

A Framework of Evaluation of Mobile Wellness Apps for Use in a Clinical Setting

Sarita Pais, Dave Parry
School of Engineering, Computer and Mathematical
Sciences
Auckland University of technology
New Zealand
Sarita.pais@aut.ac.nz, Dave.parry@aut.ac.nz

Janet Rowan
National Women's Health
Auckland District Health Board
New Zealand
jrowan@adhb.govt.nz

Abstract— Mobile apps have been developed for monitoring health and wellness for various reasons such as self-management of chronic diseases, weight loss and maintain healthy life style. As consumers, patients are flooded with new mobile apps and are unaware if they are suitable for desired health and wellness outcomes. As much as a clinician would like to support a patient centered approach and promote mobile wellness apps, the clinicians are unable to guide their patients with new technologies such as mobile wellness apps. Reviews of apps do not have specific guidelines to follow and as new improved apps are introduced previous reviews get obsolete. Hence a framework of guidelines is necessary for clinicians to help their patients to choose the right apps for self-management of disease or general healthy wellbeing.

Keywords— Mobile Apps; Wellness Apps Guidelines; Self-management Gestational Diabetes Mellitus;

I. INTRODUCTION

Mobile Health, also called as mHealth facilitates health related practice by using mobile devices such as mobile phones and tablets. Over the recent years mobile phones have technically improved with better processing speed, battery life and memory and have the potential to enhance the mHealth capabilities such as telemedicine, patient portal, monitoring health and wellness through mobile apps. Moreover, mobile apps are more attractive to users as they are portable and users carry them everywhere unlike a personal computer, laptop or tablet.

The penetration of smart phones in the world is as high as 70% in some countries such as Korea, Singapore, UAE. In New Zealand smart phone ownership increased from 48% in 2013 to 70% in 2014 [1]. It is expected to rise to 90% by 2018 [2]. With the high use of smart phones globally, health related apps are convenient options for the promotion of good health and self-management of chronic diseases.

Many applications for mobile devices (“apps”) are available to encourage healthy eating, support weight loss and encourage exercise. These apps could fall into different categories. Some apps are designed to educate and create awareness like knowing the nutrient contents of different foods. Other types of apps are designed to monitor the human condition like step counter and

link it to calorie count goals for the day. The most sophisticated apps act as medical devices to test and make recommendations about dosage. They also support adherence to treatments. These apps are now regulated by the United States Food and Drug Administration (US FDA). Generally mobile apps not regulated as medical devices are often not assessed for quality, and there are no standards for interface or information transfer. With the increasing number of new health apps being introduced, their suitability for use in a clinical setting must be established through a set of guidelines forming a framework.

As consumers, patients are flooded with new mobile apps and are unaware if they are suitable for desired health and wellness outcomes. As much as a clinician would like to support a patient centered approach and promote mobile wellness apps, the clinicians are unable to guide their patients with new technologies such as mobile wellness apps. Reviews of apps do not have specific guidelines to follow and as new improved apps are introduced previous reviews get obsolete. Hence a framework of guidelines is necessary for clinicians to help their patients to choose the right apps for self-management of disease or general healthy wellbeing.

II. MOBILE PHONE INTERVENTIONS AND OUTCOMES

Use of phones to send SMSs has been a popular intervention to remind patients to test their blood glucose, blood pressure or encouraging messages to quit smoking. Fjeldsoe, Marshall & Miller [3] reviewed 14 studies on preventive health behaviors and positive outcomes were observed in 13 of these studies. Telemedicine using ICT enabled remote monitoring had proved successfully in clinical trials [4] to manage health conditions such as diabetes, cardio vascular and smoking cessation. However evidence for health outcomes is patchy and has not been measured adequately.

Systematic literature reviews [5] [6] of various mobile phone interventions have shown some positive outcomes for smoking cessation, behavioral programs like weight management and self-management of chronic diseases like diabetes. Short Message Service (SMS) have been used to send reminders for clinical appointments, provide health information, encouraging messages to lose weight or stop smoking. As mobile phones are portable and ubiquitous they are intuitively attractive for applications engaging in behavioral change programs. Studies

have also included patients using a mobile phone to self-monitor blood glucose, keeping a food diary, nutrition and exercise details. Various outcomes were studied [7] such as haemoglobin A1c, self-efficacy and body mass index (BMI). The incentives of rewards through gamification in a mobile app has improved blood glucose outcomes for young adolescents with Type 1 diabetes [8]. The outcomes from various studies showed results like improved self-efficacy and blood glucose levels.

Most studies are using apps developed for the purpose of research study. There have been few recent studies involving downloadable apps.

III. MOBILE PHONE APP REVIEW

Research studies [9] [10] were undertaken to review commercial mobile apps available on iPhones and Android for various features like glucose tracking, insulin tracking, carbohydrate tracking, exercise, weight tracking, food diary with food database and electronic sharing of these wellness data.

