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Atypical Use Scenarios as Design Intervention in Healthcare Product Design Application

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Abstract

User experiences of atypical conditions leading to adverse events have the potential to discover latent user needs and improve usability in design outcomes. This study introduces atypical scenarios as a design intervention to student designers working on healthcare product design projects. These atypical scenarios are framed from real-world clinical experience related to individual projects. 40 participants from a healthcare product design course comprising of 8 teams were involved in this study. Results indicate a positive influence on design and designers in terms of usability in the design process.

Keywords: user-centred design, healthcare design, design activities, design process

1. Introduction

According to the guidance document of Human Factors Engineering – Design of Medical Devices, medical devices that are not designed with usability in mind are frequently "unsafe, prone to use error, difficult to use, difficult to learn to use or detract from user efficiency or satisfaction" (AAMI/ISO HE75). Usability is defined as "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO 9241-11:2008). The critical role of usability engineering in medical device design is to foresee various scenarios and use-cases that lead to safety-related problems or close-calls and ensure the device is safe to use in such events. The usability engineering process recommended in currently available standards for medical devices permits manufacturers to assess and mitigate risks associated with correct use and use errors, i.e., everyday use and not abnormal use (IEC62366-1:2015). Latent conditions, which may lie dormant within the system before they combine with active failures and local triggers, often create an accident opportunity. "Latent conditions arise from decisions made by designers, builders, procedure writers, and top-level management. Understanding these conditions lead to proactive rather than reactive risk management. Organizations focusing on highly reliable products continually rehearse familiar failure scenarios and strive to imagine novel ones" (Reason, 2000).

A growing body of research claims numerous benefits of including users' perspectives in the medical device development (Shah and Alshawi, 2010; Money et al., 2011; Martin and Barnett, 2012; Caixeta et al., 2013; Graffigna and Graffigna, 2015; Tóvölgyi, 2016; Carthey, 2021). Various design studies conducted with students' design projects in the past reported in the literature show positive design outcomes with different types of design interventions. A study conducted by Raviselvam et al., introduced simulation tools as an extreme user approach and recorded activity diagrams with user need statements before and after the treatment phase of the study. This study uncovered that designers' extreme user perspective helped identify latent user needs and various user interface aspects in designing medical device products (2019). In another study, a design research study was conducted among the

first-year undergraduate students who were provided with design briefs asked to sketch concepts using the 6-3-5 method collaboratively. Their sketches were evaluated for creativity under the criteria of novelty, appropriateness, and usability. It was observed that the inclusion of physical stimuli led to higher usability scores among the students (Koronis et al., 2021). Narrative inquiry used among student designers in the context of healthcare experience seemed to heighten empathy within the design process and offered an effective means to surface misconceptions about end-users (Carmel-Gilfilen and Portillo, 2016). Mieczakowski et al., proposed a design-led research approach to capture contextual data from users through contextual inquiry about usage patterns, feelings, and impact on patient-clinician care relationship in the application of telehealth design (2014).

Previous studies in literature exhibit the benefit of introducing user perspectives in the form of interviews, simulation tools, extreme use conditions, and design briefs as design interventions. Still, no studies assess the impact of atypical scenarios on the usability of early designs in healthcare applications. This paper addresses this gap by introducing atypical scenarios as design intervention in a study conducted among student designers working on healthcare product design projects. These atypical scenarios framed from clinical experience. The scenarios are project-specific and were tailored based on input from clinical mentors to individual healthcare project topics. This study answers the following questions

1. *How did the design intervention benefit the students in understanding device use and usability of their product designs?*
2. *How did the design intervention impact the usability aspects in the conceptual design outcome of the project teams?*

2. Background

Medical device users are highly heterogeneous. Primary users of medical devices such as inhalers and glucose monitoring devices are patients, and for devices such as endoscopes and surgical needles, the prior users are clinicians. User requirements captured in the early phases of design must cater to the needs of these heterogeneous groups. “Measuring and fulfilling user requirements during medical device development will result in successful products that improve patient safety, improve device effectiveness and reduce product recalls and modifications” (Martin et al., 2006). For the same user, user requirements for a product could change based on various use scenarios, even if that does not occur commonly.

