Medical apps for smartphones: lack of evidence undermines quality and safety

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Increasing numbers of healthcare professionals are using smartphones and their associated applications (apps) in daily clinical care. While these medical apps hold great potential for improving clinical practice, little is known about the possible dangers associated with their use. Breaches of patient confidentiality, conflicts of interests and malfunctioning clinical decision-making apps could all negatively impact on patient care. We propose several strategies to enhance the development of evidence-based medical apps while retaining their open nature. The increasing use of medical apps calls for broader discussion across medicine's organising and accrediting bodies. The field of medical apps is currently one of the most dynamic in medicine, with real potential to change the way evidence-based healthcare is delivered in the future. Establishing appropriate regulatory procedures will enable this potential to be fulfilled, while at all times ensuring the safety of the patient.

Introduction

Smartphone applications—so-called apps—are becoming increasingly popular among medical professionals.[1–3] By 2015, 500 million smartphone users worldwide will be using a medical application.[4] Studies report that over 85% of health professionals use a smartphone, and 30–50% use medical apps in clinical care.[5–7] Apps have huge potential to improve patient practice, system efficiency and communication by providing a quick reference tool accessible at the point of care.[8] To date, there are 10 000 apps available in the 'medical section' of Apple's 'App store' and over 3000 on Google's 'Play store'.[9 10] Since these platforms facilitate development and distribution of mobile applications by clinicians and other developers, rapid proliferation of the market will likely continue.

However, there has been minimal description of the dangers posed by medical apps within medical literature. Recent studies have addressed the lack of evidence and professional medical involvement in their design and development, raising concerns regarding the reliability and accuracy of their medical content, and the consequences for patient safety.[2 3] It has been proposed that medical apps should be peer-reviewed by clinical experts and that regulatory measures should be increased in order to safeguard quality of care.[1] Regulation and guidance are urgently needed. Medical professionals must be made aware that some apps contain unreliable, non-peer-reviewed content so that they can choose carefully which apps to use in clinical care.[11] In this paper, we propose possible strategies that could enable the medical app market to be controlled and evidence based, while simultaneously minimising unnecessary bureaucracy so as not to hinder app development.

Lack of clinical involvement in medical apps

Most medical apps lack authenticity details; authors, manufacturers and distributors are not listed and references are unavailable or out-of-date. To illustrate, searching for an app to interpret arterial blood gas values produces a list of dozens claiming to have such a function, but few would be useful to physicians. Instead, most are irrelevant, non-evidence-based or even downright dangerous due to inaccurate content. Furthermore, it is unclear as to whether these apps will be updated if new evidence arises. Two recent studies in the fields of dermatology and microbiology revealed that less than 35% of medical apps had medical expert involvement during their development.[3] Eighty-six percent of 111-reviewed pain-management apps were found to have no medical professional involvement.[12] Only 12% reported a physician as the app's author.

As with any new healthcare technology, it is important to establish where responsibility and control lies. Indeed, this was the topic of a research project undertaken 10 years ago[13] that recommended ways of accrediting healthcare-related software, and proposed a scheme like Conformité Européene (CE) marking.

Dangers of medical apps in clinical practice

The very nature of smart phones poses a potential risk. As medical apps are increasingly used to support diagnosis and management of diseases (eg, apps that allow the user to input patient-specific information along with reference material to automatically diagnose a disease or condition), facilitating the appropriate use of information technology becomes crucial. Recently, a pharmaceutical-sponsored app, designed to assess disease severity, was recalled from app stores because it was giving erroneous scores in comparison with those calculated using the official formula.[14] Until now, there has been no reported harm to a patient caused by a recalled app. However, without app safety standards, it is only a matter of time before medical errors will be made and unintended harm to a patient will occur. Several websites have recently been launched by medical professionals to index, provide commentary and review medical applications.[15 16] Although this is a good starting point for peer-reviewing apps, the current assessment criteria do not address the scientific evidence for their content, but rather matters of usability, design and content control.

Commercial companies and the pharmaceutical industry are progressively developing and merchandising more medical apps for healthcare professionals.[18] Using such apps could raise substantial ethical issues. For instance, conflicts of interest may lead to conscious and unconscious bias in prescribing habits. Pharmaceutical companies may use these apps for marketing purposes,

influencing treatment options and presenting information in favour of their own drugs, with knock-on effects for patients' care.