There are relatively higher number of mobile apps in the iPhone app store compared to Android market place [10]. In most cases the wellness data collected in these mobile apps had graphs to show trends on blood glucose and weight.

Although there are studies with clinical trials and reviews of commercial mobile apps, there is insufficient evidence of integrating wellness data to clinical systems. An iPhone app called Easy Diet Diary which is free for the user to download can allow to share its data with the clinician. The clinician needs to purchase a license for the Nutrient Analysis software called Foodworks which can open data shared by the user from Easy Diet Diary app. Currently Easy Diet Diary app is available on iPhone but is not available for Android phones. Such sharing of patient managed data to proprietary software does not allow patients the flexibility to choose apps of their choice. Moreover patients may want to manage multiple health conditions through an app.

Reviews of mobile apps do not consider usability issues [11] and the acceptability of integrating patient managed data in the electronic health records. Most commercial mobile apps have a provision to share wellness data with a clinician through email. However the data thus shared electronically is reviewed only at consultation and not stored for future consultations with other clinicians. Other clinicians such as the physician, nurse or dietician have no regular updates of the patient in the event they have a follow up consultation. Hence it is desirable to store the patient managed wellness data in a central system accessible to all members of the team.

The current study will evaluate the criteria for mobile wellness apps to be useful in a clinical setting. A framework for evaluation of mobile wellness apps will be presented here.

IV. NEED FOR AN EVALUATION FRAMEWORK

In order to build a framework for the evaluation of mobile wellness apps suitable for a clinical setting, literature on mHealth along with design and evaluation of mobile wellness apps is sought. Strategies to evaluate mobile wellness apps in the self-management of chronic diseases can be designed; however their success (or otherwise) will be evident through outcomes. Although the technology to aid in self-management is available, how these mHealth devices need to be assessed and applied for achieving good outcomes has not been researched in depth [12].

There are around 40,000 apps on health and fitness [13] and clinicians have difficulties in identifying good mobile wellness apps for their patients [14].

A more holistic view of the evaluations of mobile apps is required. mHealth success depends on various factors and these could contribute to the evaluation of mobile apps. Such evaluation factors contribute to create a suitable framework for evaluation of mobile apps.

In a study with key stakeholders of mHealth systems [15] the current issues of mHealth were identified and opportunities to address these issues were presented. The area of interest was in policy governing these systems and building the systems with open source software with no proprietary ownership.

Wicks and Chiauzzi [16] introduced potential areas of improvement for quality of wellness apps. Medical technology community should boost the literacy of good apps and help consumers in choosing good apps. Safe app consortium are monitored by app developers, medical practitioners and researchers. Review of apps by third party will ensure transparency and understand its internal working. Medical review is made available by app stores. Overall Government bodies should regulate the safety and quality of such apps.

It is useful to have regulatory bodies and a review group to identify good apps for consumers. However how the review needs to be conducted remains to be clarified.

Having reviewed the issues of identifying good mobile wellness apps from the many apps available on different platforms, a framework for evaluation of mobile apps is sought in major six key areas which are discussed in detail. The guidelines in the framework assist a clinician to help their patients in choosing the right app for managing their disease.

TABLE I. FRAMEWORK OF EVALUATION OF MOBILE WELLNESS APPS

Criteria	Description
Functionality	Main functionalities covered, usefulness
Architecture and open source software support	Support for hardware devices and software apps
Policy	Security and privacy of patient data, cloud storage
Usability	Easy intuitive interface
Data Interoperability	Wellness data across different systems
Adherence	Behavioral change, user engagement

A. Functionality

Required functionality to self-manage chronic disease or general wellbeing is the foremost requirement of a mobile app. Most wellness devices can track physical activities such as steps, calorie count and sleep activity. These tracking devices can synchronize the data to the user's mobile phone. Patients with chronic diseases can also use mobile wellness apps to record glucose readings, keep track of carbohydrate count and calculate insulin dosage. Most apps allow manual entry of data. Mobile phones and apps which can automate the process of downloading readings from a glucometer need FDA certification in the US. Patients are unaware if the app functionalities are adequate and correct to monitor their health and wellness data.

Consumers will need to check online resources about the mobile app reviews. However a clinician will be best person who

could suggest if the evaluation framework covers all the necessary points to recommend an app to their patients.

B. Architecture and open source software support

Mobile apps developed on an open architecture will have better acceptance with third party vendors and other systems. Data interoperability has been an issue in clinical systems and will be relevant in the patient-centered health and wellness management systems. Hence a standard for such shared health data needs to be adopted in the open architecture systems with software programs like Application Program Interface (API) written to support most medical devices and mobile apps. Collaboration with different industry partners is essential for long term sustainability.

