MEDdesign Nov 2012 Blog Entry

"The Rise of Mobile Health and the Importance of Human Factors"

The rise and benefits of mobile health applications

Human factors engineering as applied to the design of medical devices has never been as important as it is today, especially since the release of the U.S. FDA's draft guidance document "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" in June 2011. With the imminent rise of mobile health applications, human factors engineering principles will become even more vital to the success of this emerging industry and to the safety of the patients for whom they are designed.

Numerous factors have contributed to the recent explosion of mobile health applications and remote patient monitoring, creating a perfect storm of opportunity for this sector of the medical industry. Economic trends such as the push for cost reduction and new regulations mandating disincentives or penalties for the readmission of Medicare patients into hospitals within a certain period of time are pushing healthcare providers toward a more vested interest in keeping patients at home. Technology trends such as the migration to electronic health records, the advancement of digital health applications, cloud computing, the widespread use of social media, and the ubiquity of mobile devices play a huge role. The ability to self-monitor and keep a diary of health issues through the use of mobile apps is strengthening relationships between healthcare providers and their patients.

Consider the following points:

- By 2015, 500 million smartphone users are expected to be using medical apps, according to Research2Guidance, a global mobile research group. (Kaiser article [i])
- The market for mobile health apps is expected to quadruple to $400 million by 2016, according to ABI Research. (Forbes article[ii])
- 3+ million patients will be monitored over cellular networks by 2016. (Juniper Research[iii])
- $3 out of every $4 spent on US Healthcare is for chronic diseases, and family caregivers are estimated to provide 80% of all long term care for chronic diseases. (Juniper Research[iv])

FDA to start regulating mobile health/medical apps

In July 2011, the FDA released a draft guidance document on mobile medical applications "to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms."

(FDA Draft Guidance, 2011[v]). Since the release of this document, there has been movement within the app development industry to understand and anticipate exactly which mobile applications will require FDA approval. The guidance indicates that the following types of mobile applications would be subject to regulatory processes:

- Software applications that can be executed on a mobile platform, or web-based software applications that are tailored to a mobile platform but are executed on a server; and
- Software applications that have an intended use within the scope of the concept of medical "device" as regulated by the FDA; and
    - Are used as an accessory to a regulated medical device (for example, an app that connects to a medical device for the purposes of controlling the device in some way); or
    - Transform a mobile platform into a regulated medical device (for example, an app that remotely monitors patients' vital signs).

(Note that according to ANSI/AAMI HE 75:2009 a mobile medical device is not limited to only mobile phones and tablets, but any device that can be mobile, whether by carrying or rolling.)

You may notice that the guidance does not apply to mobile apps intended to analyze, process or interpret medical data; the FDA has indicated that it will address these types of mobile applications in a separate guidance document. However, the important takeaway is that the FDA will soon be releasing legally enforceable guidelines that will apply to a plethora of medical and health apps already on the market and many more under development. In fact, a bill set to be introduced in the U.S. House of Representatives called the "Healthcare Innovation and Marketplace Technologies Act" (HIMTA) proposes to establish an Office of Mobile Health at the FDA specifically to provide recommendations on mobile health issues and create a support program to help developers navigate HIPAA privacy regulations.

Importance of applying human factors to mobile apps

The implementation of human factors engineering throughout the design process will be critical for emerging mobile health applications, not only because the FDA is exerting its responsibility to protect and promote public health by regulating these new mobile 'medical devices,' but because it's good practice and is an essential tool for decreasing patient safety risks while increasing usability and effectiveness.

Take it from someone who has already been through the process. An article written by Brian Dolan for mobihealthnews in May 2011[vi] describes a panel that he moderated with several mobile health app companies who have already navigated the FDA's 510(k) process successfully. In the article, WellDoc Founder/CEO Ryan Sysko is quoted as saying that if he could

change one part of the process he "would have the FDA provide greater clarity around what successful human factors testing looked like."

Our research and usability team at Farm knows the detrimental consequences of failing to apply human factors engineering to product development efforts; we have helped many clients whose medical devices have been rejected by the FDA for their lack of necessary or appropriate human factors evaluations. As we always remind our clients, human factors is not a one-time testing event that occurs at the end of the development cycle, but rather an ongoing iterative approach that starts at the very beginning.

The importance of implementing an iterative approach in the design of mobile medical apps is as relevant as applying the process to physical devices. As the more savvy companies have learned, a robust process starts with the gathering of user requirements and includes preference testing of multiple design concepts, design verification which could include several rounds of formative usability testing of the product itself and related documentation, and a final summative validation test which proves the successful mitigation of use-related safety risks. As is the case with physical medical devices, mobile medical app developers will be expected to follow the user-centered design guidelines of the international standard IEC 62366: 2007.

During the development process, mobile app designers should turn to established human factors guidelines, particularly those set forth in the ANSI/AAMI HE 75:2009[vii]. Here are some examples from HE75 that could apply to mobile medical devices and/or apps:

- Carefully analyze the conditions under which the mobile device is going to be used (for example, when a user is moving or being moved, in moving vehicles, while wearing the device or during stationary use, on a rack, above the head, etc).
- The display on the mobile device should not be obstructed by additional accessories, wires or devices.
- Auditory indicators can be used to supplement visual indicators and should provide the ability to adjust volume, on/off and native language (when feasible).
- When possible, aim to work with existing technologies that already have protocols in place that work with medical industry standards, such as the IEEE 802.11 series of standards for LANs, Bluetooth and cell phone protocols.
- Carefully analyze the conditions under which the mobile device is going to be used and how detrimental it is when the battery runs low.
- Keep important tasks immediately identifiable.
- Ensure that the design takes into account the small size of the screen, limiting the amount of images and text.

- Remain consistent; place information in the same place over a series of screens.
- Offer more than one way to navigate through the system.
- Provide guidance such as prompts or pop-ups when applicable.

Below are some mobile app design best practices published by the mHIMSS Design Tenet Workgroup in January 2012[viii]:

- Eighty percent of screen real estate should be dedicated to data; 20 percent to interface.
- For readability, a single sans-serif typeface and up to six type treatments for the typeface are used.
- Color is used sparingly and helps the information, the interaction, and the user experience accomplish the apps' intended purpose.
- The app displays controls in a progressive manner; only the ones needed at specific points along the intended workflow.
- The app works within mobile device limitations such as: no hover text feature, larger target size and smaller display.
- The app leverages new capabilities such as touch-based interactions, location awareness, proximity sensitivity, integrated communications and push notifications.

Conclusion

The rise of the mobile health industry is underway and offers an outstanding opportunity to revolutionize healthcare. In September, it was announced that the FCC would act on key recommendations from its mHealth Task Force to adopt wireless health technology (fcc.gov[ix]).

In order for mobile health application developers to be successful, they must create safe, easy-to-use products that can pass the rigorous FDA approval process. The critical path to this success begins by stringently applying the principles of human factors engineering. Drawing a reference from the Hippocratic Oath, the ultimate goal for designers is to first do no harm, and then do everything possible to provide the best possible product experience for the patient. The only way to do this is to involve end users in the design process from start to finish.

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