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The Development of a Methodology for Contextual User Research in Healthcare Design Projects

Donal HEALION[a,1], Enda O'DOWD[b] and Sam RUSSELL[c]
[a,b,c] *National College of Art and Design, Dublin.*

Abstract. The impact of human factors in the usage of medical devices and delivery of healthcare is increasingly being recognized as a significant contributor to patient experience and safety. This paper presents a methodology for undertaking contextual user research during healthcare design projects (in home, primary or acute care settings) by which all relevant human factors of a procedure can be recorded, documented and analyzed. An innovative method of graphically representing the results of this analysis is proposed which visualizes the interactions and interdependencies between all stakeholders and artefacts involved in a procedure and the environment in which it takes place. The proposed methodology is intended to assist researchers, designers, architects and healthcare professionals during the research phase of a healthcare design project to reveal user needs, identify potential risks, provide documentation for regulatory adherence and inform the development of a comprehensive and inclusive design brief. The paper presents the context and development of this systematic process, which draws on empirical and theoretical methodologies, a studio based pedagogy, and the experience of delivering real-world educational design projects in partnership with healthcare clinicians and medical device companies. It also highlights the capacity for this form of learning to align with Universal Design for Learning (UDL) principles. The application of the methodology has the ability to extract key environmental, user and human factors insights. Most importantly, these insights can inform the design process, positively impact on patient experience and safety through improvements in device development and care delivery, and enable the creation of more inclusive and accessible healthcare solutions.

Keywords. Human Factors, healthcare, task analysis, visualization, pedagogy.

1. Introduction

In order to facilitate and create independent and dignified access to healthcare for all, a design process for healthcare related projects that empathizes with the physical, social, mental and emotional requirements of those who both seek and deliver healthcare services is desirable. Such a design process should develop solutions to healthcare challenges in a holistic manner, taking into account the many varied factors that can influence and affect the quality of an interaction with healthcare services. By focusing on the Human Factors involved in healthcare interactions, the authors intend to develop a methodology that will help to capture the relevant information, analyze its significance,

[1] Corresponding Author, Donal Healion, Product Design Department, National College of Art & Design, 100 Thomas St, Dublin, D08 K521, Ireland; E-mail: healiond@staff.ncad.ie.

and present the results in a way that can be easily understood, incorporated into a robust design brief and used to inform the subsequent design process to deliver products and services that take into account the diversity of physical and cognitive abilities of potential users.

Human Factors (generally regarded as synonymous with ergonomics) is defined by the WHO [1] as examining "the relationship between human beings and the systems with which they interact by focusing on improving efficiency, creativity, productivity and job satisfaction, with the goal of minimizing errors." The paper aims to create an understanding of the importance of human factors in the delivery of safe and efficient healthcare, and highlight the challenges associated with uncovering research insights in such a demanding and complex environment. By outlining a proposed process for contextual user research and the visualization of the interwoven and layered findings of this research, we hope to create a useful methodology that can be adopted and adapted by various stakeholders in the development of inclusive healthcare products and services.

2. Background

Globally, the size, demographics and health profiles of our populations are changing more rapidly than ever before. United Nations (UN) estimates predict that the world population will increase by almost a billion people from 2018 to 2030 (7.63bn to 8.55bn - medium variant projection) with a further 1.2 billion rise predicted by 2050 [2]. The World Health Organization (WHO) estimates that "between 2015 and 2050, the proportion of the world's population over 60 years will nearly double from 12% to 22%." [3]. Levels of obesity (Body Mass Index $\geq 30 Kg/m^2$) have almost tripled worldwide since 1975 [4]. The WHO recognizes that this growing, ageing and less active population with all its attendant healthcare requirements will exert increasing pressure on healthcare delivery stating "All countries face major challenges to ensure that their health and social systems are ready to make the most of this demographic shift" [3]. In order to meet this increasing need for healthcare provision, it is estimated that the global demand for healthcare workers will rise to 80 million by 2030, double that of 2013 levels [5]. There is an obvious and urgent requirement for new, alternative approaches and creative measures to ensure equitable access to safe and efficient healthcare while reducing pressure on the staff that organize and deliver that care.

