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mHealth Quality: A Process to Seal the Qualified Mobile Health Apps

Mobin YASINI[a,1], Jérôme BERANGER[b], Pierre DESMARAIS[c], Lucas PEREZ[a] and Guillaume MARCHAND[a]
[a] *DMD Santé, Research and development department, Paris, France*
[b] *KEOSYS, Scientifical, Ethical & Medical departement, Saint-Herblain, Paris, France*
[c] *Desmarais Avocats, Attorney at law and data protection officer, Paris, France*

Abstract. A large number of mobile health applications (apps) are currently available with a variety of functionalities. The user ratings in the app stores seem not to be reliable to determine the quality of the apps. The traditional methods of evaluation are not suitable for fast paced nature of mobile technology. In this study, we propose a collaborative multidimensional scale to assess the quality of mHealth apps. During our process, the app quality is assessed in various aspects including medical reliability, legal consistency, ethical consistency, usability aspects, personal data privacy and IT security. A hypothetico-deductive approach was used in various working groups to define the audit criteria based on the various use cases that an app could provide. These criteria were then implemented into a web based self-administered questionnaires and the generation of automatic reports were considered. This method is on the one hand specific to each app because it allows to assess each health app according to its offered functionalities. On the other hand, this method is automatic, transferable to all apps and adapted to the dynamic nature of mobile technology.

Keywords. Mobile health, assessment, smart phones, health apps, certification

1. Introduction

There are over 165000 health-related applications (apps) available in app stores (e.g. Google Play store and Apple's iOS app store) for smartphone devices [1].

The intersection of mobile technology, apps, and health care is currently in its most dynamic phase, meaning that there is a need to ensure that patient safety is not compromised before this field matures [2]. The high number of mHealth apps makes it difficult for any kind of users (health professionals or patients) to distinguish the right apps, with good quality in all aspects. The information provided in the app stores does not allow the users to review the quality of apps. The existing five star rating scale system provided in the app stores is not a reliable assessment method [3]. Mobile medical apps may provide information that could be the source of critical decisions made by both health care professionals and patients. In the recent literature, various studies have highlighted a number of medical apps that can compromise patient safety and are potentially dangerous in clinical use [4–6].

[1] Corresponding Author: Mobin Yasini MD, MPH, PhD, DMD Santé, 53-55 rue la Boétie, 75008, Paris, France. Email : mobin.yasini@mhealth-quality.eu

The traditional methods of evaluation are not suitable for fast paced nature of mobile technology. Quality reviews and audits based on a reliable methodology conducted by impartial and trusted parties are required to give confidence to both clinicians and patients regarding appropriate mHealth apps.

The main aim of this study was therefore to develop a new multidimensional assessment program for rating the quality of mobile health apps and to seal high quality apps by mHQ (mHealth Quality) logo.

2. Methods

In order to identify various criteria to determine the validity of an mHealth app, we first defined three content axis to evaluate: medical aspects and content validity, legal consistency including medical device distinction, and ethical issues. Two technical axes were then added to complete our audit strategy: IT security aspects and usability. For each content axis, we created a working group including at least five experts in each group. Eighteen experts with various professional profiles including health professionals, expert patients, health lawyers, and ethics experts in the field of e-health and medical aspects, participated in our working groups.

Based on our previous study, various use cases define the needs that may lead to the consultation of an app [7]. A literature search was conducted to identify existing app quality evaluation criteria [8–10]. For each use case, a hypothetico-deductive approach was used in each working group to define the audit criteria. Therefore, for each use case [7], the criteria were listed incrementally as they were created in the working groups. The existing national or European legislation, privacy, security standards, and recommendations regarding health apps and computer softwares were taken into account by the working groups. Several meetings were set up to discuss the criteria found by different experts to harmonize the criteria drafting. A content analysis of the criteria was performed and the guidelines were validated by expert panels.

Once the criteria had been developed, they were integrated in a self-administered questionnaire. The purpose was to create understandable questions for everyone. Five health app developers from non-medical and non-juridical fields were asked to answer the questionnaire for their apps to test the readability (reading with understanding) of these questions. The questionnaire was then validated by the expert panels.

Some of these criteria were considered as high importance. The wrong answer to these questions will be prohibitive and lead to call the quality of the application into question. Other criteria are not eliminatory, but play a role in scoring and would contribute to provide better apps.

Health related apps may offer various use-cases[7]. A classification questionnaire was developed to detect the use cases offered by an app. Once the use cases of an app are discovered, the appropriate criteria will be selected automatically to assess the health app.

All of these questions were then implemented on our web site www.mhealth-quality.eu. A dynamic report on the health app is automatically generated according to the answers that the app editor provides in the questionnaire.

For usability testing, we set up a usability questionnaire including system usability scale [11,12] and Health-ITUEM [13]. We adapted these methods to mHealth apps. Some open-ended questions were then added to register the feedback of evaluators. For each app, at least ten target users (health professionals, patients, and/or healthy

individuals) will be recruited from our evaluation community to assess the usability of the app.

If the self-administered questionnaire and the usability test are satisfying, the app will be checked for security aspects. Security audit is done by an external service provided by our partner specialized in mobile apps security (http://pradeo.net/en-US/).

3. Results

In total, 312 self-administered questions were extracted from various criteria in all axes. Each axis includes various subjects. Table 1 represents the number of questions in each axis. The medical aspects & content validity axis has various subjects including validity and reliability of medical contents and medical databases, reliability of calculations and measurements, clear distinction between scientific and non-scientific (promotional) contents, the selection of scales and formulas, the choice of measurement units, using complete and updated non-medical databases, existence of prerequisite information to the user, clarity and appropriateness of this information, statement of aims and purposes, statement of target users, reliability of used sensors, correct data requisitioning and data management, statement of restrictions and limitations and the possibility of interoperability and exchange with existing standards.