Technology enabled health ecosystems are emerging where systems are integrated with mobile apps and personal wellness monitoring devices such as glucose meter, blood pressure monitor and weighing scale. PHR system like Microsoft HealthVault has integrated over 200 devices with over 100 apps.

IBM introduced Greenolive an open platform for wellness management [17]. The intention was to connect and integrate different apps and devices for a single user to monitor wellness. The platform is not supported anymore and IBM has introduced Blue mix; an open platform based on PaaS for developing and deploying mobile apps [18]. The APIs available should make it easy for developers to easily build applications on this platform and store the mobile data in a cloud based system. The app can share data with other systems.

Open mHealth [19] has the architecture which allows patient managed health and wellness data in mobile apps and other interacting devices. Several schema for health data such as blood glucose readings, blood pressure are defined in open mHealth. The schema are linked to health standards such as SNOMED CT, LOINC and RxNORM. This makes it easy for developers without a health background to develop apps using Open mHealth and connect to one ecosystem.

Although there are efforts from different organizations to offer an ecosystem to develop new mobile apps and share on a cloud based system, there is limited evidence of such adoptions and practices. App developers need to build apps using an open source software which aids in sharing a patient's health and wellness data with clinicians.

C. Policy

Government led policies around the use of mobile apps, health management and integration to health system have to be considered for a wider acceptance. The US FDA has regulations around medical devices connected to mobile phones. Mobile apps with insulin dose calculator need to comply with medical app regulations set by the FDA. Privacy policy and sharing of health data should be covered under the policy. However policies about security, privacy may differ in different countries. The same applies to cloud based hosting of data to consider the privacy and security of patient data. In New Zealand, HISO 10029:2015 Health Information Security Framework [20] is drafted to protect patient health information when storing and sharing in different health systems. National Health IT Board projects encourage different health systems to 'talk' to each other to improve the electronic sharing of health information.

In the US, most apps do not explain the security features. The Health Insurance Portability and Accountability Act (HIPAA) (US) has a policy on privacy about an individual's identity and

health information. Of the 71 apps studied by El-Gayar [11], only one app was HIPAA compliant.

D. Usability

The uptake of any software system depends on the easy interface for users. The mobile app interface has more challenges than the PC, laptop or tablet screen because of the small screen size. Traditional menu options of a web interface are not applicable in a mobile app interface. Meaningful icons need to be incorporated and the selection of a user choice should be intuitive, as users with web interface experience will look for similar options in the small screen of a mobile phone. Hence some of the golden rules from mobile usability are to be considered.

Other than small screen size, mobile apps have other issues like connectivity, context, screen resolution, limited power, processing capability and restrictive data entry [21]. With the recent uptake of smart phones hardware and operating system are improved. The context is enhanced with user profile and GPS location. Data entry is still challenging when users do not want to type or click many options to fulfil a functionality requirement. Potential data entry errors could be avoided if devices like glucose meter are connected to the mobile phone. Some exercise apps are linked to sensor devices like Fitbit, Jawbone and collect data from these devices in the mobile app. Users want to take photo as evidence of the data entry for food intake. Image processing and annotations need further improvement to automate this process.

My Meal Mate (MMM), an app [22] available on Android and iPhone has features like saving favourite food combinations, take photographs of food for memory recall and recently logged food entries. Other desirable functionalities could include graph of calories consumed on various days, analysis of important macronutrients. In pilot randomised controlled trials (RCT) for weight loss [23], it was observed that smart phone app MMM had greater acceptance and satisfaction when compared with other interventions like paper diary and website supporting weight loss programmes.

In a study called eCAALYX (Enhanced Complete Ambient Assisted Living Experiment) [24] the mobile interface had large buttons targeted at older people with chronic diseases. The lessons learned from such projects and other projects [25] were that interface functionalities should be self-explanatory and only required functionalities should be made available.

E. Data Interoperability

As different mobile apps are built by different developers for different platforms, there is no standard about the data schema of the wellness data stored in the mobile apps. In such case it is difficult to combine data from different mobile apps into the clinician's system. Health informatics standards are not explored outside the clinical system. Data from mobile apps need to be interoperable for it to be used in the clinical system. Hence it would be ideal if an ecosystem can be built to access data from various sources.

Wellness apps suitable for the management of chronic diseases such as diabetes log relevant data such as blood glucose levels, food entries preferably from an existing food database, carbohydrate data, insulin dosage details, weight and activity data.

Relevant wellness data suitable for self-management of chronic diseases such as diabetes are available in various mobile

apps were logging blood glucose data, food entries preferably from an existing food database, carbohydrate tracking, insulin dosage details, weight tracking, activity tracking.