The potential for the consideration and application of human factors to assist in the improvement of patient safety and experience, risk management and healthcare delivery is widely recognized [6]. However, for a number of reasons, the consideration of human factors within healthcare provision has been slow-paced and uneven [7]. Given current pressures on national health systems worldwide, there is a greater need than ever to develop methodologies to allow the integration of human factors into the design process of healthcare projects. It is the authors' contention that for these methodologies to be genuinely useful, they must have the input of the healthcare community, both institutional and industry, to ensure that the relevant input, output and usage requirements are met. This approach recognizes that end-users within the healthcare system are not only those seeking treatment but also those who are involved in the delivery of care, be they clinicians, support staff or administrators who are under increasing pressure to deliver the highest quality of care whilst also striving to achieve efficiencies and adhere to rigorous safety protocols.

Current best practice internationally in the application of Human Factors in healthcare is being led a mixture of academic and healthcare institutions and other bodies. The Clinical Human Factors Group (CHFG) is an independent UK charity established in 2007. Using precedents from aviation and other safety-critical industries, the CHFG develops and applies human factors methodologies and risk assessment models to healthcare scenarios in order to deliver safer patient care. The Human Factors in Complex Systems Research Group, led by Dr. Patrick Waterson in Loughborough University researches how humans manage dynamic situations in complex socio-technical systems created by the interactions between people, products, technologies, services, procedures, policies and culture. Based in the University of Cincinnati, Mary Beth Privitera has published widely on contextual inquiry in the development of medical devices [8].

3. Context

In order to facilitate independent and dignified access to healthcare for all, those responsible for the future development of healthcare related products, services and facilities need to be aware of, and respond to, the complex range of human factors relevant in these environments. The education of those involved in healthcare developments, should therefore, prepare them to integrate human factors into their design process and solutions. The pedagogical approach outlined in this study seeks to support students in assessing and understanding these factors across a wide range of healthcare contexts using expertise developed in the Product Design Department of the National College of Art and Design (NCAD), Dublin. Since 2009, the department has run a MSc. program in Medical Device Design, during which students develop solutions to real-world healthcare problems working in collaboration with clinicians and industry partners. These projects typically begin with a period of contextual user research in order to understand the environment in which a device may be used and to establish the requirements of potential users to inform the design solution. Through the development of this process, an expertise has developed within the department in the creation and execution of methodologies to conduct contextual research in complex environments and to interpret and visualize its results.

The students of Medical Device Design at NCAD are exposed to a studio based design education that is combined with direct access to clinicians and healthcare environments in order to develop an understanding of a range of medical processes. Studio based design education values participation in practice with teaching focused on human centered research, problem solving and/or an exploration of a particular line of enquiry and active engagement with ideas. This form of learning aims to provoke students to generate new and innovative designed outcomes through practice that values risk-taking, questioning the status-quo, empathy with human experience and environment, and informed intuition [9].

This combined learning environment moves beyond a lecture based delivery of content to supporting a student-centered education that places a strong pedagogical emphasis on peer-to-peer learning and group working [10]. It also combines students from different disciplines with a range of capabilities to share learning. This approach has much in common with the principles of Universal Design for Learning with students and clinicians having access to multiple means of engagement, representation and action or expression [11]. Learner engagement is supported through a collaborative learning

experience that has diverse modes of information gathering, which facilitates analysis and understanding of complex tasks and that embeds reflection on practice. Representation of information, both taught and learned, is illustrated through multiple media combining imagery, video, models and verbal presentation. Healthcare procedures are analyzed, broken into stages and visualized in detail to support a greater comprehension across disciplines, needs and capabilities. This non-traditional form of representation allows a shift in understanding and supports communication of unmet needs or inefficiencies in a given process. In mapping the tasks, participants and environments it also supports a more strategic overview and assessment of processes.

