

A mobile revolution for healthcare? Setting the agenda for Bioethics

ABSTRACT

Mobile health (mHealth) is rapidly being implemented and changing our ways of doing, understanding and organising health care. mHealth includes wearable devices as well as apps that track fitness, offer wellness programmes or provide tools to manage chronic conditions. According to industry and policy makers, these systems offer efficient and cost-effective solutions for disease prevention and self-management. While this development raises many ethically relevant questions, so far mHealth has received only little attention in medical ethics. This paper provides an overview of bioethical issues raised by mHealth and aims to draw scholarly attention to the ethical significance of its promises and challenges. We show that the overly positive promises of mHealth need to be nuanced and their desirability critically assessed. Finally, we offer suggestions to bioethicists to engage with this emerging trend in health care, in order to develop mHealth to its best potential in a morally sound way.

Keywords: Mobile health [mHealth], health apps, wearable sensors, bioethics, self-management, social justice

Introduction

In April 2015, Apple Inc. officially launched the Apple Watch. Already before its take-off, many online fora and media published discussions on how the development of the Apple Watch confirmed the multinational company's interest to enter the health and wellness market. So it was not a surprise that on the very day the Apple Watch began shipping, already 264 Apple Watch apps related to health or fitness were found in the App Store. These apps (mobile applications) included "fitness" (or work-out) programmes, systems for medication adherence, hydration, and fertility and pregnancy tracking systems. As this example suggests, the world of wearable devices has been connected to the world of health and wellbeing at its very onset.

The Apple Watch is only one among many examples in the emerging market of wearable devices, apps and sensors offering health-related services, which is also described as mHealth.[1,2] mHealth is a broad label for a variety of services and technologies supported by mobile devices, such as smart phones, patient monitoring devices, personal digital assistants, and other wireless devices to improve healthy behaviours, quality of life and wellbeing of individuals. An increasing number of websites showcases sleek wearable gadgets with apps continuously capturing body movements, producing graphs of daily calories consumption or workouts, providing health advice and self-management tools to chronic patients. Not only healthy individuals and chronic patients, but also healthcare professionals are expected targets of the mobile revolution. According to digital health proponents, like cardiologist Eric Topol or "medical futurist" Bertalan Mesko, the healthcare of the future will be powered by digital tools;[3,4] market reports, user

surveys, and policy strategic documents by national and international organisations confirm that the mobile health revolution is on its way. [(1,2)] According to a market report, 97,000 mobile health apps were released in 2013, the expected revenue would be of \$26 billion in 2017 while 485m wearable devices can be expected to be sold in 2018.[5] User uptake also seem to increase: as shown in a 2012 Pew Institute report, 31% of cell phone owners, and 52% of smartphone owners, have used their phones to look up health or medical information and 19% of smartphone owners have downloaded an app specifically to track or manage health.[7] More importantly, mHealth receives support from regulatory institutions such as the European Commission, arguing that it could be one of the tools to tackle the challenges faced by European healthcare systems, such as the ageing of the population and increased budgetary pressure.[2]

mHealth, as a subset of the broader field of “digital health” (or digital medicine), comes with promises of revolutionising healthcare by increasing patients’ self-management and empowerment, fostering efficiency and disease prevention and promoting accessibility to health around the globe. The rapid growth of this field has up until now only received little attention from bioethicists. In this paper, first we describe and critically assess the promises of mHealth and their ethical relevance. Subsequently, we offer some suggestions to promote further ethical reflection on this rapidly growing development.

mHealth: the promise of a revolution

The expectation of a “mobile revolution” in healthcare is based on the fact that mobile phones are always in our pockets, portable, and increasingly cheap.(eg: [3]) According to these narratives, the portability of mHealth systems and the ubiquity of the mobile network allow patients to freely move around while being checked remotely by healthcare providers and monitoring themselves outside the spaces traditionally dedicated to healthcare. This results not only in a wider range of places for health care, but also a change of roles for patients and for physicians. Mobility is considered revolutionary because it allows for people in rural areas to be as connected and cared for as people in more equipped urban places.[1,7] Furthermore, although the relatively cheap and easy movement of health data from sites of collection to sites of analysis and decision-making allows for the inclusion of more data-rich and real-life data in care, it also requires to rethink roles and responsibilities in the data interpretation and therapeutic decisions. As it has happened in the past in the fields of nanotechnology, genetics and personalised medicine, mHealth claims to revolutionise healthcare and solve many pressing healthcare challenges. The narrative of a revolution, is based on a certain techno-optimism, which rests on the promise that technological inventions are good in themselves. [8] As it has been pointed out in other cases, such claims of healthcare revolutions are rhetorical devices and they need to be assessed carefully with respect to their plausibility [9] before we can engage in a reflection on the new ethical challenges that these technologies arise. At the same time, however, mHealth does indeed initiate new practices in the medical domain which need careful assessment, whether they are novel ethical challenges or more familiar ones. Earlier debates around revolutionising technologies, in fact, have shown

that we have to critically assess these far-fetched promises, in order to steer the development of technologies in such a way that we can benefit from its positive effects, but also anticipate downsides and possible risks.

