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# Mobile Medical Apps and mHealth Devices: A Framework to Build Medical Apps and mHealth Devices in an Ethical Manner to Promote Safer Use – A Literature Review

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**Abstract.** This paper presents a preliminary literature review in the area of ethics in the development of Mobile Medical Apps and mHealth. The review included both direct health apps and also apps marketed under the area of well-being in addition to mHealth devices. The following words and combinations of them were used to carry out the search for publications, mHealth, Apps, Ethics. The search engines used were Google Scholar, and PubMed. The paper is restricted to publications since 2012. The total number of papers found was 1,920 of which 84 were reviewed. The reason for so few being reviewed was that the majority only considered security. The search revealed many papers dealing with security for all types of apps and mHealth devices but there are very few papers dealing with the ethical issues related to Apps or mHealth devices in the area. It is noted however that the number of apps is increasing in number exponentially and therefore it is argued that it is necessary to pay attention to the ethical aspects. There are now estimated to be 165,000 apps available in this area. How ethics are addressed in health and well-being apps is important as they can have an effect on the health of the individual using them. In a similar way, the need for addressing ethical issues for development of well-being apps is evident. In a study [1] it was noted that even though Electronic Health Record (EHR) was the highest ranked tablet-related task only one third of clinicians said that EHR was optimized for smartphones. When apps are integrated with the EHR they fully optimize productivity. In the same study the significant challenges identified included the method of evaluation and selection of mobile health solutions in order to ensure that clinical outcomes, care and efficiency are included. Security is mentioned but again wider ethical issues were not a consideration. From the literature review it is clear that there is a need for guidelines for how developers of medical ad well-being apps and mHealth devices should address ethical issues during development, and the generation of these guidelines is the subject of ongoing research by the authors.

**Keywords.** mHealth, Apps, Ethics

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## 1. Introduction

According to the Oxford English Dictionary Ethics are moral principles that govern a person's behavior or the conducting of an activity. Ethical issues can arise in relation to the devices themselves, the software and the users. Examples for the devices include: do they work as intended, for software has it been thoroughly tested and for users what are the user interface design and privacy issues. Ethics in the area of IT in general is lacking and in the development of Apps is non-existent. In June 2016 the American Medical Association, at their Annual Meeting, [2] approved a set of guidelines for the ethical use of telemedicine. These were based on the fact that medial ethics should not be sacrificed for technology. There are a variety of smart phones and other devices available now all with significant power and memory. Fitbit is an example of another device which is designed for this monitoring eHealth. While the information passed between mobile phones, like wired telephones, is on a one to one basis this is not the case with many apps that store information about the users in the phone for further use. However there are not many rules, regulations or laws covering the use of, or even sale of, personal data collected by the App suppliers [3]. Prior to smartphones the most searched for items on the Internet were health related. This has now translated into a significant high rise of health apps being made available. Although a recent review [6] identified recommendations for mHealth applications in the areas of Privacy and Security, the comprehensive review did not include any references to other Ethical issues in the area. Apps have a set of "Terms and Conditions" attached but very few people actually read them before downloading. This opens up the users to numerous ethical dangers.

In section 2, the paper outlines the scope of areas that require Ethical consideration. Section 3 discusses the need for ethical guidelines for technology development in the area. Some of the ethical issues related to the usage of Apps are discussed in Section 4. Section 5 argues for the need for further development of ethical guidelines for apps and devices in the health and well being areas.

## 2. Ethical Scope

### *2.1. Health and Well-being Apps*

The use of Apps in Health can be divided into three areas from an Ethical point of view, Apps with indirect health implications, which are copies of established text books, search engines for retrieving up to date publications or pharmaceutical catalogues. They are based on established facts that have been peer reviewed. These apps are mainly used for reference, training and education [4].

The second area is apps with direct health implications, apps for diagnosis, collection of health data, decision support, medical imaging and calculation of dosage for drugs. Associated with these there are many ethical issues for example accuracy of diagnosis using decision support or imaging, incorrect calculation of dosage. Healthcare is increasingly being affected by migration and the need to communicate in various languages. Smartphones can be used for translation between speech and text [7].

The third area is those apps used for patient monitoring. Examples of Apps available are from those for measuring clinical blood levels which are able to communicate with an EHR, to Apps that detect falls or lack of movement in the elderly.

This can raise ethical issues if incorrect information leads to incorrect prescribing. If a patient constantly drops a device and a false fall alarm is detected this may lead to the monitor not responding to a genuine fall later. The latest monitoring device to come onto the market is a biosensor. This is a patch that can monitor vital signs or certain external conditions like sunlight. It is in the form of a lightweight patch, likened to a patch to help smokers stop smoking. The first patch, Vital Patch, was unveiled at HIMSS16 in March 2016. This patch measures single lead ECG, heart rate, heart rate variability, respiratory rate, skin temperature, posture, step count and fall detection. The patches are disposable. They raise ethical issues in the area of collecting personal information and then being discarded with the information.