Mobile apps have the ability to share user's wellness data such as food diary and glucose readings from the mobile phone to the user's clinician. It is usually sent through email as an attachment. Data is sent through various formats such as CSV file, a report as pdf file or uploads to cloud based storage such as Dropbox. El-Gayar et al. [11] reviewed 71 apps from Apple App store and most of them could email the data stored in mobile devices to clinicians. However the connectivity of these apps to Patient Health Record (PHR) was 21%. On further investigation it was found that only certain wellness data was allowed to be shared. In many cases details of food consumed was not allowed to be shared; this could be because of the sheer volume of data that needs to be shared. Some apps allow users to share their app exercise or calories data on social network sites and blogs. Sharing data with a clinician can foster a patient-centred clinical consultation and improved self-efficacy for a patient. While sharing data on social networking sites could be to promote support from family and friends and to enhance competition with other users. Integration of such wellness data from the user into a health provider's system is challenging. Apps such as Diabetes Buddy can share data as an email attachment. While other apps such as Diabetes Pilot involved additional costs on the user to synchronise the data to a computer.

Food database was useful to obtain supplementary information about the nutrition in the food including carbohydrate contents. Food databases specific to the food composition table of a country are useful to discuss dietary plans with a dietician. Introducing universal standards to represent food and names of popular dishes will help in data interoperability.

F. Adherence

The features and functionality built in the mobile apps should promote adherence to the new technology. Users should readily accept and continue to use it to reap long term benefits.

1) Behavioural Change:

Automatic SMS messages from smart phone apps can be beneficial to remind users about food log, increasing exercise and motivate participants to eat a balanced diet with fruits and vegetable [26]. Useful tips on educating users on food portions could be sent through SMS. These SMS could sometimes be annoying to users if there are sent in continuous succession. It would be useful to send a reminder once if a user misses a day, a week or a fortnight of entries. Thereafter it is best to stop as user may have stopped using the app.

2) User Engagement:

Apps should have features to keep users engaged long term. Some of these features could be facilitating social network support and status, goal settings, calories countdown status for each day. The analysis reports and charts could add to promote progress and maintain loyalty to using these apps. Self-monitoring and tracking progress was found in 74.8 % of the 550 iPhone apps in a study [27]. Apps should have the option to connect to social media to get support from friends to keep the user engaged and loyal to the app although others may choose not to go public with their wellness profile. Points and awards through gamification are a growing trend in maintaining the

adherence level. Reminders through alarm and SMS are prevalent in many apps.

A measurement of adherence could include self-reports and self-monitoring such as blood glucose testing and electronic testing [26]. However there are limitations with these testing measures. Self-reports are based on recall and can be erroneous. Electronically logging the data in a mobile app can be useful in this case.

Although six major areas are discussed in the framework, the evaluation of mobile wellness apps can be further strengthened through clinical trials and certification of mobile apps. The uptake and popularity can be built through business models with reduced cost for users.

H. Apps Certification

Many organisations like Happtique had set up digital platforms to build a system of certified apps that were safe and reliable for users [28] and which could be recommended by medical staff. However the certified apps by Happtique were exposed to patient data privacy and security issues and the organisation ceased to operate thereafter [29]. DocGuide [30] has a catalogue of iPhone and iPad medical apps suitable for health professionals. A similar catalogue is not available for other types of phones such as Android. iMedicalApps, an online publication has a medical team to review the iPhone and Android mobile apps and publish their findings on its website. App store has such medical reviews to every app released to public. Smart phones that can be attached to a glucometer are considered by FDA as high risk as the readings can affect clinical decision making. Similar standards are expected from other organisations worldwide like, for example the European Medicines Agency (EMA). To improve the quality of medical apps such as insulin dosage calculator, app store owners should maintain transparency about the development and medical calculators built in the app. The apps development have comprehensive documentation which can be reviewed by clinicians. The testing of the app should be done as a "whiteboxing" method as against a "blackbox" approach.

Generally mobile app developers lack medical knowledge. Regulatory bodies such as FDA and EMA can ensure safety of these devices for patients.

I. Uptake and popularity

There are many studies done in the last few years to review various mobile apps suitable to manage diabetes [9]. Most of the apps reviewed by Tran, Tran & White (2012) cost between \$1.99 and \$14.99 to download. Mobile apps with a price to purchase/download were generally of superior quality than free ones [31]. It would be beneficial if Government bodies invested in standards for the uptake of mhealth [32].

V. CONCLUSION

Smart phones have the potential to improve the adherence for self-management of diseases. However although there are pilot clinical trials performed, the efficacy of the apps is not tested through empirical studies. The testing of commercially available mobile apps by users is scarce and new apps flood the app market.

As there is no one easy way to identify good mobile wellness apps, the framework defined in this paper is suitable to make a decision in adopting an app. This will aid clinicians to help their patients choose the right app to self-manage their disease or

wellbeing. Consumers too are guided to choose the right apps for monitoring their wellbeing.

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