Exploring the Variability of Human Factors and Usability Testing Methods for Evaluating Medical Devices - Preliminary Results

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ABSTRACT

The success of a medical device is based on its ability to be deployed according to its use specification to safely achieve the intended outcome. Central to this is the design of the device which, if poorly executed, contributes to 'use error' which affects the efficacy, safety, and user experience of a medical device. Human factors guidance provides recommendations to evaluate the user experience in a bid to improve design efforts and ultimately the safety and usability of medical devices. The heterogeneity of the industry means that the interpretation of these guidelines is subjective and adapted differently to suit the use specification of the devices. The aim of this study is to explore the perceptions of medical device industry professionals on factors influencing the evaluation of the user experience in the design of medical devices. A bespoke survey approach is currently being undertaken to achieve this objective and to interrogate the key issues. There is a lack of substantial evidence in the literature that indicates which user experience testing methods are most favoured and widely used in practice, across all stages of device development from concept to post-sales testing. This study is designed to shed light on industry practices; the variability of user experience testing methods of medical devices, as well as the preferred methods, and the aspects of user experience considered in medical device design.

CCS CONCEPTS

• **Human-centered computing** → Human computer interaction (HCI); HCI design and evaluation methods; Usability testing.

KEYWORDS

UX research methods, Usability testing, Human factors, Medical devices

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1 INTRODUCTION

Medical devices transform healthcare by improving safety, efficiency, and overall quality. Therefore, the product development process is complex with effort going into ensuring that the devices are designed for safety, quality, and ease of use [1]. Medical device use error is responsible for many adverse events in healthcare, with most of the errors attributed to design faults [2].

Usability engineering or human factors engineering is the "application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of medical devices" [3], [4]. The application of usability engineering during the medical device development and design process improves effectiveness, ease of use, satisfaction, learning curve and overall safety. It also allows for the facilitation of regulation and increases commercial success for the device manufacturers [2].

The usability engineering process includes validation testing to assess user interactions with a device to identify errors that would result in serious harm. This involves the evaluation of the user experience; the user's perceptions, feelings, and quality of the interaction with a system or product and usability which are the features of the user interface that facilitate use and thereby effectiveness, efficiency, and user satisfaction in the intended environment of use [5].

Authorities provide human factors guidelines with recommended methods and processes for all devices, and it is the development team's responsibility to determine which methods to apply for their devices. There is a lack of evidence from industry on which methods are applied for the different use specifications of medical devices. The purpose of this study is to understand the distribution of evaluation methods in the design and development process of medical devices, and the aspects of testing the user experience and usability of medical devices and which of these methods are considered important in the medical device industry.

1.1 Aim of Study

The aim of this study is to explore the perceptions of medical device industry professionals on factors influencing the evaluation of user experience in the design of medical devices. It explores the relationship between use specification and human factors regulations

in the selection of usability testing methods, aspects of user experience considered important and the role of the user in usability evaluation.

The research questions that this study explores are:

- 1. Which aspects of user experience and usability does the medical device industry prioritize?
- 2. Which user experience and usability evaluation methods are popular in the medical device industry?

2 LITERATURE REVIEW

A well-designed medical device is easy to use with a user interface that meets the user's expectations and experiences [3]. The use specification is central to identifying all aspects related to classification, controls applied and compliance requirements to be considered during device development and design [6], [7]. The Food and Drug Administration (FDA) Design Controls methodology promotes quality practices to ensure transparency by identifying user needs, intended use, validation, and verification.

The medical device industry borrows best practices in design from engineering and industrial design. The nature of medical device design lends itself to a user centered approach which is iterative with consistent design evaluation to advance usability and focuses on the end user.

Although end user involvement will vary depending on the intended purpose of the device and design approach, it is common to engage the user during formative and summative evaluation [8]. In some cases, the user is considered an active stakeholder during the design process via a participatory or co-design approach [9], [10]. User involvement improves usability by contributing to better quality of user requirements, interface design and increased functionality [11]12 [13].

The application of human characteristics including capabilities and limitations knowledge in the design of tools and systems is known as human factors engineering or ergonomics [14], [15]. For medical devices, the aim is to consider cognitive, emotional, sensory, and physical abilities in development and design evaluation to improve human performance [2]. The FDA human factors guidance focuses on three considerations for the device user system as the device user, use environment and the user interface. Interactive device use leads to two possible outcomes; correct use which is effective and safe or use error which is ineffective and unsafe [16].