## 3. Ethical Guidelines for Design and Development

### *3.1. Requirement for Guidelines*

Designers of Health and well-being Apps and medical devices must be aware of the consequences of errors in the development. This is not only an education issue but we argue one that requires guidelines for developers. Thus it is important to be clear on the requirements such a set of guidelines need to meet. As medical research is constantly bringing in new treatments, the systems have to be updated in line with medical progression. All potential uses of the system must be explored to ensure they cannot be used in a non-ethical manner. The guidelines for a developer will have to cover all ethical concerns in an easy to follow manner. They will include reference to the legal and non legal requirements. The primary concern will be for the safe development of the apps/devices so they will do no harm to the individual using them or to those who rely on the data generated. When building ethical guidelines into the mHealth and App Development lifecycle they cannot make the lifecycle more cumbersome to use.

### *3.2. Ethical Issues Associated with the Storage of Data*

If the data is going to be stored in the cloud extra Data Protection Regulations will apply to ensure that ethical issues are avoided. In Europe the data must reside on a server within the European Union. Therefore it is necessary for those using the cloud to know the terms and conditions under which the cloud operates. If the data is to be combined with other data for research then the origin of the data needs to be known. Protection of data from being sold to a third party must also be guarded against. Some privacy policies are very loose or in some cases do not even exist. Many apps require a lot of personal details to be included which is then saved in a place that is unknown to the user. All of the information, including non medical data, has a market value [8].

## 4. Ethical issues related to the Use of Smartphones and Apps

### *4.1. Health Care Organisations*

Health Care Organisations are using apps and mHealth devices increasingly for a variety of reasons. Reminders about appointments are in widespread use. One area of

ethical concern associated with this is to ensure there is follow up if patients do not respond. Ethical issues arise when a Health Care Organisation decide to implement a policy on the type of apps and mHealth devices to approve for the various functions they perform to support their overall work. All apps should be thoroughly tested by the organisation before being deployed and only those approved by the organisation should be employed. The best know app in the area of health support is Epocrates [9], this is now in version 16.6 and so it can be said that this has been tried and tested over time. Epocrates comes in two versions one a free one and also a subscription one each with a wide range of uses.

### *4.2. Primary Care*

A review [10] revealed that 90% of physicians use smart phones in their professional life. One third of the physicians have recommended an app to patients [11]. The main reason for not recommending Apps is the lack of regulation by the FDA [12]. In 2013, the FDA came out with regulations and rulings of what apps are deemed appropriate as health apps and published its ruling (US Food and Drug Administration, 2014) [13]. The document states that "Only apps that serve as medical devices or transform a device into a medical device or perform patient - specific analysis and then provide a diagnosis or treatment on the basis of it will be regulated". The Health Informatics Unit of the Royal College of Physicians produced guidelines in April 2015 on using Apps in Clinical Practice [14]. The main theme of the guidelines are that even if the App has a CE mark it does not necessarily mean that it meets best practice. If an App is used for any medical purpose it is classified as a Medical Device. If an App uses patient specific information then it needs a CE mark. However ethical issues in the areas of accuracy, security and privacy are still issues for most health apps and the use of them will be limited by physicians.

### *4.3. Images*

Prior to the introduction of smart phones all medical images were typically taken by professional clinical photographers. Clinical photographs can be used for a variety of purposes including diagnosis, treatment, education, research and medical legal situations all of which carry ethical issues with them, including identification of a patient, Data Protection, and ensuring that the image is clear to enable a valid diagnosis. It is important that informed consent is received from the patient for using the image. All of these aspects are requirements under the Data Protection Legislation [15].

### *4.4. Decision Support Systems*

There are also ethical concerns particularly in relation to medical or wellness apps for Decision Support. One of these concerns is in the area of the accuracy of the app to do what it is meant to do. This can manifest itself in both apps used for monitoring and also for those used for Clinical Decision Support. A study [16] investigated the use of Apps by junior doctors for advice in the absence of a senior colleague being available. It found that the junior doctor will not necessarily know if the information supplied is accurate.

## 5. Conclusion

Having undertaken the preliminary literature review, it is clear that there is a need for guidelines for technology developers to consider and address ethical issues during. A Framework for incorporating ethics into the development of Health Apps and mHealth devices is being developed by the authors of this paper and will be based on the following definition, "a framework generally provides a skeletal abstraction of a solution to a number of problems that have similarities. A framework generally outlines the steps or phases that must be followed in the implementation of a solution without getting into details of what activities are done in each phase" [17].

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