

# Safe, sound and desirable: development of mHealth apps under the stress of rapid life cycles

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Smartphones, tablet PCs and other seemingly “smart” devices are ubiquitous and they are on their way to becoming an integral part of everyday life. Mobile technology seems to fulfill Marc Weiser’s statement from 1991, which was almost prophetic considering today’s use of these devices, where he declared that “The most profound technologies are those that disappear. They weave themselves into the fabric of everyday life until they are indistinguishable from it” (1).

Health and medicine are not exempt from this phenomenon, and in fact, mobile solutions seem to be available for almost any health-related question, with steadily rising usage rates (2,3). While much has been said about the opportunities mHealth technologies may provide with respect to improving healthcare in a general sense, e.g., by allowing for a more efficient use of available resources, as well as by empowering patients to become active participants in maintaining or improving their health, there are other points still to be lamented (4). On the one hand, in many areas where mHealth is already being made use of—be it for professional medical applications or rather non-professional uses such as fitness and wellness—there is still a lack of solid scientific evidence about its efficacy. Where evidence is available, its scope is often quite narrow (4). The lack of evidence aside, while there are undoubtedly many high quality mobile applications, there are also many where quality is questionable and these may even place

their user’s health, or their social or financial integrity at risk. On the developer’s side, this is usually not intentional; rather, many developers in the mHealth universe simply fail to keep up with the high demands of developing solutions that are not only pleasing and comfortable to use, but that also respect the appropriate guidelines and regulations that are of special importance in sensitive areas such as health and medicine, in order to ensure their products’ safety and trustworthiness.

In their work, based on an analysis of literature available in 2014, Chatzipavlou *et al.* (5) are describing the developers’ roles and responsibilities in relation to other stakeholders (e.g., doctors, patients) in the mobile health market, with an emphasis on the developers’ own perspective. In succinct form, they give an overview over regulatory aspects as well as the mHealth market itself, but also over technical and design related questions and the hurdles developers are confronted with. Last but not least they touch upon the societal and moral factors that developers need to consider when creating apps and other mobile products for an mHealth context. For each aspect mentioned, they also give a short recommendation of what developers need to consider.

Chatzipavlou *et al.* (5) recognize the fact the mHealth market itself, but also applicable laws and regulations are undergoing constant changes—the former due to rapid technological advances that are of course also having an

impact on the mHealth sector, even if they were originally meant for use in other areas, the latter due to lawmakers trying to keep pace with what is being developed in order to ensure safe use of these innovations. On the EU level, there have recently been a number of efforts regarding mHealth, especially with respect to assessing apps as well as providing a privacy code of conduct for them (6), although much still remains to be done. Adaptations to regulatory frameworks and guidelines, which may become relevant for developers as well as other stakeholders, are often time consuming, and regulation, once it is forced by circumstances, e.g. negative publicity regarding a technology due to adverse events having occurred may well overshoot the target and hinder rather than encourage innovation. Therefore, risk prevention or lessening any potentially negative effects is in the best interest not only of users, but also of developers who always want to stay on top of the technology's potentials (7). The trustworthiness mentioned by Chatzipavlou *et al.* as being "of vital importance" (5) should not only rest upon following applicable regulations and standards (as not all of them apply to all classes of apps) when designing and developing apps. Distrust often arises from users being provided with insufficient information, which makes it difficult for them to assess whether an app potentially meets their needs or can be deemed safe (8). Transparency throughout a product's life cycle, from its inception through development to distribution, is of essence in order to gain the trust of users and also to prevent disappointing them, e.g., due to an app either not providing the expected functionality or simply not being adequate for one's level of knowledge. For developers, providing the necessary information, following a standardized structure, e.g., in the form of a synopsis, does not require much effort (9), but may well give them an advantage over their competitors.

Chatzipavlou *et al.* (5) also provide an astute assessment on the need for developers to carefully determine the needs of their target group(s) and a user centric approach to implementing the functionality their apps provide in order to be successful. They emphasize that keeping users' motivation high is an important part of an app's success (10) and in fact, in literature, there have also been mentions of motivation significantly contributing towards preventing high attrition rates that may otherwise be caused by the initial excitement of technology rapidly wearing off (11).

Another aspect also comes to mind in this context, which may also touch on the societal and ethical aspects described by Chatzipavlou *et al.* (5). Developers need to carefully

consider the mentioned aspects of navigability, interactivity and customizability, which are stated to be key elements for user satisfaction, along with comprehensibility of the provided content and functionalities. Developers should however not only do so with the "average user" in mind, but also take the requirements of those with special needs, e.g., physical or other handicaps under consideration. Only then will it be possible to ensure good accessibility for all those who may benefit from using these apps. This, along with other aspects such as carefully weighing user autonomy *vs.* control by providing users with the possibility to know what is being recorded, for which purpose, and how this can be prevented if desired, is also an imperative from an ethical point of view (12).

Finally, technical aspects need to be carefully scrutinized and these are in many parts closely interrelated to the aforementioned aspects. For example, regarding the aspect of "security" Chatzipavlou mention as a challenge (5), while implementing an app in a manner that is consistent with ensuring the highest possible level of data protection and data integrity, which requires sufficient technical expertise on the developer's part, this also plays a role regarding legal aspects, e.g., evidenced by the requirement to respect data protection laws that apply for the markets where an app is to be distributed. Regardless of a health app's purpose—whether it provides diagnostic or therapeutic functions, thereby making it a medical device with all entailing consequences, or is simply meant for fitness or wellness—quality assurance throughout an app's life cycle is of utmost importance (13).

There are a number of norms that developers may refer to in this context, some of which define a minimum set of measures developers are expected to respect (7), but some of them even being a requirement depending on the jurisdiction(s) involved, especially in cases where apps fall into the medical device category and have to undergo the appropriate regulatory processes before being allowed on the market (7). Essential points laid down in these norms (e.g., ISO 250xx family of norms, PAS 277:2015 4 and others) deal with criteria such as functionality, efficiency, compatibility and usability, but also reliability data protection, privacy and security and finally maintainability, portability and user safety. While not all of these are required by law, and they are often not considered in scientific literature, developers should nevertheless be advised to consider them as part of good practice.

In summary, developers, who often come from diverse, not necessarily professional backgrounds need to become

more closely aware of the fact that when developing in a health context, there are many additional aspects to consider, which may significantly contribute towards an app's actual as well as perceived safety and trustworthiness and thus its success. In addition to protecting users from adverse effects, this will assuredly also benefit the developers themselves, by actively reducing the potential for adverse events relating to the apps and thus reducing the developer's risk for liability.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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