The medical device regulatory standards distinguish usability as related to safety and effectiveness, and user experience as aligned with the satisfaction aspect including goals and aesthetics. However, as human factors aspects they are distinct. Usability emerges from the interaction of the user, product, and environment [17]. While on the other hand, user experience is multifaceted focuses on both the interactions and user's attitudes comprising of both pragmatic and hedonic aspects by measuring affect, usability, and user value [1].

Similarly, usability methods focus more on task performance while user experience methods concentrate on pleasure and emotions [18]. Usability evaluation focuses on performance by assessment of effectiveness, efficiency, and safety of the device by the iterative improvement of the user interface design. User experience evaluation is subjective in nature and seeks to understand the end user's attitudes and emotions towards the device in fulfilling their expectations and motivations [18] 19 [20].

Bitkina et al (2020) identified three categories of assessment methods based on the measurement aspects affect, usability and user value measurement methods [1]. The various medical device evaluation methods identified in their systematic review include interviews, observation, systematic reviews, focus groups, benchmarking, heuristic evaluation, think-aloud protocol, and cognitive walkthroughs. These methods correspond to the human factors recommendations for evaluating medical devices which also include other user experience research methods.

3 METHODOLOGY

This study is designed to explore the perceptions and views of the medical device industry professionals on the methods applied to evaluate the user experience and usability of medical devices. A preliminary review of literature was conducted to determine the different elements that would be required in the development of this survey research. There were varied sources of data including journal articles, specialist websites, industry reports and human factors guidance from the competent authorities all of which provided the necessary information.

A survey research approach was chosen as the best approach to achieve the study's aims. A self-administered questionnaire gives an opportunity to craft the research structure and data collection properly. It is also convenient for the intended respondents to complete the survey at their own pace.

Lastly, it eases the distribution as reach is theoretically limitless on the internet. JISC Online Surveys is leveraged as the survey tool for this research as it is available to use for specific academic institutions, has relevant features and meets standard confidentiality requirements.

The survey is designed to facilitate the collection of views on the various aspects of user experience, usability testing methods, methods used in different development and design processes, and demographic details of the respondents. A mix of closed and open questions is used to collect specific data required and the general viewpoints consecutively. The sequence of the questions is also done to mitigate bias, and the overall layout of the survey is easy to navigate. The survey has three sections to collect distinct groups of data on demographics, medical device details and measuring user experience and usability.

The ethical considerations were identified with ethical approval granted by Ulster University's Art and Design Research Ethics Filter Committee in accordance with university procedure (Ref: FCART-22-006). The survey has been distributed on different online platforms so far with the aim of reaching a variety of professionals and stakeholders in the medical device ecosystem. This study is entirely explorative with voluntary participation; therefore, the application of a formal sample size calculation is improbable.

This survey approach uses a mix of non-probability sampling methods, with purposive sampling being key, based on the population as this study is targeted towards professionals in the medical device industry. This method was selected as it is cost and time effective, it also allows the generalization of findings to the specific group. The

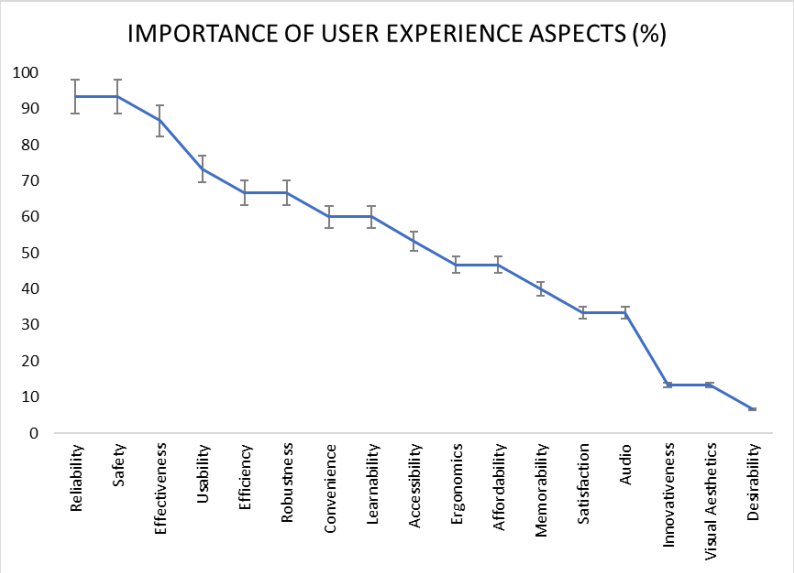

Figure 1: User Experience and Usability Aspects

responses were screened to determine data quality, and all meet the quality threshold as complete.

