International Journal of Medical Informatics 118 (2018) 54–57

Contents lists available at ScienceDirect

International Journal of Medical Informatics

journal homepage: www.elsevier.com/locate/ijmedinf

How standards and user involvement can improve app quality: A lifecycle approach

ARTICLE INFO

Keywords:
Health apps
Mobile applications [MeSH]
Medical device legislation [MeSH]
Standards
Digital health

ABSTRACT

Health apps have great potential to improve the quality of care and reduce costs, but this has not yet been achieved. Unfortunately, there are many low-quality, unsafe health apps, resulting in different types of risks. This Perspective addresses the current failure to adopt standards for the development and implementation of health apps. For each theoretical stage of the app development lifecycle we discuss problems, examples, reasons, and solutions. We believe that adapted versions of existing professional and technical standards and tools developed for clinical information systems, medical devices and medicines could help mitigate risks throughout the health app lifecycle. Adapted standards should bring more effective user involvement and cooperation amongst stakeholders. We argue that these efforts will ultimately provide users with a wider choice of higher-quality health apps, give healthcare providers access to better quality data, and allow developers to innovate without unnecessary time-consuming restrictions.

1. Introduction

'*Quality is much better than quantity. One home run is much better than two doubles*', said Steve Jobs, two years before introducing the iPhone in 2007 [1]. Over a decade later, this statement does not yet appear to be true for health apps. There is much 'apptimism' about the potential of health apps to improve the quality of healthcare and reduce costs [2]. However, despite rapid growth in the health apps market, with an estimated 325,000 health apps available in 2017 [3], this potential has not yet been achieved.

There are many low-quality, unsafe health apps and even apps with potentially harmful content, resulting in different types of risks for users [4,5]. Furthermore, the quality of health apps is challenging for users to assess [6]. The clinical risk of using a health app is influenced by the function(s) of the app, user and contextual factors [4]. Regulatory organisations such as the Food and Drug Administration (FDA) use a risk-based approach to determine which health apps are high-risk and classified as medical devices, such as clinical-decision-support apps, and lower-risk apps that are not, such as wellness and fitness apps [7].

All health apps should respect the privacy of sensitive user data, be based on sound evidence, be usable and behave predictably, and give accurate output or advice to mitigate the risks to users [8]. Standards can sometimes ensure the security, quality, and consistency of products such as health apps but are by no means a panacea, especially with fast-changing technology. Standards are collaborative documents written by experts with the aim of providing "*requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose*" [9]. Standards can be developed by professional standards organisations such as the International Standards Organisation (ISO), European Committee for Standardisation (CEN), or by expert technical groups such as the SMART Health IT Project [10]. Standards often have economic benefits such as contributing to economic growth, productivity, and exports. For companies, using standards can also enhance their reputation; improve compliance with regulations; and encourage innovation through the diffusion of knowledge [11]. Standards do not necessarily lead to regulation, but allow for regulation to be acted upon when they are not met.

There are many standards, regulations and related guidance for medical devices, clinical software, and medicines. For example, the BSI publicly accessible standard PAS 277:2015 sets out quality criteria for health and wellness apps across the life cycle [12]. This builds on more established approaches for medical device software, health IT systems, and therapeutic active pharmaceutical ingredients. However, we still lack appropriate, trusted adapted standards and tools to guide the development of the different types of health app recognized by patients, clinical professionals, and developers.

This paper addresses our current failure to adopt standards for the development and implementation of health apps and the risk that this poses to patients and the public. We discuss problems, examples, reasons, and solutions for each stage of the health app development lifecycle [12], from design to build, test, regulatory approval, appraisal for reimbursement, and post-market surveillance.

2. Design

The design of many apps is inadequate, with common issues including a failure of developers to adequately understand the problem to be solved, user-friendliness and engagement [13]. For example, there are a large number of pink floral design apps for fertility tracking based on stereotypical assumptions, without options for women who prefer a different design [14]. While a considerable proportion of people download health apps, many stop using them because of data entry burden, loss of interest, and hidden costs [15].

https://doi.org/10.1016/j.ijmedinf.2018.08.003
Received 25 June 2018

Technology use is a social practice that requires consideration of the complex social system and the needs of users [16]. However, for many apps there is often strong technology push with very little consideration of the clinical or self-care pathway and users [17]. Providing one generic technology solution is problematic due to the wide variation in the needs of different users, e.g. patients vs. clinicians, and within user groups, e.g. different age groups [18].

Effective user involvement in app design can help understand the problem and context of use as perceived by users and overcome usability issues. There are well established usability evaluation methods such as scripted user-centered design workshops, user testing in the wild, and interviews that can improve the safety of health apps [19]. A basic set of standards for the design of health apps can then be adapted to different user segments [20]. This requires multidisciplinary work between the different stakeholders, building on initiatives such as the Oxford Digital Health Roadmap that outlines the questions developers should ask at each stage of developing a health app, starting with the design [21].

