

GUIDELINES FOR MOBILE HEALTH APPLICATIONS

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Mobile health (mHealth) is a fast-growing industry that facilitates the management of healthcare by both patients and healthcare providers (Zapata, et al, 2015). The growing popularity of this platform and general lack of regulatory oversight has led to wide variation in adherence to sound human factors and usability principles. Thus, a set of guiding criteria would help developers streamline their processes through standardization. As part of a project referred to as the Xcertia Guidelines, a workgroup of industry experts and stakeholders developed guidelines for incorporating usability principles into the development of mHealth applications. Using an iterative process, the workgroup conducting research to generate content covering 10 distinct topic areas for a draft publication released in February, 2019. After an open comment period, an updated version of the guidelines will be released to the public.

INTRODUCTION

The mobile health (mHealth) sector has exploded in popularity over the past several years. According to R2G, a digital healthcare research and strategy organization, there are now 325,000 mobile health apps from 84,000 app publishers on the market (R2G, 2017). Furthermore, 78,000 new health apps joined the market in 2017 alone. This ubiquity warrants a critical investigation of the application of human factors and usability engineering to promote safe use, adoption, and retention. However, usability in the medical industry focuses largely on what is regulated by the Food and Drug Administration (FDA), and much of mHealth does not fall under regulatory purview. This lack of unified oversight can result in development and assessment processes that vary greatly between developers. Though some guidelines for mobile apps already exist (e.g., Apple's Human Interface Guidelines [n.d.] and Google's Material Design Guidelines [n.d.]), these on apply to specific operating systems and are not optimized for mHealth. As such, the mHealth industry would benefit from formal guidelines that address the design, development, and testing needs of both regulated and unregulated mHealth applications.

Xcertia, an mHealth collaborative founded by the American Medical Association (AMA), American Heart Association (AHA), DHX Group, and Healthcare Information and Management Systems Society (HIMSS), set out to address the need not only for a set of usability guidelines, but for a larger set of guidelines covering multiple topics relevant to mHealth. The five overall topics (privacy, security, content, usability, and operability) comprise the Xcertia guidelines. Each topic section was generated by a separate working groups of

industry professionals. Together, the guidelines address an important need to provide a consolidated resource that, when applied as intended, will be a useful resource for a variety of stakeholders.

Guidelines Goals

Xcertia initiated the process of developing the guidelines in 2012, setting out to achieve several goals with the ultimate publication. There are potential benefits to healthcare systems and providers if, in knowing that mHealth meets the recommended guidelines, they can spend less time evaluating apps under consideration for purchase. Similarly, patients using mHealth can have increased confidence that apps meet known standards for efficacy, and that data is safe and secure, a particularly important consideration for lay users who may be concerned about keeping their personal health information private. Finally, the key target audience of mHealth developers will be able to utilize the document to streamline the development process and create standardized processes of their own that meet the guideline expectations.

Usability Workgroup Goals

The workgroup for the usability guidelines also established goals separate from those of the overall Xcertia effort. One goal was to assemble information from a variety of known and widely referenced usability sources to increase efficiency on the development side. This will alleviate the burden on developers researching this information independently, a benefit applicable to the overall Xcertia Guidelines as well. The usability workgroup also strove to consolidate input from stakeholders with varying backgrounds and create a

document that could be understood by a wide range of readers. Finally, the workgroup aimed to develop a set of guidelines that could be applied to a wide variety of situations, that is, to be universally applicable across operating systems, user types, and categories of apps ranging from simple medical information repositories to apps used by patients to communicate with medical devices and monitor health data in real time.

METHODS

Workgroup Assembly

Each of the five workgroups was composed of a group of industry professionals and subject matter experts in that particular topic. The usability workgroup included members with knowledge and experience relevant specifically to usability or human factors, or to mHealth in general. This included representatives from usability consulting, researchers in academia, app developers, clinical experts, and other stakeholders in the mHealth technology field. The team included both veteran workgroup members who had been involved in the effort since its inception in 2012, as well as new members recruited for participation when the effort was renewed in May of 2018, when the bulk of the work with the usability guidelines began.

The recruitment of new members was initiated when usability was identified as an individual topic. Before the renewed effort began in mid-2018, the operability and usability topics were consolidated. However, the workgroup leaders quickly determined that the topics were distinct and should be discussed in different sections. Thus, the workgroup was divided into separate operability and usability groups. Because the consolidated workgroup had focused primarily on operability until the division, new members were needed on the usability team to ensure that industry expertise was represented.

Development Process

The privacy, security, content, and operability groups utilized draft versions of their sections for discussion and update. However, when the usability section was spun off from the operability group, the existing content focused entirely on operability (Abts, 2019). Consequently, the usability group was charged with generating completely original content for the new section. To accomplish this efficiently, the team engaged in an iterative process of literature searches, content generation, and discussion via bi-weekly workgroup meetings before the usability section was combined with the other four sections for publication.

Student Engagement

The division of the operability and usability topics required the usability group to conduct a substantial amount of background research to generate new guidelines. To handle the workload and keep pace with publication deadlines, the team engaged a group of graduate students from Arizona State University (ASU) enrolled in the Human Systems Engineering (HSE) and User Experience (UX) programs to assist with the process. These students were well suited to assist industry professionals and provide research in the areas of human factors, usability, and interface design.

The students followed an iterative process with their research, first reviewing current usability literature and other existing standards or application guidelines, then compiling their findings into an internal document that was further condensed and reviewed by students organizing the project. Workgroup members reviewed the document and provided feedback during meetings, after which the students continued to research additional topics and locate information of interest.