3.1 Scope of Analysis

The objective of this preliminary analysis is to explore the findings from the survey responses to date and will be limited to these responses. The survey which is open on JISC currently has 15 responses so far and a response rate of 30% (JISC approximation). Therefore, the data has not reached a normal distribution at this stage.

This analysis will cover specific areas of interest which include the respondents' views on important aspects of user experience for medical devices, the usability testing methods and user involvement in usability testing efforts.

4 PRELIMINARY RESULTS

Early results suggest that the most important aspects of user experience and usability in order of preference are reliability (93%), safety (93%), effectiveness (87%), usability (73%), efficiency (67%), robustness (67%), convenience (60%) and learnability (60%). Figure 1 shows all the aspects as ranked from the responses.

The application of user experience research methods varies throughout the usability engineering phases (Figure 2), with the most applied being observation (60%), usability testing (55%), use scenarios (51%), task analysis (51%) and interviews (48%). The least popular overall are in order participatory design (19%), heuristic analysis (19%), and fault tree analysis (14%).

The top three usability testing methods with 80%, 73% and 67% consecutively are questionnaires, interviews and think aloud protocols. Mid-range we have benchmarking (53%), focus groups (40%) and eye tracking (26%).

The distribution of survey use across the usability engineering phases in descending order is user research (47%), post market analysis (40%), summative evaluation (33%), formative testing (27%), design conceptualization (27%), analysis (20%), design finalization (13%) and the rest do not use them at all.

The popular standardized questionnaires are Standard Usability Survey (33%), NASA Task Load Index (20%), Post Study System Usability Questionnaire (13%) and Questionnaire for User Interface Satisfaction (13%). However, 40% do not use any of the questionnaires indicated for several reasons but mainly because they prefer custom questionnaires to fit their requirements.

The usability metrics collected in testing are task success rate/task completion time (100%), time on task (60%), error rate (53%), severity of use errors (53%), task level satisfaction (53%), test level satisfaction (40%) with the final 2 participants selecting other. The other options specified are test leader assistance, instructions used to complete task; "Participant explanation of cause of use errors and difficulties. Qualitative information on user's experience in study."

Although the usability testing environments varied, the preferred usability testing environment from the options presented was in-person simulated with 53% selecting very often and always while the least preferred was unmonitored remote testing environment 67%. The nature of the real-world environment simulated Cognitive stress (73%), noise (60%), visual (53%) and 2 participants who selected other mention "psychological pressure by requiring tasks to be performed in a certain time with a countdown clock visible" and that they do not use real world environment.

User involvement varies in the response always (33%), very often (27%), sometimes (20%) and rarely (20%). The number of users involved in testing is between 5 – 20 73%, and 20% involving more than 20. Recruitment of participants is conducted through affiliate academic research groups (13%) , product customers (20%), user testing recruitment agencies (40%), social media (27%). The rest recruit through clients, affiliate hospitals and charity.

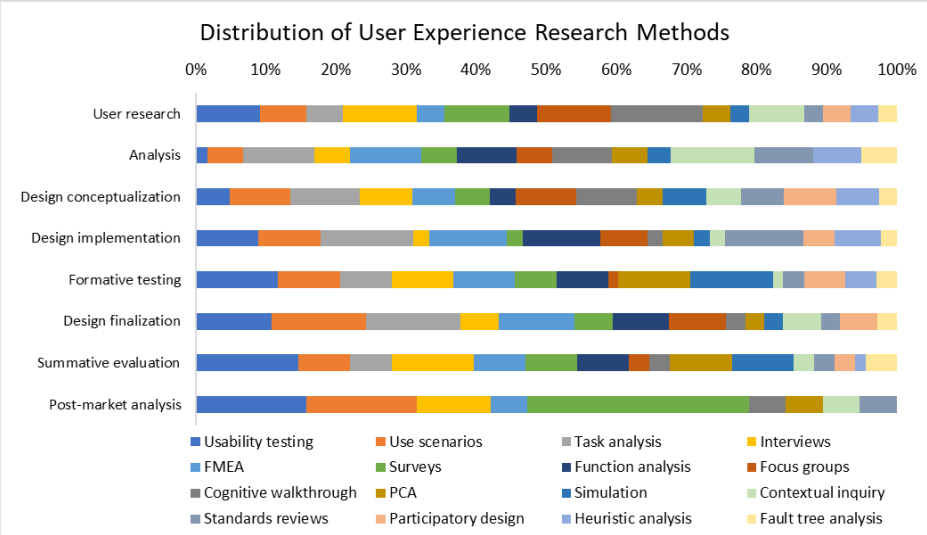

Figure 2: Distribution of User Experience Research Methods

Table 1: Popular User Experience Research Methods

User research	Analysis	Design conceptualization	Design implementation	Formative testing	Design finalization	Summative evaluation	Post-market analysis
Cognitive walkthrough	Contextual inquiry	Task analysis	Task analysis	Observation	Task analysis	Observation	Surveys
Focus groups	Task analysis	Cognitive walkthrough	FMEA	Usability testing	Observation	Usability testing	Observation
Observation	FMEA	Focus groups	Standards reviews	Simulation	Usability testing	Interviews	Usability testing
Interviews	Cognitive walkthrough	Interviews	Function analysis	PCA	FMEA	Simulation	Interviews
Surveys	Function analysis	Participatory design	Usability testing	FMEA	Function analysis	PCA	PCA

