Commentary

Human Factors Engineering and Diabetes Technology: A Close Relationship

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Introduction

Manufacturers of digital diabetes solutions employ human factors engineering (HFE) as an interdisciplinary area of expertise that focuses on human-device interactions to evaluate the intended effects of products.

As many medical products for the treatment of people with diabetes (PwD) are on the market today, we are used to the fact that a given product, once it was developed and approved, stays on the market for several years ("lifecycle") until the next generation of the same product or a new product comes to the market. However, in reality, the given product (eg, an insulin pump) might have undergone several small (or not so small) modifications during its time on the market. Such modifications might be driven by changes in the technology for production or by new scientific insights. All changes have to be reported to the regulatory agencies, but only more impactful ones would require a new approval process. Many of such smaller "improvements" take place without notification of the user/health care professional (HCP) by the manufacturer. Digital medical products such as medical software or patient-facing smartphone apps undergo frequent updates. Sometimes, these updates are happening in the background to guarantee the software will remain functional. Other times, these adaptations might be visible to the user; they might improve the interaction with the device to enhance safety and/or its efficacy.

What Is Human Factors Engineering?

Realizing user-centric software development for smartphones requires intensive HFE. The international standard IEC 62366-1:2015 defines it as a way of achieving "adequate usability" of medical devices (including software) by understanding human behavior.[1] The term HFE encompasses more than "just" usability and centers on people instead. Currently, modern software development increasingly emphasizes a good user experience; this leads to products that primarily focus on actually solving user needs. This is in line with the approach we see more and more prominently in medical device engineering.

Throughout the formative phase of the product, different functions come together to give shape to the product. The manufacturer has to determine who this product is for, what their needs are, and the circumstances under which they might use the product. This is based on medical expertise, market analysis, user research, technical possibilities, the regulatory landscape, and other factors. These insights define the intended use, the intended user groups, and the intended use environment. It forms the basis of the product requirements that the product/solution development team takes as a starting point for their work. As soon as the first product outline comes to life, HFE can start with its research activities. Subsequently, five of such activities are listed, along with a description of what they entail and how they are applied in the development of a given product:

1. Task analysis (inspection method): A detailed task analysis describes exactly what use scenarios might occur and what tasks need to be carried out, both manually and intellectually. This leads to more clarity on how the product can be used, uncovers functionality gaps, and lays out potential pathways on how the product might be misused or which errors could occur. As such, the task analysis is a helpful

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resource for a Failure Mode and Effects Analysis (FMEA), which will be described more closely below.[2]

2. Usability testing (testing and inquiry method): Usability testing has different forms. For example, tests can be carried out with PwD. This ranges from simple, unmoderated tests focusing on one aspect of the product, eg, the understandability of warning messages, to moderateD think-aloud tests during which participants go through all possible use scenarios and share their thought process as they go. It is important to note here that the value of usability testing lies in the combination of being able to observe how people interact with the product and what they might say and think about it. A participant might take the accurate action in the product but feel uncertain if they are using it right. Conversely, they might use the product incorrectly, but their reasons for doing so are understandable or justifiable. Similarly, a user might be confident they have entered all their therapy settings, but an observer can see that they missed one or two fields. In such cases, manufacturers have to consider the potential medical outcomes and determine to what extent there is a need to tweak the design to make sure that PwD can use the product with confidence and that differing approaches to product usage would not lead to medical harm.
3. Heuristic evaluation (inspection method): This inspection method is based on comparing (design) standards with the actual product. Regular evaluations based on common user interface design principles should be carried out (see Nielsen 2020 for an overview of these principles, commonly known as design heuristics).[3]
4. Walk-throughs/expert interviews (inspection method/inquiry method): The algorithm that underlies, eg, a bolus calculator (BC) had already been available as part of a different product on the market. This meant that insights into how a very similar product might be used "out there" can be used. To gather insights, expert interviews with people involved in the marketing of and/or in the training of both PwD and HCP on the product already available are carried out. It is also an option to walk them through, eg, a BC in development, and gather their feedback. The combination of expert knowledge about another very similar device and professional feedback on the BC helps to gain insight into what worked well already and where there is room for improvement. Note that the product that is already on the market is, of course, safe and effective for use. However, with evolving technology and changing user expectations, it makes sense to look at what might be updated. Although activities like walk-throughs are commonly understood to take place with usability experts, one can argue that the experience of practitioners in the field can be as valuable as that of usability experts.[2] Especially for a specialized field like diabetes, "generic" usability insights might not be enough. Moreover, speaking to people who operate within the wider context can provide a broader and possibly more realistic perspective of how a product might be put to use.
5. Risk-specific: Failure Modes and Effects Analysis (inspection method): FMEA is a specific method to uncover potential usability issues that could lead to risk for the user, patient, or the environment within which the medical device is used. As it was suggested by the FDA, an analysis team should include a user (= PwD), a medical expert, members of the product development team, and a human factor engineer.[4] This systematic approach helps to uncover hazardous situations and potential issues that could lead to those situations. For example, what if a user has requested a bolus recommendation from the BC but has not entered all previous insulin injections into the app? How would this information gap impact the recommendation? An issue like this is a lot harder to discover in a usability test that purely investigates how users interact with a product. This is why a mixed-methods approach is so valuable.

Post-launch

Once a product has been launched, HFE receives information through post-market surveillance activities, customer support, and other monitoring activities. Especially in software development, manifold real-world data can be gathered to monitor and analyze the user's behavior. For example, tracking users' interaction with and usage of an app can provide useful insights for improving and optimizing how the app is designed. But foremost, information like this is assessed to make sure that new, non-anticipated risks are adequately dealt with. If it becomes clear that risks exist that cannot be maintained with a minor improvement but rather require a major product change, then the HFE process starts again from the beginning.

Summary

With our traditional understanding of medical products, very often the health care team plays a crucial role when it comes to the handling of products such as insulin pumps. With software, and specifically smartphone apps that are instead directed to the patients, manufacturers need to recalibrate their understanding of who is the target user and must not forget about the "human factor" that comes with this direct interaction between patient/user and product. Because in the end, "the fish must like the bait, not the angler."

Abbreviations

BC, bolus calculator; FDA, Food and Drug Administration; FMEA, Failure Mode and Effects Analysis; HCP, health care professional; HFE, human factors engineering; PwD, people with diabetes

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