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Is User Experience a suitable goal in the development of medical devices?

Abstract: Product development in medical technology is largely governed by Regulatory Affairs. In contrast, for consumer products Human-Centred Design (HCD) is the guiding principle. Both approaches are laid down in international standards and overlap many aspects such as procedure, applied methodologies and development activities. For medical devices patient safety and therefore risk management is the guiding development goal. In HCD the focus lies on User Experience (UX), a positive experience throughout the entire product life cycle. The question arises whether UX could play a more important role in medical device development, particularly considering the similarities of the two development processes.

Keywords: Human-centred Design, HCD, ISO 9241-210, IEC 62366-1, MDR, user experience, usability, product development, risk management

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1 Introduction

Product development is supported by international standards. Development of medical devices must comply with IEC 62366-1 and further regulations such as MDR in Europe. Engineering of consumer systems and products should follow ISO 9241-210, human-centred design. While in medical device development application of usability engineering is a regulatory necessity, for consumer products it is advisable to follow the state-of-the-art approach of HCD.

Both approaches set out a number of activities that shall be applied in organisational development processes. However, interpretation, extent and detail to which these activities are incorporated remains an organisational decision. Both approaches have striking similarities and are overlayed in Figure 1 below, as shown in [1].

IEC 62366-1 aims to assess and mitigate risks associated with correct use and use errors [2], in contrast ISO 9241-210:2019 aims to make systems usable and useful by focusing on

Figure 1: Visualization of ISO 9241-210 and IEC 62366-1 in one common diagram [1].

users, user needs and user requirements [3]. In short, medical device development is mainly about risk management leading to safe medical devices, while human-centred design is mainly about UX leading to use- and joyful products.

Both address human-centred qualities which are [4]:

- usability
- user experience
- accessibility
- avoidance of harm from use

This leads to the question for medical device development: There might be an advantage also to concentrate on UX besides the regulatory required avoidance of harm from use?

The decision of what qualities to concentrate on when developing new products is always an organisational decision. We believe there are good reasons to also consider UX to enhance aspects of joy of use. This certainly holds for medical products that are patient devices as well as for devices used by professional staff. For bringing in UX into new products and devices the entire development team needs to get to know the user respectively the operator.

We consider a thorough understanding of users or operators to be vital for predicting and pinpointing potential use errors as well as potential positive user experience, i.e. user experience that exceeds solely efficient and safe use.

A thorough understanding of users and operators is based on the knowledge of user groups' characteristics in detail. Further to knowing characteristics in detail one needs to build a relationship, gain empathy for the person the team is developing a new product or device for.

The whole development team shall be able to relate on a personal level to future users and operators and focus on their needs and requirements throughout the entire development process.

This is supported by the persona-technique as first applied in software development and reported by Alan Cooper [5]. A persona that represents a user group must be based on empiric information. Gathering this information is usually carried out by user requirements engineers or user researchers in activities 5.1 (user specification, IEC 62366-1) and 7.2 (understanding the context of use, ISO 9241-210) see also Figure 1.

In short, either one has existing knowledge of user groups or one starts with an experience-based guess of possible user groups, carries out contextual interviews and determines respectively confirms user groups. Based on interview information and often additional accessible information qualitative user researchers compile a persona representing a user group. By adding a fitting name and picture as well as other personal information one gives the user group a face and a name to relate to.

1.1 Motivation

We applied the persona-technique in a study on daily diabetes management with the aim identify user groups and develop personas for each user group found. Secondly, to see if team members, also team members outside the contextual interview team, were able to relate to these personas and being able to form a necessary empathy level.

To focus on our initial question again, we wonder if there is an advantage to consider UX besides avoidance of harm form use in medical device development. The advantage of an UX-focus is more apparent to see if user and operator are one and the same individual, in contrast if user and operator are different individuals. However, Burmester and Zeiner [6] show that in professional working environments positive user experience is also important besides efficiency and safe use. They list 17 experience categories clustered in 6 groups for professional working environments that lead to a positive experience of use.

2 Methods and Results

To collect information about individual disease management, we conducted eleven in-depth context of use interviews with diabetics. Recruitment criteria were:

- a diabetic diagnosis
- minimum level of technical affinity.

