Cons

Time consuming, difficult to recruit representative participants, difficult to engage participants in the study.

Points to Ponder

Do you have the right type of participants?

Are the tasks the participants are carrying out the most critical?

How are you going to analyse this information?

Have you tested your equipment to know it works correctly and you are capturing the information that is important to you?

Resources

For additional resources on conducting a usability study, click here (15 min read). For an in depth understanding of usability analysis, its history, why it's important, and the development of usability evaluation, click here (90 min read).

User Experience Evaluation

Understand users' reaction to the product and identify their pleasure and satisfaction when using it.

What and Why

User Experience (UX) evaluation may appear similar to a usability study; the difference is that a usability study focuses on effectiveness and efficiency whereas a UX evaluation evaluates the user perspective of the interaction with a product over time. From this we are able to understand the nuances of the product and the users' satisfaction with it. Therefore, UX builds on usability.

When conducting a UX evaluation you are exploring the following questions; How enjoyable is the product to use? Is it helpful? Is it a pleasure to use? Is it engaging? Does it look good? Does it add value to the lives of the users? Through finding answers to these questions, you will be able to determine whether the product is something that users will want to use or further refinement in the design is required.

When

As UX evaluation builds from usability, so it should be run after you have refined the product through usability testing. Unlike a usability study, a UX evaluation should be run over a set period of time or number of interactions with the product. Depending

on the product being developed, these evaluations may take place in a lab setting (e.g., patient monitoring system) or participants may be able to test it at their homes (e.g., blood glucose measuring device). The method used to conduct the UX evaluation should reflect the location where users will be able to assess the product.

How

The User Experience Honeycomb is an evaluation tool for UX, see Figure 6. The honeycomb enables researchers to ensure that the fundamentals of UX are addressed, which are: useful, usable, desirable, findable, accessible, credible, and valuable (see UX Honeycomb for more details on each of these). To understand these needs you will need to adopt a longitudinal data collection technique, that is, something you can leave with your participants to capture their impressions of the product after using it. These investigations should be designed so that as many areas of the honeycomb can be considered and evaluated.

Figure 6 Honeycomb model Peter Morville (2004)

Longitudinal data collection techniques are designed to capture user's thoughts, feelings, and actions when using the product. Typical modes of collecting this data include diary studies, card sorting, interviews, or surveys. Depending on the product, users, and timeframe, each of these modes have their pros and cons. Diary studies allow the users to record their own thoughts (either written or voice recording) and take photos (if able) of interactions they want to share. Card sorting activities vary, but typically include a set of predefined cards that a user can arrange in a prescribed way to provide insights. Interviews and surveys are classic means for researchers to gain insights. Within healthcare, set surveys may be the easiest method to incorporate; however, diary studies, although taking more effort to both prepare and for users to undertake, deliver better insights.

In short, longitudinal data study could be structured as:

- Use a method that best suits the users and the location where the evaluation can be conducted
- Ensure the method allows users to capture as many aspects of the UX honeycomb as possible
- Provide clear instructions to the users on how you wish them to engage with the method
- Let the users know the duration of the study, and when or how often you want them to evaluate the product
- Send gentle reminders to users to record their thoughts, feelings, and actions using the method you have provided
- At the end of the evaluation thank the user and provide any agreed incentive

Pros

Identify users' desire to use the device; highlight key areas that need improvement.

Cons

Some users may give poor feedback, UX is subjective, and over time users may 'go through the motions' of providing information. Typically, a large data set and depending on the method used may require transcribing, which is time consuming.

Points to Ponder

Under what conditions will this product be evaluated?

Does my method allow me to fully understand all facets of UX?

How long does the evaluation need to run for?

How many users do you need to understand the UX?

Resources

For examples on how user experience has shaped design, click here (25 min read).

'In the Wild' testing

In the wild testing, also referred to as naturalistic observation, goes beyond user experience testing, as it evaluates the product being used within its designed context. During in the wild testing users are evaluated interacting with the product as they see fit, which can lead to identifying unforeseen issues by the development team.

What and Why

In the wild testing involves carrying out a Usability study and User Experience Evaluation when the product is being used in the context it was designed for by the intended users. It is important that in-field testing is carried out prior to moving towards the market as it allows the regulatory design requirements to be evaluated and to identify any unforeseen issues to be captured and their risk determined. This may include the product not being used as intended or being used in a manner it was not designed for, identify unknown constraints, and understand how the introduction of the product will modify existing workflows and task distribution. “Examples of the need for Human Factors” highlight issues that in-depth ‘in the wild’ studies should have been able to identify, thus allowing design changes to be conducted to improve the product’s ability to perform its task and improve user satisfaction and safety.