2.1. Atypical scenarios

Paltrinieri et al., define atypical accident scenarios as those which deviate from standard expectations of unwanted events or worst case reference scenarios and, for this reason, are regularly not identified by common hazard identification techniques (2013). Atypical scenarios in this context are those uncommon scenarios that deviate from standard expectations of the device, humans (clinician or patients) involved in the device interaction, and device use environment. Some unidentified atypical scenarios may lead to adverse events while products are in use. *Use error* is defined as undesirable or unexpected events resulting from the interaction between a user and a device. *Abnormal use* includes actions that the user knowingly intends to make that are inappropriate. *Unorthodox uses* are not associated with use scenarios that designers can reasonably anticipate or prevent by applying risk-control measures (AAMI HE75). Even though the intention of the action is different for user error and abnormal use, the effect of the undesired outcome is either experienced by the user or the patient the device acts upon. These instances of abnormal use or use error are to be avoided by design, if possible.

2.2. Adverse events

An adverse event is any undesirable experience associated with using a medical product in a patient (U.S.FDA, 2016). An adverse event is not necessarily the result of one person making a mistake at the frontline of healthcare; instead, conditions in the system often enable the adverse event to occur (Reason, 2000). The occurrence of an adverse event has several detrimental effects on both patients and healthcare workers, including physical and psychological harm, a loss of trust in the healthcare system, and reduced

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staff morale (Rafter et al., 2015). Errors, accidents, and adverse events can only be avoided by understanding why they occur and applying lessons learned from similar past events (Sanchez et al., 2017). While exploring the causes of adverse events, human causes are the predominant causes of adverse events in hospitals (Smits et al., 2010). Analyzing adverse events related to user interface and use of device problem categories in U.S. FDA'S Manufacturer and User Facility Device Experience (MAUDE), we believe that incorporating the insights derived from adverse events (although the possibility of occurrence of some adverse events may be low) will increase the focus on usability in design. However, the adverse events reported in the MAUDE database do not contain complete information to understand the causes of such events. In this study, having the advantage of clinicians collaborating with the healthcare product design teams, we captured clinician insights on scenarios possibly leading to adverse events to frame atypical scenarios relevant to the projects as design interventions.

3. Methodology

3.1. Healthcare design course

This study was conducted in a healthcare product design course open to both graduate and senior undergraduate students at the Singapore University of Technology and Design (SUTD). In this course, students follow the water flow model of the product design process on a chosen topic. This course in SUTD was designed to bring early hands-on experiences for students in developing medical devices for real-world clinical problems under the mentorship of clinicians and a course instructor. The project topics are bred from the real-world clinical trials pitched by clinicians from various hospitals in Singapore during week 1 of this course. Participants were recruited from the class who attended the healthcare product design course at SUTD in 2021. A total of 40 students participated in this study and comprised 8 teams with five students in each group. There were 24 male students and 16 female students, with each team consisting of at least one female student. The students who participated in this study were 39 senior undergraduates and one early graduate student. All the students have prior design knowledge and experience working on design projects. Table 1 lists eight project topics with descriptions included in this study.

Table 1. Healthcare design projects selected by the team

Project. No	Topic	Description
1	Expiratory muscle trainer	Design an expiratory trainer with proper mouth seal and regulated air flow for patients with Parkinson Disease.
2	Leg elevator	Design a portable device for leg elevation for patients with leg injuries.
3	Inhaler dose monitor	Design a device to monitor inhaler dose to ensure patients compliance with dose prescription
4	Needle guide	Design a device to guide one or more needles for tumour ablation
5	Paediatric wheelchair	Design a wheelchair to meet the growing needs of paediatric patients with neuromuscular conditions.
6	Crawler for infants	Design a device to automatically train coordinated limb movement in infants with cerebral palsy.
7	Endoscope for ENT	Design a portable endoscope to perform single-physician operated basic Ear-Nose-Throat (ENT) procedures in primary healthcare settings.
8	Heat modality for hand injury	Design a compact device to provide controlled superficial heating for the affected upper limb.