3. Build and test

Unfortunately, many apps are poorly built and tested. [22] Patient harm can potentially result when a user acts on incorrect information provided by the app, which may result in poor choices, incorrect medication, and deterioration in health. Previous research showed a lack of attention to quality in, for example, breast cancer [23] and insulin dose calculators for diabetes [24]. Recent clinical software incidents (eg. Qrisk 2 – see BBC news article 2016 [25]), have sparked renewed interest in the value of clinical risk and accuracy assessment and highlight the need to update current standards [26].

Apps can be developed quickly, at any place and time by anyone interested, including people with non-medical backgrounds. This, together with the innovators' mantra of starting with the minimum viable product, can create conflicting views on rapid technology development versus thorough evidence-based evaluation [27]. Apps are often developed by start-ups with limited research resources, which results in short duration pilots with small participant numbers. Traditional healthcare companies with larger financial resources, such as pharma, have realized that they need to engage with digital health, but are struggling given the differences between the development methods for drugs and digital tools. Developers are often concerned that adhering to standards will be time-consuming.

For technical standards, developers could work with validated standards-compliant platforms to share code, either by building a new platform or by contributing to current initiatives [28]. For professional standards, developers could make use of adapted versions of existing standards for health apps, such as the BSI PAS 277 standard mentioned in our introduction [12]. However, more work is needed to make these standards appropriate for the different types of health apps. For example, health apps are increasingly used in combination with medication, so high-risk health app development would benefit from guidance for therapeutic active pharmaceutical ingredients, such as Good Automated Manufacturing Practice [29].

There is the concern that standards will inhibit innovation, so there needs to be a balance between efficiency and basic principles for safe development of clinical software that allows products to be built correctly. Standards can also encourage innovation. For example, WhatsApp is widely used by clinicians across the UK NHS without meeting relevant privacy and other standards [30]. As a result, there are efforts to produce innovations that meet standards for messaging in clinical settings. To reduce the time it takes to develop and disseminate standards for a health app, we need to build on efforts to develop more proportionate and adaptive governance for innovative technologies [31].

4. Regulatory approval, appraisal for reimbursement, and post-market Surveillance

4.1. Regulated health apps (medical devices)

Apps that fall under the definition of medical devices are regulated by organizations such as the FDA in the US [31]. In the European Economic Area, developers of those health apps classified as medical devices are required to obtain a CE-mark to show that they have been assessed as meeting safety, health, and environmental protection requirements. However, a CE-mark or FDA approval does not guarantee that a health app is without issues. For example, the CE-marked 'Sepsis 6' app that provides tools for the diagnosis and management of sepsis was found to be faulty (see acknowledgments). An error in the app prevented the user from scrolling down and seeing the full list of actions to carry out when a patient is severely septic. This unusable but approved app could result in a delay in administering urgent effective treatment when a user is reliant on it.

We have the technical tools available to assess health apps at scale, but regulatory organizations have been slow to adapt their processes. At the time of regulatory approval, the data collected about an app is often sparse, and long-term outcomes and sustainability of treatment effects are lacking. In the medical devices industry, we have historically seen a similar shortage of evidence because regulators are evaluating medical devices at an early stage of their development life cycle. This even more likely for health apps, given their rapid development process.

Fortunately, apps can easily capture large amounts of a wide range of real-world data (e.g. geographical, movement or behavioral data) over extended periods of time that would be hard to obtain from other sources. App developers could provide regulators with such real-world data to augment the evidence required for approval, appraisal and post-marketing processes [32]. Currently more efforts are need to defined outcomes against intended use and metrics for the monitoring of 'in use' data.

4.2. Non-regulated apps

Health apps for which the developers have not sought regulatory approval are freely available on the app stores without a standardized appraisal process in place. While the risks posed by these apps are usually smaller, using a suboptimal app (eg. Instant Blood Pressure, discussed below) can result in significant opportunity loss when an effective health intervention would have been used instead. This requires careful balancing of the time to market, (cost)effectiveness and access to different interventions. There is considerable patient pull and clinical push for health app approval, but introducing an over complex evaluation process could reduce innovation [33].

An example of a low-quality but transiently successful health app is 'Instant Blood Pressure' that claimed to take an accurate blood pressure measurement without the use of cuffs. While this app might meet the definition of a medical device, its developers added a disclaimer that it was "for entertainment purposes only". It was one of the top 50 best-selling iPhone apps (at $4.99) for 156 days between its release in June 2014 and removal in July 2015. In September 2015, researchers showed that its blood pressure measurements were highly inaccurate, with approximately four-fifths (78%) of people with hypertension falsely reassured that their blood pressure was within the normal range [34].

Previous efforts to assess health apps and provide guidance about them to the public have proven challenging. The European Commission mobile health working group aimed to develop guidelines in 2016 for assessing the validity and reliability of health apps, but a lack of consensus resulted in no published guidelines [35]. However, there are several commercial initiatives to appraise the quality of health apps with increasing market share [36,37].

The European Commission is preparing regulation that will ask app