When

In the wild testing is the last formal test carried out by researchers before moving to mass production and can provide a summative evaluation of the product. During this testing, unforeseen challenges may become apparent that could not be picked up in usability and user experience evaluations conducted in non-contextual environments. Therefore, carrying out these studies again but being used in the environment they were developed to be used in is essential. The duration of testing also needs to be taken into consideration to ensure that enough data is captured to ensure a realistic evaluation of use is captured. For example, when you have designed a new dialysis machine than this product may only be used every couple of days, so, the time frame may be dependent on having the user perform dialysis a set number of times. However, if the product being developed helps take common patient bedside readings, such as temperature, heart rate, oxygen saturation levels, etc., then an evaluation period of a week may be sufficient.

How

In the wild testing involved reconducting usability and user experience evaluations, with the main difference being the location and the users. To ensure that all possible outcomes are understood, evaluation of the product should be conducted by as many participants as possible at varying locations. For example, a device to be used by neurosurgeons should ideally be tested at a number of hospitals by both senior and junior surgeons. Similarly, a product developed for in-home use should be evaluated by different households and trying to capture a wide range of users.

Pros

Understand how the product works in its true environment, identify unknown constraints and exactly how the introduction of the product modifies existing workflows and task distribution.

Cons

Difficult to manage data collection and (depending on the product) may be difficult to conduct evaluation studies. The studies will also generate a large data set, which will need to be analysed and assessed.

Points to Ponder

Does the product impede existing practices?

How many locations and users are required to properly evaluate the product?

Is the product being used as intended?

Resources

For additional information on the pros and cons of 'in the wild' testing, read the section on Naturalistic Observation here (2 min read). To better understand the importance of 'in the wild' testing, click here (3 min read).

Data Analysis

All of the previous methods used to understand user needs, help during the design stage, and to test and refine the healthcare product cannot provide the level of detail required to improve healthcare products without the analysis of the collected data. Within human factors, and in particular the methods above, the data is typically both quantitative and qualitative. As mentioned in the introduction, as quantitative data is widely used within engineering it is not addressed in this document; therefore, the focus of this section is on qualitative data.

In this section qualitative data will be discussed, including what it is, why it is beneficial, and how to perform qualitative analysis.

Qualitative Analysis

'[*Qualitative insights] bring statistics to life, because we now have a better idea about how a particular experience is lived. They can also make us think about the similar circumstances but also the different circumstances that may lie behind a set of statistics.*' (Haddon, 2011).

What and Why

Qualitative analysis is the process of arranging all of the gathered information into context to draw out users' needs. In most cases, qualitative data is analysed using a bottom-up approach, also known as inductive thematic analysis, which consists of first familiarising yourself with the data and then systematically coding the data relevant to the context. This is contrasted with a top-down approach, where a set coding scheme is used to explore the data, and the researchers are looking into the data to find issues. When examining qualitative data there are two main ideas that the researcher should be considering: is what the participant telling me a facilitator or a barrier. A facilitator is a factor that benefits the user to perform tasks. Conversely, a barrier is a factor that impedes the user performing their task, which impacts them achieving their goal.

When

Qualitative analysis should be performed as part of each study in which users' perceptions are gathered to inform the design for the next task.

How

When performing a coding scheme for a thematic analysis, after familiarising oneself with the data, the researcher should be able to identify key themes within the data. From here, they would create subthemes within these key themes and begin coding the data. As they are coding, new themes may be uncovered which can be included

in the coding scheme. However, when this occurs, all previously analysed data will need to be reanalysed to include the new codes. Figure 7 is an example of a thematic coding scheme.