Eight project topics were selected after the project pitch presentation by clinicians in week one, and user need statements were submitted by teams in week 3. The teams presented their 1st design review in week four, and no design intervention was introduced to the students until this point.

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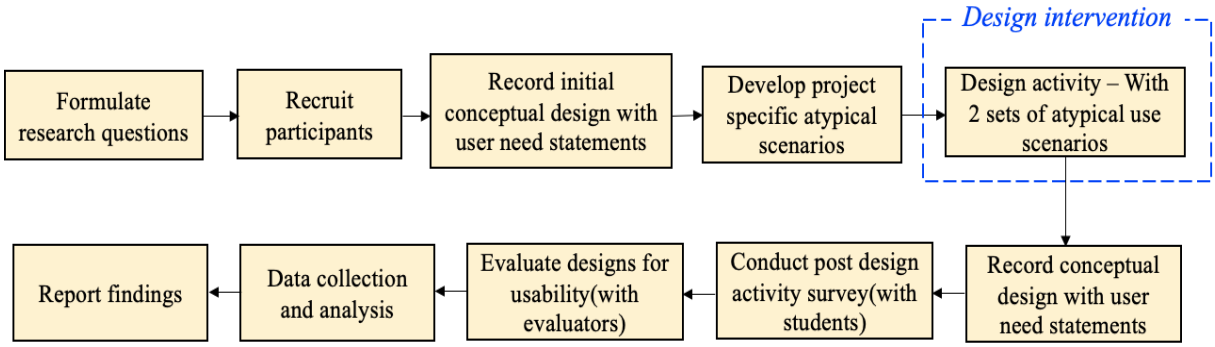

Figure 1. Experimental method

Figure 1 displays the methodology executed in this study. The initial set of users, statements, and conceptual design were recorded. Meanwhile, clinicians' insights about adverse events and atypical scenarios specific to the project they mentored were collected. The insights were analyzed to form themes and personas.

3.2. Design intervention

During week 6, the design intervention was done with a 20-min presentation on human factors and usability in medical device design, along with a few examples of adverse events related to usability problems and their consequences in healthcare. For each project team, 2 different atypical scenarios were framed with a persona (the persona was created based on clinician input explicitly given to the individual project context). Example from project #5, *Scenario 1: Matt is a 12-year-old boy with cerebral palsy and is heavily dependent on his wheelchair. Matt has a sibling and friends who visit him. They are curious about Matt's wheelchair and explore with various levers and knobs when no adults are watching. Matt is instead very active and keeps fidgeting his hands and does not have perfect cognition. He has a detachable table mostly fixed to his wheelchair (which is meant for some activities). While visiting for his check-up, he flipped, and the chair toppled in the hospital. Unfortunately, Matt experienced some injuries due to the fall.*

Participants were asked to use the provided scenarios, revisit their user need statements, update them if needed/appropriate, and submit the revision within a week (called a design activity). This was a team task, and participants were informed that data collection related to the design activity would not be graded. The teams presented their 2nd design review in week 8. Conceptual designs developed after the design intervention were recorded to understand the design intervention's impact. A survey on the design activity was conducted to understand how the design activity helped students in their projects.

3.3. Design evaluation

To understand the impact of the design intervention in the usability design of projects, the designs recorded before and after intervention were evaluated by three raters. All the raters chosen in this study for evaluating design ideas had a design research background and prior experience assessing the design for usability, but one rater has specific experience in healthcare product design. Each rater was asked to evaluate the conceptual design for usability with information recorded in a design sheet consisting of conceptual drawing/model with annotations, problem statement, and need statement in a randomly generated design sheet order to blindfold the raters about the design before and after the intervention. Each rater was asked to rate the design on a scale of 1-5, with 1 being the lowest and 5 being the highest in each usability criterion. Usability was evaluated for 4 different criteria (ISO/IEC 25022:2016), such as 1) Effectiveness -1a) in terms of task completion 1b) in terms of objectives achieved. 2) Efficiency -2a) time efficiency 2b) physical effort 3) Satisfaction of use 4) Free from risk. Each criterion was given a single score by combining the sub-criteria (1a & 1b, 2a & 2b) to an average score. So, each rater scored 16 designs (N=16) for the given criteria on a scale of 1-5, for designs before and after the intervention.