4. Proposed Methodology

The methodology presented has been iteratively developed and refined through usage over several years in the research stage of medical device and healthcare design projects. The methodology has been used to study a wide range of procedures, in both human medicine and veterinary contexts, from those requiring high cognitive load and manual dexterity in time-dependent, high risk surgeries to low risk scenarios such as patient home-care briefings. The intention is to produce a methodology could be equally applied to almost any task performed by healthcare professionals.

The basis of the methodology is the application of design ethnographic methods during the contextual user research stage. These methods focus on primary research conducted in the actual usage context so that the researcher gathers as much data as possible in order to understand all the various interlinked factors that affect the user and that have the potential to influence a design solution. This is supported by secondary research into particular medical conditions and procedures and set these in context within the wider healthcare provision scenario.

The methodology consists of four stages:

1. Project scope
2. Data collection
3. Data analysis
4. Data presentation

Project Scope

Although a wide range of projects and scenarios can be examined using this methodology, in any study it is important to establish the scope of the contextual research stage, which can be further focused as the research progresses. It may be useful to maintain a broad viewpoint at the beginning of a research study as the actions leading up to and after a procedure under study can have significant bearing on the experience for both staff and patient. A first examination of a procedure or patient journey can reveal areas for further scrutiny and identify “pain points” or issues that require resolution. The purpose of this initial stage is to generate a framework for the analysis of a procedure or task, to identify and prioritize the important steps from the point of view of both the patient and the healthcare staff.

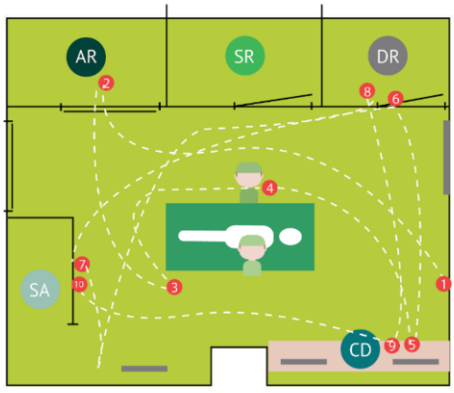
Data Collection

Secondary research into the relevant condition or procedure is undertaken using a variety of sources including textbooks, articles and on-line material. These sources can be used to build an outline task analysis which can be validated or revised during subsequent observation sessions.

Primary research is the key component of this methodology and can be conducted by a number of means depending on the nature of the task or procedure being analyzed. Having first received any required ethical approvals from their own and/or their host institutions to conduct the research, students should endeavor to gain the perspective of the user through immersive study using a variety of the following methods.

Observation

a. The researcher should observe the relevant procedure at least once in the actual clinical setting, ideally in number of locations to observe clinical or institutional differences in procedure.
b. Individual roles can be allocated (e.g. note-taking or photography) to divide the workload if more than one researcher is permitted to observe a procedure.
c. If ethically permitted, the procedure should be recorded by video and audio means for later analysis.
d. Still photography is useful to document particular complex tasks or procedures.
e. The researcher should take notes and sketch a storyboard of the task or procedure flow, particularly if photography is not allowed.
f. If a task or procedure is performed across a number of locations, the physical movements of the healthcare staff involved should be traced on the relevant floor plans as shown in Figure 1.
g. The researcher may request healthcare staff to verbalize their experience of the task or procedure while conducting it for retrospective verbal protocol analysis [12]. This allows the researcher to ask relevant questions for later analysis in order to gain insights into the execution of the procedure.



AR – Anesthesia Room SR – Storage Room DR – Dirty Room
SA – Storage Area CD – Computer Desk

Figure 1. Spaghetti mapping of the circulating nurse in an operating theatre. Image by Nikita Parikh

Interview

Interviews with as many of the relevant stakeholders as possible should be sought, including clinicians, healthcare support staff, administrators and patients if permitted. If possible, these interviews should be audio recorded as this allows the researcher to establish a rapport with the interviewee by maintaining eye contact (rather than note-taking). Recording allows later analysis of the conversation, which sometimes reveals points missed during the interview.