Regulation by government health authorities

Recently, the American Food and Drug Administration (FDA) published a draft guideline on how to regulate medical apps.[19] The FDA states that an app can be considered a medical device when 'it is used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device'.[19] As an example, they describe that a light-emitting diode (LED), included on most mobile phones, can be used to illuminate objects. In this case, neither an app controlling the LED nor the mobile phone itself are considered medical devices. When, however, an app is promoted for providing a light source to examine patients, it would meet the definition of a device. The FDA plans to actively regulate certain types of apps (box 1). In our opinion, this is a positive development. Nevertheless, at the same time, government health authorities should not over-regulate medical apps so as to retain their open nature. The regulation process should be managed primarily by the healthcare community itself. However, it would be beneficial for government health authorities to provide official certification marks guaranteeing the quality of apps so that physicians can make an informed choice as to whether an app has evidence-based reliability.

Adoption of medical apps by medical publishers

We believe there to be various ways in which medical apps could be developed to ensure quality and safety. First of all, the content of all medical apps should be evidence based, externally peer reviewed by medical professionals and provide up-to-date clinical information. A peer-review system could be implemented by allowing physicians' associations or patient organisations related to a specific app's topic to 'adopt' or develop peer-reviewed apps. In addition, guidelines for medical apps, such as the future FDA guideline, should be used by app-developers and app-reviewers to preserve and monitor their quality and reliability. Evaluating the impact these technologies might have on improving healthcare would be highly advantageous, reducing the likelihood of medical mistakes and protecting patients. Medical app-developers should be encouraged to register their app in an international registry and to submit a premarket notification to accrediting bodies and medical experts in order to assess the effectiveness and safety of the proposed app. It should be noted that one disadvantage of such a system is that it would significantly decelerate innovations in this industry.

Box 1 Groups of medical apps the Food and Drug Administration intents to regulate[19]

- Apps that control a medical devise or display, store, analyse or transmit patient-specific medical device data (such as an electrocardiogram)
- Apps that, with help of formulae or algorithms, output patient-specific results, such as a diagnosis, treatment recommendation or differential diagnosis
- Apps that transform the mobile platform into a regulated medical device by using attachments or sensors or similar medical device functions

Medical apps selected by individual hospitals

Following the completion of medical app development, reliable, high-quality apps would be placed in app stores. Owing to the vast quantity of medical apps available, finding an appropriate and usable app can be problematic for physicians. At present, there are several methods by which medical apps are advertised. One example is the subset of medical apps offered by specialised commercial companies as part of a substore of 'useful and high-quality' apps.[20] Pharmaceutical companies are also widely involved in the development and distribution of medical apps.[8] The inevitable aim of such companies, however, is to make profit, and a conflict of interest cannot be ruled out. One way to bypass this problem would be to allow hospitals, or physicians' associations, to preselect apps and make them accessible to their employees, comparable with a medical library.

Future of medical apps

The advances in mobile health technology and the adoption of smart phones means that medical apps will be of vital importance and an integral part of daily medical practice in the near future. But while the rapid development of medical apps is engaging the attention of healthcare professionals and improving accessibility to medical knowledge, there is increasing concern regarding the potential dangers related to the use of medical apps. We are convinced that, to some degree, medical apps should be regulated, and that they need to be thoroughly peer-reviewed in order to ensure validity. Medical applications should have an assured quality, be scientifically sound and cost-effective in their use. All stakeholders in the mobile medical market should be involved in the regulation process. A shared decision-making approach in the creation of a regulatory guideline would both facilitate its acceptance among all stakeholders and enhance compliance to the guideline. Figure 1 provides a clear overview of the different stakeholders in the medical app field. Governmental healthcare authorities should provide guidelines which app-developers and reviewers should follow. Hospitals, healthcare institutions, medical publishing companies and physicians' accrediting bodies play a pivotal role in selecting and providing apps for healthcare professionals. Looking ahead, we believe that, since mobile technology has acquired a dominant role in society, further research on the use and implementation of medical apps in clinical practice will be necessary. The integration of medical apps will significantly contribute to accessible and evidenced-based healthcare. Medical apps constitute one of medicine's most dynamic contemporary fields, with considerable potential to change the way healthcare is delivered in the future. Establishing

Figure 1 Different stakeholders in developing a guideline for the regulation of medical apps. This figure is only reproduced in colour in the online version.

appropriate regulatory procedures will enable this potential to be fulfilled, while at all times ensuring patient safety.

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