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4. Results and analysis

4.1. User need statements

The revised user needs were developed by project teams for the given atypical scenarios. It was observed that 7 out of 8 teams came up with new user needs to meet additional use requirements from atypical scenarios, and all 8 teams modified at least 1 user need to complete the atypical scenario provided to them.

Table 2. Number of modified and new user needs developed

Project #	Modified user needs	New user needs
1	3	6
2	2	2
3	1	6
4	2	Nil
5	1	5
6	1	6
7	3	2
8	3	2

Table 2 displays the number of user needs each project team developed or modified. Example of new need statements and modified need statements generated by project #8 are stated in table 3. However, it was noticed that some of the user needs identified in this stage by some of the project teams were not incorporated in the design drawing and 3D design submitted after the design intervention, which were used for usability evaluation by raters.

Table 3. Examples of modified and new user needs before and after design intervention

Project No.	Type of need	Before design intervention	After Design intervention
#1	Modified user need	Have a feedback mechanism	More obvious feedback to ensure the patient is able to see or notice (visual or auditory).
#1	New user need	NA	A hand grip to assist the patient to increase stability while holding
#8	Modified user need	Readily available STOP button for safety	Emergency stop button easily accessible yet not accidentally pressed.
#8	New user need	NA	Allow user's skin to adjust gradually to surrounding temperature after exercise is complete

4.2. Post design activity feedback

A post-design activity survey conducted among teams, which was answered individually, revealed the students' perspective of the design intervention. 92.5% of the students either agree or strongly agree that they could better empathize with their target users (Clinicians/patients) after the design activity. 97.5% of the students either agree or strongly agree that the activity invoked their ability to visualize atypical environments that their users might encounter. 90% of the students either agree or strongly agree that they could better imagine things that might happen to their target users before and after the device use. 70% of the students either agree or strongly agree that they asked more questions about various use cases and the use environment to their clinical mentors. Finally, 87.5% of the students either agree or strongly agree that they could better understand the importance of usability in their product design.

4.3. Design evaluation

Three raters (rater A, rater B and rater C) evaluated the designs for individual criteria pre-defined for usability. For analysis, the data consisted of 4 scores for each design (N=16). Inter-rater reliability was

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checked for consistency between the two raters (rater A and rater B) with IBM SPSS version 25. Cronbach's Alpha (α=0.621) was calculated on standardized items. Intra-class correlation with 95% confidence interval lies between 0.377 and 0.770. It was found that both rater A and rater B gave a better score for post-intervention design to projects #1, #2, #3, #7, and #8 under 1 or more usability criteria. Rater C's (rater with specialized healthcare design experience) score on usability of the projects were better for projects #1, #2, #4, #6 and #8 atleast in one of the usability criteria. However, the inclusion of an "expert" in the field interms of individual scores against each criterion of usability did not significantly alter the evaluation of designs.

5. Discussion

It was observed that, although some of the project teams introduced additional user needs in the week after design intervention, the design evaluation scores given by the raters did not show improvement in their usability design. For example, Project #6 introduced 6 new user needs and modified 1 user need to accommodate the atypical scenarios given. Still, both raters A and B scored less the post-intervention design for at least 2 criteria of usability. A similar pattern was observed in project #5. Whereas project #4 did not introduce additional user needs and modified 2 user needs post design intervention, the raters scored less in at least 1 criterion or no change in scores. The introduction of atypical scenarios in the design process positively affected 5 projects and had no effect on 1 project. Whereas for 2 projects, the design intervention triggered additional user needs, but the design improvements were not seen predominantly in the subsequent design review. On the other hand, evaluation of rater C showed the projects that improvement on usability based on their presented design sketch. Rater C scored projects #4 and #6 better atleast in one of the criteria. Individual scores showed minimal differences in the scores given by the three raters. However, further investigations to understand how well the new and modified user needs were incorporated into design presented could help converge the inter-rater score and hence evaluating the final product design could show the overall improvement in usability.