In the following, we critically analyse three recurrent promises of mHealth – fostering efficiency and prevention in healthcare, increasing patient self-management and empowerment and promoting global accessibility to health – showing their “rhetorical contradictions” (8): not only expectations often do not resonate with their practical use in healthcare, also they are not necessary as positive as they are presented but instead raise several ethical issues that need consideration.

Efficiency and prevention

mHealth is argued to offer efficient and cost-effective solutions for disease prevention, monitoring and management. Take for example an app that uses smartphone cameras to check moles for skin cancer risk (for example, <https://skinvision.com/>): the user holds the device over a spot on her skin and takes a picture; the app’s algorithm immediately analyses the spot and recommends an action to take (e.g. whether the user should go to a specialist) or provides relevant information on skin cancer. This system allows users to archive their skin pictures, keep track of changes over time and share them with their doctor. These types of apps claim to prevent risks of skin cancer by offering a cheap tool for early self-assessment.

In order to live up to these promises, mHealth systems, like other medical interventions, should not harm and should (preferably) benefit users. However, despite the hype around mHealth, there are still many uncertainties around the safety, reliability and accuracy of mHealth systems. (10,11). Risks include not only security issues and harms that may derive from potential disclosure of sensitive information to third parties or identity theft,(12)] but also risks of false results. For example, a skin screening app may not be accurate and might fail to recognise an early stage melanoma, falsely reassuring rather than alerting the user.(13) Other concerns have been raised concerning the efficiency of these devices: it has been argued that most sensors are unreliable in their signal detections, that it is unclear whether these device can induce people to change their behaviour towards healthier lifestyles;(14) and that clinical professionals are unaware of how to integrate these systems in their work flow (15).

Moreover, when weighting the benefits and harms of mHealth, one needs not only think of *which* benefits and harms are involved, but also to consider *who* will actually benefit and who will experience the harms from such technologies. Some apps are primarily helpful for patients and may simultaneously help physicians, health care personnel or commercial parties to monitor the patients, to do research or sell products. The benefits and risks may not be evenly distributed among these stakeholders. It is important to ensure that the risks of harm will not predominantly lie at the user/patient-side, because they are the more vulnerable actors and may have no understanding of or protection against such harms.

In general, despite the promise of providing an effective and efficient tool for disease prevention, the actual benefits of mHealth are still unclear. Although mHealth systems are sometimes presented as a replacement of traditional care, it is unlikely that they will completely replace traditional healthcare. Empirical research has indicated that patients and physicians are happy about the quality of web-consultations, (16) but little is known about their safety, feasibility, cost-effectiveness and efficiency. It is not clear in what contexts and situations these tools are the best possible option to meet patients' care needs: for example, it may not always be desirable, as face-to-face contact can be preferred, more efficient, or simply irreplaceable, because of the need for physical examination, sensitivity of the problems, validation of mHealth data or for the maintenance of the doctor-patient relationship. Also, more research is needed in order to understand which types of interventions and monitoring can be left to apps and wearables and when the personal, synchronous care relationship will need to be kept in order to ensure good care.

Self-management and empowerment

Another promise is that mHealth will empower patients.(2) Many apps and wearable sensors provide self-management functions for patients or healthy citizens who want to engage in healthy lifestyles. Having access to one's own health data, without the interference of health professionals, is argued to be a prerequisite to understanding, controlling and managing one's behaviour and therefore regarded as empowering patients and supporting their autonomy.(17-19) An example is offered by the apps provided mymHealth.com for patients with asthma, COPD, diabetes and heart disease that enable patients to "achieve their goals and self-management" while being followed by a clinical team (see <https://mymhealth.com/>).