Role Playing

Physically role-playing the various stakeholders involved in a procedure, as shown in Figure 2, can be useful to gain the perspective of the different actors and provide insights into what factors influence their actions at each stage of a procedure.

Figure 2. Role playing a minimally invasive surgical procedure.

Data Analysis

Sense Making.

The information gained from the data collection stage is analyzed to extract critical elements and key insights which can be organized thematically and sequentially to build a detailed “rich picture” or narrative of a procedure as shown in Figure 3.

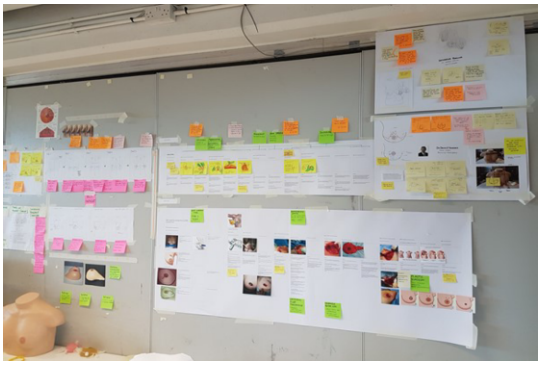


Figure 3. Building up a rich picture of a task using a combination of digital and analogue methods.

Analogue Storyboard.

Figure 4 shows an analogue draft of a storyboard constructed using sticky notes, sketches and images to create a linear account of a procedure. As recommended by the Food and Drug Administration (FDA) guidance shown in Figure 5, each step of the procedure is analyzed by perceptual inputs, cognitive processing, and the actions involved in performing that step [13]. This level of analysis enables the researcher to identify, at each stage of a procedure, what the relevant actor is perceiving from surrounding information channels, their comprehension of that information and their resultant decisions and actions based on that comprehension given the procedural context.

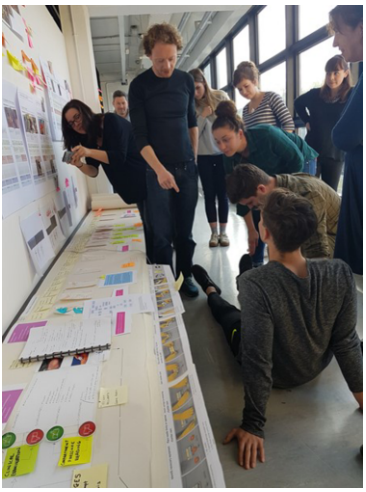


Figure 4. Analog presentation of task analysis.

Ideally, the analogue storyboard is discussed with the relevant stakeholders to check its accuracy and validity, make amendments and establish key insights. This enables the researcher to identify areas for greater scrutiny or directions for possible design solutions. The stakeholder feedback at this point is often vital to identify key opportunities for design interventions.

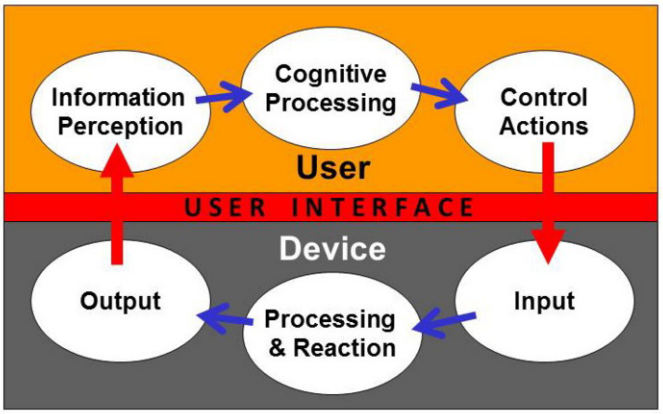


Figure 5. Device User Interface in Operational Context (adapted from Redmill and Rajan, 1997). FDA [13].