Due to the pandemic, the study was implemented via video call. In a semi-structured qualitative survey, subject areas of the interview guideline were:

- disease history and current usage behaviour of devices and mobile applications concerning diabetes management
- obstacles in everyday life with diabetes
- view on possible future developments in the field of disease management

During note taking, analysis of interview protocols and comparing participants' answers, we detected similarities and differences between them concerning their context of use resulting in the deduction of qualitative clusters. Based on interview data gathered we were able to define four clusters of diabetics and were able to make them accessible to the team by formulating personas. Participants were assigned to one of the groups by identifying and comparing similarities and difference concerning their pain points, goals and wishes as well as personal characteristics such as technical interest and usage of mobile diabetes applications.

"The Technophile", Figure 2, is distinguished by his interest in new technical devices, different kinds of software and applications. His active involvement in (online) diabetic communities keeps him informed about new devices and developments. Personal data privacy is of less importance to him since it hampers exchange of data which could improve applications and their compatibility.

Another persona portrays "The Familiarised" that is characterised by a well-established routine in personal diabetes management. Whilst keeping an open mind concerning new technological developments, this group has established a stable disease management in terms of applications in use, fixed times and situations for blood glucose testing.

"The Passive", Figure 3, invests as little effort as possible, prioritizes comfort over perfect blood sugar levels and relies primarily on advice by medical professionals, showing little own initiative in diabetes management. This group's interest in new technologies and use of mobile diabetes applications is limited to the extent of time and work saved due to use of new technologies.

Finally, "The Unexperienced" pictures recently diagnosed patients without extensive experience and knowledge of the

Figure 2: Persona Close-Up: "The Technophile".

Figure 3: Persona Close-Up: "The Passive".

disease resulting in a need of time-consuming preoccupation with documenting and weighting food to manage blood sugar levels. This group requires the opportunity of testing different devices and applications to support them in their personal diabetes management.

These derived personas enable a view from different perspectives regarding use of technical devices and present an approach of depicting trends in the use of devices. We explored the view of a smart watch as a device tracking blood sugar levels. One exemplary finding is the "expected enhancement of quality of life". While "The Technophile" was enthused by more connectivity and data analysis, "The Passive" was simply looking for easier and more comfortable management of personal blood sugar levels.

3 Conclusion

We set out with a qualitative study and recruitment criteria spanning a whole lot of expected user groups. Analysing data we quickly found similarities in personal as well as diabetes management characteristics thus being able to form four user groups and compile personas from all information collected in the interviews.

Interestingly we observed from interview data and interviewees' retrospectives that all interviewees belonged early on in their diabetic life to the user group, namely "The Unexperienced". Later in their diabetic history they have developed to a different user group, represented by different personas, due to becoming more familiar and experienced with their disease.

We also observed that those team members not being part of the user research team were able to easily capture the data collected once it was presented in the context of the four personas. This supported an empathy build up and thus an easier access and understanding of the interview data.

Other UX-methods such as user journey maps and empathy maps can deliver an even more detailed picture of users, their needs and motifs and lead to a further better understanding of users and – if applied – an increase in user-centricity of systems in development.

We are confident that applying the persona-technique is also worthwhile for professional medical staff. There is more to their daily operation of medical systems besides safe and efficient use. There is plenty of room and benefit for identifying user groups that are based on personal

characteristics, task and goals, needs and motifs. Possible personal user needs are experiencing competence, being confident to work diligently and patient safety-oriented culminating in a positive user experience rather than being overwhelmed by complex systems and machines. UX methods enable the development team to increase empathy and the possibility to build relations to future users which will ultimately increase user-centricity in medical systems.

This becomes even more important with technological innovations in the medical sector that will lead to new and advanced devices – also in diabetes management. Some of the diabetics interviewed expressed positive curiosity and cautious expectations while others expressed scepticism due to their limited experience and imagination.

All future developments and devices need instructions and training. A thorough and empathetic understanding of users and their needs helps to fulfil these challenges and is supported by the application of vivid personas.

Author Statement

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