The claim that these digital tools empower patients and support their autonomy through self-management should be critically assessed with regard to the degree and types of autonomy that these tools promote. The underlying idea of self-management of such apps induces patients to complying to a strict (medical) regime rather than enhancing their self-determination.(20) As these devices influence or direct behaviour of the users, concerns have been uttered that these technologies may be disciplining the users to perform specific medical tasks, rather than truly empowering them.(18,19) Moreover, as described in the context of governmental surveillance of internet use, so-called 'chilling effects' (21) can make users of mHealth adapt their behaviour when using wearables and apps because of the feeling they are being monitored, rather than because they are themselves motivated to behave in a certain way. This means that mHealth technologies indirectly hinder them to act in the way they would have otherwise, and raise questions concerning the true meaning of the promised patient empowerment. Not only expectations that apps and self-monitoring devices empower patients are deceptive because they promote a specific medical quantified regime rather than supporting a

plurality of self-determined patients' value¹, they also seem to assign extra responsibilities to patients. In fact, these apps and wearables delegate some tasks to patients that are traditionally carried out by health care professionals (e.g. monitoring vital signals, updating symptoms) and continuously demand patients to perform tasks within a certain timeframe. This shift of tasks is the flipside of having direct access to health data and falls into the general neo-liberal trend of shifting responsibilities from the State (or healthcare providers/experts) to citizens (or individual patients), a trend often referred to as 'responsibilisation' (see, <http://nuffieldbioethics.org/report/personalised-healthcare-2/what-is-personalised-healthcare>). Several concerns have been raised towards such trend and are likely to apply to the field of mHealth (19)²: first of all, it may charge patients with additional practical burdens and labour which would otherwise be taken up by healthcare professionals.⁽²²⁾ Also, such burden may cause unduly emotional stress for patients who may feel left alone to their own care by the system. Furthermore, as several empirical studies indicate, merely having access to data does not imply that people have an increased control over their behaviour and health outcomes, as for behavioural change to happen the intervention of a health professional or counsellor is often necessary. ^[(23)]

Whether the expectations of empowering patients are indeed met or not, an aspect that needs close consideration is how these devices and practices influence the doctor-patient relationship. It is not only a matter of introducing more distance in the doctor-patient interaction via online tools, but also a matter of giving patients tools to control their health and rethinking the roles that doctors have in healthcare.⁽²⁴⁾ By shifting tasks and responsibilities, proposing specific roles and offering tools to understand health and its correlation with lifestyle, these systems introduce new interactions between care providers and patients. This raises questions on how these relationships will take shape, whether valuable features of traditional relationships will get lost, whether medical training needs to be rethought or patient expectations redirected.

Yet another critical aspect related to promises to support patients' autonomy concerns the confidentiality and control of data. Data collected and processed by wearable sensors and apps may contain sensitive information that is made accessible to several actors as once such data is obtained it can be reproduced and used endlessly. For example, data may be analysed by the manufacturers for improving the app performance or sold to third parties for research or marketing. Users of such wearables and apps often have limited control over who has access to their data behind the scenes. Third parties access to health-

¹ Sharon and Zandbergen (34) critically assess this claim and show how, in some cases, measuring practices of "quantified selves" (people using self-tracking tools to measure their lives) embody different values beyond the ones from the medical sciences. For example, a woman would track her symptoms after her mother's death as a way to understand and process her grief.

² Natasha Dow Schüll (35) offers a critical perspective on this point suggesting that self-tracking devices do not increase responsibilisation in users but rather are the object of a process of de-responsibilisation as users delegate to them some tasks (e.g. reminding medications) that they would otherwise have to personally accomplish.

related data can be harmful for app users who could, for example be profiled by marketing agencies and receive targeted unwanted or upsetting advertisements (25) or incur in discriminatory policies by insurance companies or employers. Although safeguards are in place and users have the right to know what data will be collected, how it will be processed and to whom it will be distributed, this appear to be problematic and complicated in practice in the age of increasing data collection and big data analytics³. (26) Just to mention two issues: first, in a context wherein credit card purchases reveal individuals' lifestyle choices (e.g. eating or working out habits) and enable correlations with health conditions through linkages with medical or health data (collected via apps, for example), the distinction between sensitive and non-sensitive data is ambiguous and the definition of health-related data becomes too broad to be meaningful (27). Second, traditional safeguards in the clinical context, like practices of informed consent, are inapplicable in a consumer-focused domain where the mediation of healthcare professionals and researchers is shrinking. In an age of ambiguity between commercial and medical domain, confidentiality of health data is constantly challenged and there is a need to discuss the moral basis of governance models that foster autonomous choice and encourage mHealth users to make an informed decision and control which data remains protected.⁴

Wide accessibility to health and social justice

Finally, mHealth comes with the promise to make health care widely accessible. [2] mHealth is argued to have the potential to bring healthcare to areas that are difficult to reach, or to people who have mobility problems and cannot easily go to the hospital to receive care. An example can be found in a campaign raising health awareness in Bangladesh via SMS (text-messages) to mobilise citizens for National Immunisation Day. [1] In the context of this campaign, messages were sent to encourage parents to bring their children to get vaccinated, along with the event's date. A similar campaign involved pregnant women in remote villages who could register their mobile numbers to receive prenatal advice related to their gestation stage. With the spreading of mobile phone use in developing and rural areas, mHealth is considered a tremendous opportunity to improve healthcare in resource poor countries in affordable ways.