5 DISCUSSION

The respondent's cohort is highly educated with bachelor's degree, masters, and PhDs; with clinical, design and human factors specialists and other titles as staff clinical engineer, computer scientist (HCI/HIT) and a senior lecturer. There is a disparity in gender representation with more male than female respondents.

The user experience factors held in high regard are reliability, safety, effectiveness, usability, and efficiency. These results indicate an alignment in industry to human factors guidelines with a central theme of risk management with the key objectives of efficacy and safety. The aspects indicated lean towards the pragmatic which is expected given the nature of medical device use. This also aligns with Aaron Walter's hierarchy of user needs in which he highlights the foundational needs (functionality, reliability, and usability) as prerequisite to achieving the superior needs (delight and pleasures) at the top of the pyramid [21].

The user experience research methods listed in the survey were collated the recommendations from both the FDA and MHRA human factors guidelines while the usability engineering method is based on the MHRA. Observation and usability testing are applied throughout the usability engineering process with the responses indicating preference for formative testing and summative evaluation. The unpopular methods are participatory design, heuristic analysis, fault tree analysis which are mostly favored for design conceptualization, analysis, and summative evaluation consecutively. Table 1 gives a summary of the top user experience research methods for the different usability engineering phases.

The common usability testing methods used by the respondents are surveys, interviews, think aloud protocols, benchmarks and focus groups with eye tracking and visual ethnography not as popular.

Standardized usability questionnaires are used with the Standard Usability Scale (SUS) being the most prevalent followed by the NASA Task Load Index (NASA TLX), Post Study System Usability

Questionnaire (PSSUQ), Questionnaire for User Interface Satisfaction (QUIS) and User Experience Questionnaire (UEQ). However, the comments in the other option show that these standardized questionnaires may not be useful for some use cases with a preference for targeted custom questionnaires.

The usability metrics collected in order of rank from the responses are task success and completion rate, time on task, error rate, severity of errors, task level satisfaction. The other metrics from the responses not listed in the options include test leader assistance and instructions for use, and participant feedback on use errors and user experience. The metrics are more objective than subjective which is expected considering the pragmatic aspects selected as important.

The responses show that most devices are tested between two to four times and some more than five times, suggesting that the design process is iterative. The popular methods and usability metrics selected suggest that end users would be involved in usability evaluation and is proven with most of the participants admitting 80% user involvement. The research participants are recruited from user testing recruitment agencies, social media and professional networks including clients and affiliate establishments. The results also suggest that research participants would get an incentive.

The respondents agree that medical devices with high usability and user experience lead to valuable outcomes including better product quality, increased user experience, improved patient outcomes and customer satisfaction, increased adoption, device approval, increased revenue, and adherence in order of rank.

6 CONCLUSION

The results from the survey so far show that usability testing methods vary, with different methods preferred for the different development and design stages. The usability and user experience aspects lean towards a more pragmatic than hedonic preference and the usability testing metrics are similarly more objective than subjective measures. A simulated real-world environment should include cognitive, noise and visual aspects as all are important in medical device usability testing. User involvement and testing iteration strongly indicates a human centered approach in the formative and summative stages of the development process.

This study is designed to shed light on industry best practices, the gaps, and the variability of UX testing methods for various medical devices, as well as the preferred user experience testing methods, and the aspects of user experience considered in medical device design. From these preliminary results it is evident that the objectives set for this study will be achieved to a satisfactory level.

7 FUTURE WORK

Participant recruitment is still ongoing, the survey will be open until an acceptable rate of responses is achieved. The data collected from the survey is to be analysed and is expected to highlight the various user experience testing methods that are used and the gaps at different medical device design phases within industry, throughout the product development lifecycle. The association between use specification and the evaluation methods applied will be identified and the medical device professional's priority hierarchies for user experience and usability of medical devices should be distinguished. The findings will provide a foundation for creating a framework guide to recommend evaluation methods for the different use specifications of devices.

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