MPO MEDICAL PRODUCT OUTSOURCING

06.04.24

The Smart Way to Achieve a Safe Medical Device Interface

Dorothy Shamonsky, Ph.D. and Stephanie Van Ness, Integrated Computer Solutions (ICS) and Boston UX

Practicing effective usability design is a proactive action that involves an upfront investment.

Incorporating professional usability design into your medical device lifecycle can shrink project costs; elevate customer satisfaction; and allow you to deliver a much better, safer product.

Safe use of a medical device is of utmost importance—that is well-agreed upon. However, how to get there is always evolving. Consider this: Safety and usability are deeply intertwined because the foundation of safe use is clarity. Clarity is the users' perception of how the interface works and how they can complete their task by navigating the interface. As a result, one might logically assume that achieving safety would always be paired with professional-level usability design. Unfortunately, that's not the case.

Although safety is a high priority for medical device makers, effective usability design is not always a high priority. One reason may be that major safety issues can be remedied by recognizing risks and mitigating them. It's a stop-gap method of design but it's effective relative to the serious risks—a workable and economic solution.

Another reason could be that practicing effective usability design is a proactive action that involves an upfront investment. It is the device maker's choice whether or not to do it. Conversely, safety regulation is a reactive action mandated by the U.S. Food and Drug Administration (FDA) so it must be done for all Class II and Class III medical devices.

It's easier to be reactive than proactive, but that doesn't mean it's necessarily better.

Who's to Blame for a Medical Device Causing Harm?

Historically, medical devices have had notoriously difficult-to-use interfaces. Whether the cause was economically driven, based on a belief that medical professionals tolerated hard-to-use interfaces, or something else entirely, proliferation of sub-par designs and the resultant harm concerned the FDA. The agency began to regulate medical devices in the first place because of these types of issues.

In the past, so-called "use errors" on devices that caused unnecessary harm, or even fatalities, were blamed on user actions. But today, blame falls rightfully on the device's design. The FDA has stepped in to force device companies to be more fail safe.

Medical device user interfaces aren't necessarily better designed because of FDA actions, however. Only safety risks are addressed because that is the agency's fundamental concern regarding a device's interface. The harmonized regulatory standard IEC 62366 describes a usability engineering process that identifies and minimizes use errors and thereby reduces use-associated risks.

While this standard acknowledges the need for skilled human factors design as devices become more complex and users become more diverse, the criteria for evaluation is safety. The FDA does not prescribe how to design an interface or set standards for clarity or ease-of-use; it simply prescribes that an unacceptable level of risk must be recognized and removed.

The FDA is doing its job as a regulatory agency, operating in an appropriate realm of black and white decisions. It is the device maker's job to be concerned about overall good or bad design, ease-of-use, understandability, or efficiency.

Designing for Safety vs. Designing for Usability

Ask yourself: What is the relationship between designing for safety and designing for usability? We argue that safety is not a completely black and white issue and it extends into the whole design. If a user doesn't have clarity about how a device works because they are confused by options on a screen, they can get flustered and lose patience, causing them to think less clearly when making decisions about how to navigate the interface.

If a user feels like they can easily follow a procedure in an interface, they're less likely to fumble around or do something incorrectly or risky. They may not make fatal mistakes but they still might make smaller (yet significant) errors, such as giving a patient less than the recommended dosage via infusion pump or gathering data that is not quite accurate. In both of those scenarios, the patient receives less than optimal care. Even if they use a device correctly, a confusing interface can render a user less efficient.

Designing in certain safeguards such as providing an emergency shutdown mode or incorporating guardrails that block risky actions—for instance to prevent a clinician from dispensing too much medication–is a best practice in interface design. However, it isn't optimal to allow users to make even small mistakes or slightly misuse a medical device.

The Role of UX and Human Factors Professionals

Today's more stringent FDA regulations are required to guard against design failures around safety. Simply put, a well-designed interface is more inherently safe; a badly designed interface has a tenuous relationship with safety. Device makers must expand their focus to consider good use at the same time they are meeting the FDA's standards.

Hiring human factors or UX designers to professionally design a user interface makes sense in today's high-stakes regulatory environment. Even though human factors and UX designers have been around for decades, many device makers still do not utilize their expertise. This reluctance may be driven by the belief that usability professionals are too expensive or ineffective. Other reasons for hesitation include the belief that any hardware or software engineer can design an adequate human interface, so a specialized usability expert is unnecessary. It could also simply be the fear of managing a designer.

Whatever the reason, this hesitation needs to recede if we're to benefit from (at least, not be harmed by) medical devices. As they become increasingly complex and connected, it is more important than ever to leverage the design expertise of a professional with a track record for creating effective, understandable, and usable interfaces.

The Takeaway

Designing for safety is not only about blocking users from making inadvertent risky actions in the interface. It's about designing for clarity, designing in a way that humans find natural and intuitive to use so they're not confused or need extensive training. Using a difficult interface can leave someone feeling frazzled, stressed, even angry, while using a well-designed interface can leave a person feeling calm, competent, and efficient. If that sounds silly, you are not taking seriously enough the stress that the man-made environment can perpetuate on human performance, which can lead to mistakes in device use. Working in healthcare is already hyper-stressful, which is why healthcare more than most professions needs equipment that offers good user experiences.

You can see the trend line of medical device interface design. Medical devices start out with primitive user interfaces. As the devices grow more viable they become more widely used, then accidents happen. The need for better safety becomes a top priority and the FDA gets involved, requiring device makers to comply with regulations through risk analysis and mitigation. This is a reactive approach that may no longer be optimal as the industry evolves.

These days medical device usability is rapidly moving toward comprehensively professional interface design. Though consumer user interfaces have historically set the bar for good usability, that is already changing as other sectors lean into digital transformation and embrace cutting-edge IoT technologies. Embedded devices including medical devices are poised to surpass laptops and mobile devices in terms of natural, intuitive usability. For that reason, including professional designers on your team is the smart, strategic solution to medical device product development.

Dorothy Shamonsky, Ph.D. is Chief UX Strategist for Integrated Computer Solutions (ICS) and Boston UX.

Stephanie Van Ness is Associate Marketing Director for ICS and Boston UX.