Data Presentation

To enable a concise, understandable visualization of the research outcomes, only pertinent findings and relevant insights should be included in the final presentation. The researcher must objectively include all relevant findings at this juncture and not just those that suggest a preferred solution or course of action. The final format of the research presentation depends on the degree of complexity of the procedure or task and the level of detail required to adequately represent it. Journey Maps and Task Analysis are two possible formats of presenting the research findings.

Journey Maps

Journey mapping is a suitable format for presenting research on procedures conducted over a long period of time in multiple locations. Figure 6, shows a journey map of a hospital admissions procedure. This information presented can be used for value stream mapping of healthcare procedures, a discussion document for improving efficiency or for training of healthcare staff

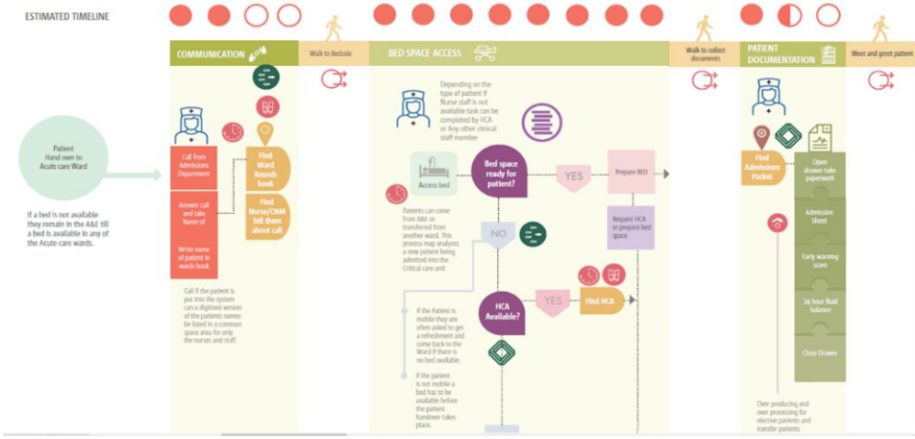


Figure 6. Section of journey map for a hospital admissions procedure.

Task Analysis

A Task Analysis is more suited to presentation of complex procedures which require high levels of manual dexterity and cognitive load. Each step of the procedure should have a visual representation to illustrate sequential progress. As shown in Figure 7, any relevant insights that emerged from the research are shown in text blocks aligned with each visual. Three streams of information under the headings of Perception, Cognition, Action highlight what the key actors are perceiving, thinking and doing at each step of the procedure. The detailed information contained in the task analysis can be utilized for training purposes, to inform medical device development or document adherence to human factors regulatory requirements