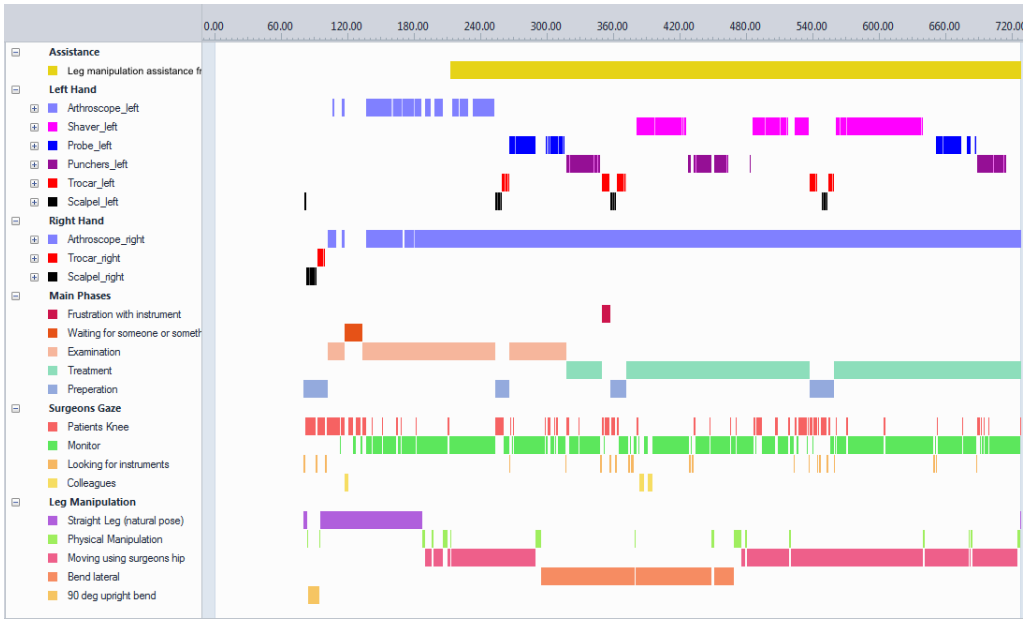


Figure 7 Thematic coding scheme example (from Opie, 2018)

There are multiple tools to help with the analysis of qualitative data, such as ATLAS.ti, MAXQDA and NVivo. These programs allow the user to create their own set of codes and then apply them to the data. From here, the user can inspect the data for each specific code to identify barriers that inhibit the user to achieve their goals and opportunities in which improvements to processes can be made.

Pros

Gain an understanding of the users' needs, seeing the problems and opportunities from their perspective.

Cons

Outcomes can be perceived as subjective and can be time consuming.

Points to Ponder

What key themes can you identify in the data you are exploring?

What facilitators can be identified from the data?

What barriers can be identified from the data?

Who is being impacted by the barriers?

Resources

For an in depth understanding of thematic analysis, click here (30 min read + videos). To investigate other modes of conducting qualitative analysis, such as grounded theory, content analysis, and hermeneutic analysis, click here (12 min read).

Regulatory Guidelines and Standards

There are a number of regulatory guidelines and standards that should be followed when developing healthcare products. These aim to ensure that medical devices are designed to reduce use errors to ensure safety to users and recipients of medical devices. There are three standards to assist in ascertaining the usability of a product: ANSI HE75 (*Human Factors Engineering – Design of Medical Devices*), IEC 60601-1-6(*General requirements for basic safety and essential performance*), and IEC 62366 (*Application of usability engineering to medical devices*).

These standards detail the human factors methods used to help identify use errors and high-risk scenarios so that the design of the system can either remove or mitigate these risks. To achieve this, they recommend using the methods provided in this document to identify, describe, and categorise use errors and hazard-related use scenarios. Using these same methods, they advocate conducting formative evaluation alongside the design development and ending in conducting a summative usability evaluation.

In Annex D of IEC 62366-2:2016, it specifies that not all reports are required in order to comply with the standards, but rather recommended to promote good usability engineering practice without becoming a paperwork generation exercise. However, there are a number of reports that are required, including: use specification, user interface characteristics related to safety and potential use errors, known foreseeable hazards or hazardous situations, hazard related use scenarios, user interface specifications, user interface evaluation plan, formative evaluation usability test reports (if conducted), and the summative usability evaluation test protocol with accompanying test report. Using the methods outlined in this document, these reports can be generated to ensure the standards requirements are met.

For more information on understanding how to apply human factors to the development of healthcare products, please visit the UK government's medical devices regulation and safety website. Other regulatory authorities have published local guidance that can complement this – for example, guidance from the US FDA.

Ethical Considerations

When conducting investigations with users it is important that ethical clearance is obtained to protect participants (the users). The participant should be informed in a detailed document exactly what the purpose of the study is and what is required of them, which they are required to sign in acknowledgement that they understand the study they are involved in. Alongside this, the mode of which data is being recorded should also be transparent to the participant. If at any time the participant wishes to withdrawal from the study, they are free to do so and may ask that all of their collected data is also removed.

Additional to collecting data, all participant information when recorded should be pseudonymised and any published data should be anonymised. This is in keeping with the main purpose of ethics to protect the participant.

When conducting user-centred studies, it is important that data protection and information governance is adhered to. This information relates to the safeguarding of participants information in the storage and distribution of data. Current legislation and additional information within the UK can be found on the NHS health research authority website. For other countries, please check your local government websites for advice.

All ethical applications need to be reviewed and approved by a Research Ethics Committee (REC), who are independent of research sponsors, thus allowing them to ensure that the participants are properly protected. The health research authority have additional information on ensuring that research is carried out correctly and describing the REC review process.

Resources

For examples on how to create human factors documents to assist with exploring and understanding user needs, UX for the masses has a number of helpful contents. These include: personas, process diagrams, scenario maps, scenarios, usability reports, and more. Further information on human factors methods that can be applied to healthcare products, such as risk and incident analysis methods, is available via the clinical engineering division website.