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Transparency and Quality of Health Apps: The HON Approach

Mayoni RANASINGHE[a], Aude CABRERA[a], Nicolas POSTEL-VINAY[b], Célia BOYER[a,1]
[a] *Health On the Net Foundation*
[b] *Hôpital Européen George Pompidou*

Abstract. We are well into the 21st century and the Internet has been around long enough that there are adults who have not known a world without this wonderful tool. And just as time has gone since the beginnings of the Internet, so too has it developed, probably above and beyond the wildest dreams of its founders. These developments, though mostly positive, also have their share of the not so positive. One of these challenges is the difficulty in maintaining accuracy and quality of all the information, data gathered, aggregated or automatically generated being displayed on the Internet on Web websites or via mobile application, and this is a concern in the health domain. In this paper, we attempt to discuss in detail, some of the latest developments along with the challenges each of them entail and proposed Code of Conduct for health apps and connected objects.

Keywords. Transparency, Code of Conduct, quality, mHealth

Introduction

Can a person without any advanced medical knowledge, tell the trustworthiness and the accuracy of the sources of information she/he accesses on the Internet? It is for this reason that the Health On the Net Foundation was created in 1995, to address this problem [1]. And now, after more than 20 years, HON has become a well-known beacon of trust and transparency, so that readers know they are on health websites which are safe ground when they see the HONcode seal, a blue and red logo on a health website certified by HON. However, with the evolution of technology comes new developments such as smartphone-based health and medical applications (health apps) connected or not to objects pose new hurdles to pass. Mobile health apps not only can provide information but functionalities which can consist of tracking, medication adherence monitoring, maintain data journals with regular medical parameter readings such as blood pressure or heart rate. Health apps offer a personalized response to the user via algorithms using and analyzing tracked and measured data. Health apps can facilitate self-management of chronic disease empower the patient and user to better care about his/her health. What about the quality of these apps, can they be dangerous, who verifies their accuracy, who is behind? For example, Huckvale and al highlights the risk carried by 67% of insulin dose calculator apps assessed providing "inappropriate output dose recommendation that either violated basic clinical assumption or did not match a stated formula" [2]. Plante et al. shown that an app

[1] Corresponding Author, Célia Boyer, Health On the Net Foundation, 2 Chemin du Petit Bel-Air, 1225 Chêne-Bourg, Switzerland; E-mail: celia.Boyer@healthonnet.org.

measuring blood pressure (BP) and downloaded by nearly 150'000 times produced false measurements underestimating higher BP and overestimating lower BP [3] [4]. These articles show a need, its utility but also the potential risk of health apps.

1. Health apps usage and challenges

We are only at the beginning of the mHealth revolution with connected objects linked to m-health apps being part of daily life of more and more individuals and healthcare professionals. The mHealth App Developer Economics 2016 report conducted by health research group Research 2 Guidance reported that for the year 2016, a minimum number of 259,000 health apps globally were made available to consumers on major app stores (including both multi-platform apps and smaller platforms) which resulted in a total of 0.2 billion downloads in 2016 [5]. The total of these apps was published by only around 60'000 mHealth developers. The rapid development of the mHealth sector raises concerns about the potential risk of health functions apps providing transmission of health data, capture of health data via sensors, self-diagnoses, disease management or diagnosis and appropriate processing of the data collected through apps or solutions since mHealth solutions and devices can collect large quantities of personal information, including personal health information (e.g. data stored by the user on the device and data from different sensors, including location) and processes them. Apps pose a new challenge that cannot be solved as we did for health content websites, mainly because of several reasons: a) all the data is visible in health websites as it is part of the content and so it is easy to check the production process of the content; whereas in an app, the algorithms used to analyze the data are kept secret and not disclosed (industrial secrets); the privacy and security of transmission and storage is very difficult to test and assess b) apps play the role of a "medical device" even if theoretically they are not which is unlike health websites which do not play a diagnostic role but only an informational role. So, the intrinsic risks posed by apps are totally different from health websites.

Health apps supporting citizen's empowerment through self-management, health promotion and disease prevention, providing personalized health advice and care has become a challenge Worldwide [6].

The "annual study on mHealth" suggests that the ubiquity of smart phones, tablets, sensors, wearables, personal trackers and similar wireless smart devices means that huge volumes of data concerning health, fitness, life-style, stress and sleep are being harvested and processed [5]. This report foresees that in 2020, 551Million users will by then actively (at least once a month) make use of a mHealth app.

The main issue then becomes how to identify the most appropriate, adapted and trustworthy health app out of hundreds of thousands of similar health apps.

Another major risk of apps is that they work according to a set formula or standardized algorithms which are relatively unchanged from patient to patient. This then does not allow the capture of the other aspects of clinical diagnosis such as clinical observation or personal medical history of the patient and his/her various signs.

Health apps have to undergo specific accreditation in the USA by the FDA to be categorised as medical devices [7]. So far in Europe, there is no such specific directive for apps except the Code of Conduct on privacy for mobile health apps submitted for approval to the Art 29 Data Protection Working Party [8]. So in Europe, health apps to be labeled as medical devices should respect the Council Directive 93/42/ECC

concerning medical devices. However, the majority of health apps labeled as non-medical device also provide medical functionalities such as auto-diagnosis and auto-medication.

Mobile apps span a wide range of health functions, with potential benefits and risks to public health compounded by the fact that these apps are potentially available to billions of people worldwide [9]. Depending on the type of the app and its intended use, the potential risk will vary and thus, the level of scrutiny given should be proportionate to the risk.

