Usability:
what to consider & how it impacts product development

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What is usability?

Usability is about one thing and that is the quality of interaction between people and products. It's really that simple. However, the process involved to ensure this quality is less straightforward. Also, to clarify, usability is human factors. They are one and the same.

The task of increasing the quality of interactions between people and products can be driven by regulation. For example, making a product safe to use. However, the commercial drivers of making the product more efficient and satisfying to use are just as significant.

It's important to know that usability isn't something that is only applied to medical products, nor is it something that is only applied to complex devices. Something as simple as a tin opener has progressed dramatically since the mid-1900s with regard to usability, as has the folding of a baby stroller and the user experience of many software applications. It's all around us.

How can it impact the outcome?

When usability is applied poorly during the product development process, the consequence is what we call 'use errors'. Put simply, a use error is any situation where the outcome from using the product is different from the intention. Wherever possible, usability aims to minimise the existence of use errors.

For example, if a tube is not connected properly on a device used in a hospital it could result in an arterial air embolism. Entering data incorrectly in some use scenarios could potentially result in an overdose. In both examples, the potential harm is critical and could be mitigated through better usability analysis which would feed into the design. The ideal outcome would be a design where it is impossible to connect the wrong tube, or where the product does not function if the tube is connected improperly. This is inherent safety by design which should always be the aim.

Some things to consider to develop a product with good usability

One mindset that can lead to better outcomes is not being committed to or romantic about the current format or embodiment of the product. To design a product with the best usability possible, there must be an open mind and insights gained from the analysis of user needs must drive the characteristics of the product so that the outcome is not tied

down by pre-existing beliefs. It may be that the overall format and architecture of the product changes significantly from its current state to deliver the best experience.

A key part of good usability is to consider every stakeholder. By stakeholder, we don't just mean those who are financially invested, but anyone who is affected by the product. Who uses it? Who cleans it? Who assembles it? Who maintains it? Who delivers it? Who sells it? This list is not exhaustive but allows us to start thinking about all the different groups of people who interact with the product. Then, we can dig down and build a user profile if there are common characteristics of the users. For example, this could be age, occupation, level of dexterity, level of experience with similar devices, etc.

In addition to identifying the different user types, it's important to identify and understand the use environments. As in, the different contexts in which the product will be used.

When all stakeholders have been identified, it's a good exercise to map out the experience journey for each and list out every interaction in as many different use environments as possible. Visibility of all interactions helps you see the bigger picture and is more likely to bring forward opportunities to simplify user interactions. This can improve usability but is difficult to do when you don't have all the information mapped out. This process is pro-active and it's incredibly important because poor usability can often come about because the task was pushed back in the development until usability issues started to arise. This is too late. You end up fire-fighting and decisions start getting made quickly without the time for proper consideration and robust thinking.

Another important aspect is to consider all human senses and their limitations. For example, detecting an audible alarm from a product may be affected by the age of the user, the possibility of hearing loss or just the noise level in the environment in which the product is being used. Another example could be memory. If there are too many steps to recall in a user task or if too much information must be remembered going from one screen to another in a digital app this could result in use errors. This is where usability feeds into the design and we can use multiple ways to improve the interactions and minimise use errors. For example, affordances that give cues to the user such as shape coding, resistance forces, size differentiation, universal symbols, orientation cues, etc.

Implementing usability as part of medical device development

A key part of usability is identifying all possible use errors. There are many exercises for this including observations, interviews, reading product reviews, reviewing known use errors, expert review, etc. An important step is a full task analysis. For example, if the product is a glucose meter and the task is placing blood on a strip, then examples of use errors could be applying too little blood onto the strip or applying the blood in the wrong location. Analysing each task like this then translates to features of the product.

When as many use errors as possible have been identified to inform the design, only then would proper usability studies be carried out to reveal more use errors and opportunities for improvement. Formative studies would be done throughout the development to

review the current prototype, uncover remaining issues and opportunities to further improve the design. Then, a summative study would be done to validate the product by testing the device in a controlled environment. These studies must be done in a particular way because part of the reason for doing them is to prove that you have gone through a rigorous process to mitigate the risks so that you can get certification from a regulatory authority. The IEC 62366 standard is a good reference point for anyone wanting to learn more about applying usability to medical devices.

In summary, usability is a key part of the process when developing medical devices. Not only is it a required component of your technical file but it brings benefits in the form of greater user experience and human interaction leading to all round better products.

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