The results answered the questions posed at the beginning of this study.

1. How did the design intervention benefit the students in understanding device use and usability of their product design? Responses of a post-study survey unveil that the design intervention with atypical scenarios benefited the students in understanding the device use, the importance of usability, and their ability to empathize with end-users.

2. How did the design intervention impact the usability aspects in the conceptual design outcome of the project teams? The analysis of user needs, and design evaluation indicates that 5 out of 8 projects positively impacted their projects in terms of usability. However, the intervention did not affect 1 project and partial effect on 2 projects in improving their designs.

Literature shows the benefit of integrating clinician perspective in healthcare design outcomes (May-Russell, 2012; Privitera et al., 2017; Healion et al., 2018) and the importance of understanding adverse events in healthcare design (Vincent, 2003; Rafter et al., 2014; McGurk, 2018; Butler, 2020). This study combined the benefit of integrating clinician insight from atypical use (and adverse events) perspective. The information included in atypical scenarios was taken from real-world clinical experiences. The characters were added to relevant personas to better visualize the scenario for the project teams. Insights from atypical use perspective have extended the user research further and positively impacted the design outcome interms of user needs and in design evaluated by raters. This design activity was mainly intended to provoke students' design thinking further in the frame of usability in medical devices and the consequence of its lack thereof. Students' feedback on the design activity was encouraging. Towards the end of the discussion with clinicians, some of the clinicians highlighted that a few questions related to atypical scenarios stretched their minds into those rare accidents and uncommon use cases which they missed discussing during the user research stage with the project teams.

6. Limitations

End-users of some of the projects considered in this study are patients (home use), and for other projects, the end-users are clinicians (clinical use), or both. Insights for atypical scenarios were collected from clinical mentors (specialized in the projects considered here) but not from patients directly due to

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COVID-19 protocols. For some of the projects considered in this study, clinicians represented patients to bring forth their users' needs. Therefore, there is a possibility of a missing link in identifying use case information for atypical scenarios. Information for atypical scenarios was gathered from clinicians from week 2 onwards, depending on their availability. A design intervention was conducted in week 6. Many students felt that conducting this design activity earlier would have enabled more improvements as some teams started working on their conceptual designs by then. The design evaluation sheet consisted of drawings/models submitted by students in the week before and after the design intervention, and the progress of each team could differ compared to the final prototype. Evaluating usability, especially task efficiency, is challenging without a physical prototype.

7. Conclusion

University students taking a healthcare product design course participated in a study emphasizing usability in healthcare design project. The experiment was conducted among 8 different project teams with individual team topics bred from real-world clinical problems. A design intervention was introduced with atypical scenarios developed from clinicians' input, and the impact of the intervention on the students' designs was analysed in terms of user needs and usability evaluation of their drawings and 3D models. We found the design intervention had a positive impact on 5 projects and no change for 1 project in terms of usability. The design invention helped students understand the importance of usability in healthcare, visualize the atypical scenarios, and incorporate them into their design considerations.

8. Future work

Design evaluation will consider adding more evaluators with better-defined rubrics for the design evaluation as an improvement to the experiment. The evaluation criteria will include key tasks involved in using the product and cost factor into efficiency in future evaluation. Clinician evaluation scores for the final product will be included to understand the final design's impact better. To improve the reliability of the judges' evaluations in future experiments, one way would be to divide these metrics into narrower sub-metrics so that the judges make evaluations based on one dimension at a time. Other methods can be considered by adding more 'objective' evaluation based on typologies of product mechanisms/functions/form or the rate of occurrence of ideas (Shah, Smith and Vargas Hernandez, 2003; Hocking and Vernon, 2017).

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