2. Methods

HON has recorded and analysed what was available on the market in terms of guidelines, tools, recommendations and scale to assess the level of trust one can have in a health app (Table 1).

Table 1 Presentation of several labels of app certification

NAME	COUNTRY	DEVELOPPER	FUNCTIONNEMENT	INVENTORY
M.HEALTH-QUALITY.EU	France	DMD Santé	Registration needed, fee based evaluation. Criteria of evaluation not disclosed	41 app assessed in Nov.2017
CALIDAD APP SALUD	Spain	Agencia de Calidad Sanitaria de Andalucia	Free 31 recommendations Assesses design, quality, services and privacy [10]	20 app assessed, 70 under assessment.
JUST THINK APP	USA	American Health Information Management Information	Brochure to inform and educate users [11].	Education No implementation
MOBILE APPLICATION RATING SCALE	Australia	Queensland University of Technology	23 questions Grading scale from 1 poor to 5 excellent [12].	Self-evaluation
CODE OF CONDUCT ON PRIVACY FOR MHEALTH APP	EU	European Commission	The Code was issued after a research study in 2014 [8].	No implementation
GOOD PRACTICE GUIDELINES ON HEALTH APPS	FRANCE	French Health National Authority	5 categories: Information to users, health content, security, data usage and technical usage [13].	No implementation
MOBILE APP PRIVACY CODE OF CONDUCT	USA	US Government	Privacy notice to disclose their practice related to data storage and usage. [14]	Voluntary Not widely used.

Various organizations worked on the issue of security, data privacy, and other criteria related to quality [9][14]. However due to the complexity and liability risks to potentially unidentified issues such as the security issue, the assessment of health apps is at its very early stages. A study highlighted that 66% of the health apps certified as clinically safe and trustworthy by the UK NHS apps Library was in fact sending identifying information over the internet without encryption and without disclosure that the app will do so [15]. This has caused the NHS apps service to close for a while. This study has raised three elements of reflection: the current lack of transparency and responsibility of apps related to data usage, storage and transmission; what can be evaluated reasonably and sustainably; and the risk that no organisation assess health

apps as the risk is too important to miss or not be able to check all the necessary elements to guarantee security and accuracy. On the other hand, should we rely only on the current model of user rating proposed by the two majors' apps platforms Google Play and iTunes iOS. Kumar et al. has demonstrated that apps that provide measurement of key indicators such as heart rate–Blood Pressure readings are commonly downloaded (up to 2.4 million downloads) and rated well [16].

With the multitude of health apps available today (more than 260'000 health apps) what can be evaluated reasonably and sustainably [5]?

In addition, to assess too many criteria as identified by the HAS will lead to nearly no assessment because the number of apps being assessed will drastically diminish because of high costs and inefficient practices. Transparency and honesty in the production of the apps will engage developers to disclose what is behind the scene and be responsible to what health app it develops. Not all apps need the same attention as they do not imply the same potential risk to consumers. For example, health apps with calculators and algorithms intended to recommend an action or medications may directly impact user's health [2].

3. Guidelines and assessment tools of health mobiles apps quality

To meet these challenges, HON has started to assess the possibilities of adapting the HONcode guidelines to health apps [17][18]. Ensuring the commitment of app developer is fundamental to induce behavioral change in the production process of health apps. As an assessment of the functionalities of the apps is very complex, the focus on the production process and the respect of current national regulations is an alternative.

With health apps providing measurements and calculation of dosage such as insulin dose calculator apps, the patients have no idea which algorithm is used based on which guidelines of which country. To have this information actively contribute to provide appropriate dose recommendation which was not the case when Huckvale et al. conducted their systematic assessment study on "smartphone apps for calculating insulin dose" [2].

When evaluating mobile apps, three points must be considered: does it use a sensible amount of data? what medical information and contact information is required? and does the app add viruses to the device? HON in collaboration with the UFML (French Union for Free Medicine) and the partners of the Kconnect European project (H2020-ICT-2014-1-644753 kconnect.eu) have developed a list of questions used to draft the first version of quality guidelines for Health Apps [18]. This first draft has aimed to be available for public consultation to receive the views of each profession involved in the development, creation, assessment, and use of health mobile application. Thanks to these comments and advice, we will be able to create guidelines to be integrated in, our code of conduct, certification, and open the community-based platform Health Curator (heatlhcurator.org) developed within the European project, KConnect and funded by the European Commission.

4. Conclusion

HON is proposing a solution for assessing health apps combining an adapted guideline for health apps with expert and end user evaluation with the platform HealthCurator.org funded by the European Commission.

Most of the proposed guidelines or code of conduct are currently not implemented by third party organisations. The unique example, is the Spanish one with 20 health apps labeled by the Agencia de Calidad Sanitaria de Andalucía, and only available for apps in Spanish. The users' ratings within Google Play and iTune are not a mean of identifying the quality of an app. So there is a need to have a global solution proposing a multilingual approach with an evaluation schema by trained experts such as the Health on the Net approach for health websites or combining with crowdsourcing/community based solution. Education is a first step to inform users and allow them to make a truly informed decision. But this is not enough because the education and sensitization of the user is long-term and ongoing and should be integrated into the smart device directly. Indeed how to prevent an app maker from requesting functionalities that the app does not need for its use? An evaluation by a third party or a community base can prevent or limit the risk of copycat app mimicking and passing for another organization, using the system in order to mislead the user, which is currently possible on GooglePlay.

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