The students' involvement proved to be mutually beneficial. While the students helped to reduce the workload on workgroup members and support an efficient review and discussion process, they also took away their own benefits from the experience. The students expressed a desire to practice retrieving information and summarizing the content for the guidelines, which they were able to accomplish through condensing research into best practices for review by the team. Students also gained experience self-organizing and dividing the larger project into smaller, manageable sections that could be reviewed and discussed by the workgroup. Reliability was vital as the students developed a workflow to meet deadlines and summarize information into concise pieces for workgroup members to translate into the larger guidelines. Students also appreciated the industry experience and working with professionals in the field. They were able to participate in general discussions and receive feedback from industry veterans.

RESULTS

The content generated through research and development was refined over the course of eight months into a draft version for publication. The usability guidelines begin with an introductory statement that defines the purpose of the section. The team arrived at a final definition statement: *The Usability Guidelines assess how a mobile health app is designed to be safe and easy to use by incorporating five key quality aspects of usability: learnability, efficiency, memorability,*

prevention of errors, and user satisfaction. Apps designed based on sound usability principles will be optimized for use by the specified users within the specified use environments. The definition includes several important ideas. First, that safety and ease of use are crucial considerations in mHealth app development. Second, it refers to the five quality components of usability outlined by Jakob Nielsen (Nielsen, 1994; 2012). The team felt that it was important to provide a well-known reference to establish credibility. Finally, it calls for a robust process that focuses on considerations for end users and their use environments. The remainder of the usability guidelines section was developed around adherence to this introductory statement.

Through the process of iteration, the team selected 10 high-level guidelines for inclusion: Visual Design; Readability; App Navigation; Onboarding; App Feedback; Notifications, Alerts & Alarms; Help Resources and Troubleshooting; Historical Data; Accessibility; and On-Going App Evaluation. The workgroup wrote introductory statements for each guideline that included a general definition, and in some cases, a brief justification for inclusion. The justification statements aimed to promote understanding of the topic and establish the basis of the guidelines in published research. Each guideline then contains a set of performance requirements that provide the reader with more detail on practical application of the guideline topic.

The selection of topics covers several categories of guidelines. Some guidelines, such as Visual Design or Help Resources and Troubleshooting, are broadly applicable to almost any product. The team felt it was important to not overlook elements of good design that were not solely relevant to mHealth. Other guidelines address requirements for common user tasks or features, such as the onboarding process. The Notifications, Alerts & Alarms guideline is a good demonstration of a common feature that may also include risk considerations. Certain apps may need to utilize high-risk alerts to relay information that, if missed, could cause harm to a patient. Imagine that a diabetic patient is utilizing an app to continuously monitor their blood glucose. If the app detects a high blood glucose level and fails to inform the user in a timely manner, or presents the information in a manner in which it could be misinterpreted, this poses a safety risk to the health of the patient. Addressing potentially risky use situations was a priority for the workgroup given that regulated mHealth falls under this category.

Finally, On-Going App Evaluation is a crucial guideline in its own right. This guideline describes a robust evaluation process that includes activities such as user research, heuristic evaluation, and user testing. The

topic was particularly critical because it provides the reader with a means to evaluate adherence to the other guidelines and ensure usability has been appropriately addressed. The guideline includes examples of evaluations that can be conducted during various stages of the development process to promote a comprehensive approach to usability.

DISCUSSION

The usability workgroup faced both unique and expected challenges while working on the guidelines, resulting in generation of creative solutions. One early challenge in the development process was the need to create original content after the usability group was formed. By leveraging the student's work, however, the group was able to streamline this process and reduce the impact of this obstacle. The workgroup was also able to use the situation to their advantage to have more control over the guidelines content, rather than being limited by iterating on the work of others.

Another challenge was prioritizing topics for inclusion. The aim was to provide enough detail to be useful, but not so much that concepts were too technical or confusing, or that they were applicable to only a narrow set of situations. To tackle this issue, the initial guidelines were drafted with a wide scope of subject areas that were gradually refined over the course of several months. The performance requirements within each guideline were then designed to adhere to the high-level principle under discussion, but also to include examples of how principles may apply to more specific situations. Technical details were generally avoided, but were included in some performance requirements when a general statement would not be useful (e.g., minimum default sizes for paragraph text).

Though the team encountered some roadblocks, the insights gathered during the development process can help other members of the community tackle similar problems. Through content prioritization and careful thinking about the level of detail provided, the team was able to create a set of standards that could be translated across different user types, operating systems, and application categories. Cross-disciplinary work is only successful when there is ample communication between disciplines, and the usability workgroup utilized their diverse makeup to address the larger scope of usability and ensure the document was universal and readable for developers, clinicians, and other stakeholders.

CONCLUSION AND NEXT STEPS

Use of an iterative process that leveraged expertise across a variety of disciplines resulted in a

draft set of guidelines that encompassed high-priority usability topics critical for development of mHealth. The draft usability guidelines, along with the other four guidelines sections, were released on February 19, 2019 for public comment on the Xcertia website (<https://www.xcertia.org/the-guidelines/>). Workgroup members will continue meeting to review feedback from commenters and make updates as needed. Public comment on the draft release closes May 15, 2019, after which all workgroups will finalize the content of their sections for another release.

Preliminary feedback has shown that there is interest from the mHealth community in these guidelines. While there is no regulation requiring application of these principles to mHealth apps or adherence to a standard usability process, it is the hope of Xcertia and the workgroup members that adaptation of these guidelines in the industry will benefit all stakeholders.

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