The conformity to the recommendations of the French data protection authority (CNIL: the National Commission for Data Protection and Liberties), the compliance with legal and regulatory obligations and personal data privacy and security is verified in legal consistency axis. Mobile medical app distinction questions allow detecting the apps that could be considered as medical devices.

Ethical issues include four ethic concepts: beneficence, non-maleficence, justice and autonomy[14] adapted to mHealth apps.

Table 1. Distribution of self-administered questions in various axes.

Assessment axes	Number of questions (%)
App classification based on its use cases	35 (11.2)
Medical aspects & content validity	84 (27)
Legal consistency	168 (53.8)
Mobile medical app distinction	14 (4.5)
Ethical issues	11 (3.5)

All of these questions are available on our web site and will be selected automatically for each app, based on its provided use cases. Table 2 presents some examples of these questions.

Table 2. Examples of questions in various axes.

Assessment axes	Examples
App classification	Does your application provide medical information to the users?
Medical aspects & content validity	Are the medical content and / or the references of your app updated?
Legal consistency	Does the user accept the “general terms and conditions of use” before starting to use the application?
Mobile medical app distinction	Is your mobile app an extension of one or more medical devices and connects to such device(s)?
Ethical issues	Does the app rely on an ethical charter at company and/or professional level?

Our usability questionnaire verifies the ease of use, readability (reading with understanding in regards to health literacy of target users), information needs, operability, flexibility, user satisfaction, completeness, look and feel of the users.

The security check includes detecting non secured connections, connection to malicious servers, sending personal data to third parties, malwares and rootkits, obfuscation rate and financial loss risk (ex: calling or sending a SMS to a premium-rate number). Our assessment process is shown in figure 1.

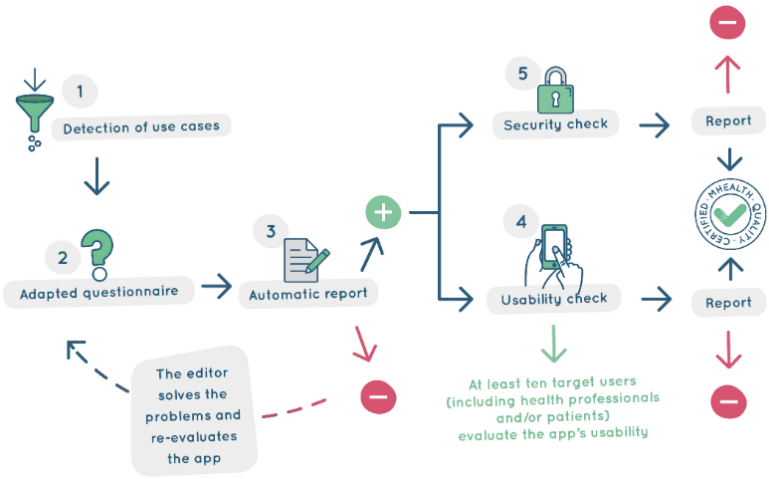

Figure 1. mHealth-Quality assessment process

The evaluation report includes the score of the app in each axis of evaluation and the recommendations that demonstrate the positive and negative points regarding the self-assessed app. In the next step, for each platform (Android or iOS), at least 10 target users of the app will be selected from our evaluation community. They install the app on their own devices and have at least 10 days to test it. At the end of this time they answer to the usability questionnaire.

4. Discussion & Conclusion

In this study, we proposed a collaborative multidimensional scale to answer to a real challenge of today's mHealth market: quality of mHealth apps. During our process, the app quality is assessed in various aspects including medical reliability, legal consistency, ethical consistency, usability, personal data privacy and IT security.

Our method allows to assess each health app according to its respective functionalities. The assessment criteria of an app that locates the nearest pharmacy with the GPS system must obviously be different from the assessment criteria of an app that contributes to follow up patients and management of diseases.

The scoring method allows to quickly determine the quality and usefulness of an application. Giving a score to an application allows the comparison among apps. However, this comparison should be made among apps providing the same use cases. Non satisfied prohibitive criteria prevent to seal the app, however, other criteria help the manufacturer to improve his app.

Medical devices need to be approved by CE mark that is a legal requirement to place a device on the market in European Union. Some of mobile health applications could be considered as medical devices. Our audit and the relevant app assessment report help the manufacturers to detect this point and to follow the process of medical device conformity assessment.

One of the characteristics of the mobile health field is its dynamic nature. Therefore, our method is considered flexible because the assessment criteria could be added or modified. This makes our method generalizable. For example, legal aspects may differ from one country to another. However, the modifications should be done at any time after the validation of the expert panels that could be specific to a country.

If the assessment should be carried out by human intervention, even with 100 assessments per working day, over six years is needed to assess all existing health apps. Furthermore, this is yet far from the reality because each application may change in versions several times a year. Our criteria are implemented to a self-administered questionnaire and the report generation is automatic. This distinguishes our method with other existing initiatives in the literature [8,9]. Although clinical trial studies or peer-reviewing methods are both reliable, they cannot include all aspects and are not adapted to assess a large number of apps with their short lifetime of versions.

Actual use of our tool and further research to test the suitability and reliability of our process with real data on application of the app check should show the effectiveness and applicability of our product.

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