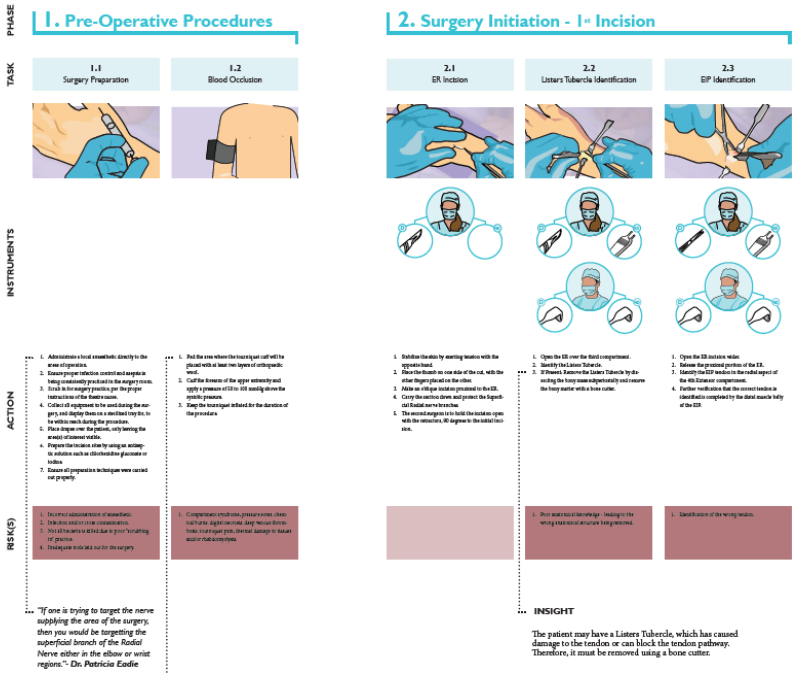


Figure 7. Section of task analysis for a surgical procedure.

5. Discussion

Insights gained from rigorous contextual user research during design projects have the ability to drive transformative change in the resultant design solutions. With national health services worldwide under increasing pressure due to demographic change, nowhere is this process more relevant than in the delivery of healthcare. The primary goal of the methodology proposed above is to discover and incorporate relevant human factors into the design process and ultimately the resolved design solution during healthcare related design projects. The methodology can be used in medical device design and development. The relevant standard, HE75:2009/(R) 2013, Human Factors Engineering – Design of Medical Devices is produced by the Association for the Advancement of Medical Instrumentation (AAMI) and recognized by the US Food and Drug Administration (FDA) as a general consensus standard related to human factors and their application to medical devices [14]. HE75 describes a methodology to discover potential user issues through formative and summative testing during the development of medical devices. However, significant time and resources have already been invested in the product under development by the time formative and summative testing takes place. Project resource and time constraints can foster a reluctance to implement the findings of user testing if the outcomes suggest significant alterations to the existing design. The proposed methodology aims to avoid this scenario through the creation of a rigorous contextual user research process where all stakeholder requirements are taken into account. This process identifies key decision making points and potential risks and presents relevant insights and findings in an understandable visual format. These findings can help generate a focused design brief and continuously inform the design process.

The mind-set and preparation of researchers at the outset of contextual user research is key to the effective discovery of data. They should obviously have conducted extensive background research regarding the area of study to achieve credibility and ask relevant questions while performing interviews. However, it is equally important to adopt the mind-set of "naïve observer" during observations which allows a line of questioning that may uncover tacit information, known to healthcare staff that may otherwise be overlooked. This approach enables the collection of a wide range of information for later analysis. The objective analysis of this data allows evaluation of current methods which may be assumed as best practice rather than critically examined. In the authors' experience, some of the most pertinent insights that have led to significant positive change have emerged from keen observation, documenting and questioning of current procedure or process and the existing supporting physical and technical environment. Adopting and maintain this mind-set when interviewing highly trained and skilled healthcare staff requires courage, rigor, persistence and trust in the ability of the process to deliver transformative results.

6. Conclusion

This paper has outlined the context and the development of a methodology for conducting contextual user research of human factors involved in healthcare procedures and presentation of the research findings. It is intended that methodology will provide transparent, traceable and accountable results which those involved in a healthcare design project can use to develop transformative healthcare products, services and interactions.

Future developments and refinements of the methodology include the creation of design research tools to guide the researcher during implementation. In order to further understand the clinician or patient experience during a procedure, new technologies for the capture of images and video such as eye-tracking glasses could be integrated into the process. Surgical or task training programs could use virtual or augmented reality to integrate the research outcomes into the user training exercises to guide progress, help in decision making, and highlight risk factors. Integration of artificial intelligence into this scenario could map the trainees' progress against an "ideal" path defined by the contextual user research findings. There is also a possibility to present the research outputs in standard formats required by industry risk management protocols.

The authors would therefore intend that the publication of this work begins a process of evaluation and potential collaboration with interested parties in order to further develop the proposed methodology and understand the inputs, requirements and outputs of the various usage scenarios across the spectrum of healthcare provision and other relevant industry sectors.

Ackn1owledgements

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