The promise of increasing accessibility to healthcare meets several challenges. For example, mHealth interventions like the ones described above, using SMS (text messages), may not reach those who are most in need of care, either because they are illiterate, or local languages are not supported by mobile phones, (28) or because apps require mobile phones with a fast Internet connection and some abilities to interact with these phones, thereby excluding certain groups (e.g. low-income groups or elderly people with less

³ The new General Data Protection Regulation (GDPR) aims at addressing this issue at the European level, but how this will rule out in practice is still an open question.

⁴ Models like layered and tiered consent, as have been discussed in the context of direct-to-consumer genetic testing, could be helpful in the context of where similarly to direct-to-consumer-genetic-testing data crosses national boundaries with different data protection laws. (36,37), (38)]

dexterity with smart phones). These issues raise the question whether the people who actually are in need of better care, or improved access to care are currently being served by mHealth technologies. Furthermore, it also indicates a certain hidden normativity in the ways in which services are offered and the expected users. Accessibility-related concerns also play a role in western countries as users of some of these technologies (e.g. iPhones, fit-bit) are on average younger, more educated and wealthier than average. These aspects threaten the promises of accessibility to health and raise questions whether mHealth exacerbates rather than mitigates issues of social justice both at a global and local level by excluding groups from using these services.

Setting the agenda for the ethics of mHealth

The preceding sections explicate why we need to be critical towards the promises of mHealth and discuss the moral concerns that are inherent to these very promises. But if an ethical reflection on mHealth is needed and if current promises are often misleading, how can bioethicists and medical ethicists approach the topic? In the following, we will outline two suggestions for approaching the ethics of mHealth.

From promises to practices

When exploring potential implications of mHealth systems, we need to be aware that developers' websites, explanations, or demos are only one side of the story describing the *intended* use. The way in which these technologies will *actually* be used in specific contexts by real people is a different matter, but both may be relevant for the ethical assessment of mHealth-technologies. Literature in history of technology and user-studies shows that there is often a gap between expected technology-driven scenarios and their actual realisation in specific societies. (29,30) When used in practice technologies often "bite back", having the exact opposite effect in practice to what they were supposed to do.(31) For example, although computers were often introduced in working spaces with the promise of creating a "paperless office", they had the opposite effect as people tended to print the same or even more than usual in order to store and distribute documents. Mismatches between designers' expectations of users' preferences and habits, on the one hand, and actual uses of technologies are very frequent as technologies introduce new burdens, labour and responsibilities that remain invisible at a first sight.(32,22) An investigation of actual uses is not always feasible (for example, the system is at an early stage of development or only used in few pilot studies, or logistical constraints prevent ethicists from engaging in such fieldwork). However, bioethicists can play a role, already during the development of devices, by uncovering the hidden normativity in the intended use and users, and by exploring possibilities for abuse and unforeseen effects. This type of early analysis can result in an alteration of the design of the device, app or service. To this end, not only the end-product but the criteria that inform different design stages should be explored and critically assessed. Bioethicists can ask questions like: is this particular system configuration going to exclude some users? Shall users be enabled to choose how they want their clinicians to monitor them through an app? These questions

can then be discussed with manufacturers and prospective users to design more desirable products.

It is therefore important for bioethicists to go beyond the abstract promises and rhetoric of mHealth and situate the ethical analysis in real world practices and specific contexts. As mHealth is often used as an “umbrella term” to refer to a broad variety of devices with diverse functionalities, it is crucial to establish relevant moral differences among these objects and raise specific normative questions concerning the types of users, places where systems are used, the type of device and practices that develop around it.

Beyond safety and effectiveness

As the problem of securing sensitive health information and protecting individual privacy becomes crucial in the context of commercial gadgets collecting health data and the question of uploading these data on medical records is explored, most policy discussions around mHealth focus on issues of effectiveness and safety of these devices⁵. While these topics are indeed crucial for the ethical assessment of mHealth as they refer to principles of beneficence and non-maleficence, these are not the only values and principles that are relevant from an ethical perspective. Issues of social justice, for example, should receive more attention. As discussed above, while mHealth has the potential to serve a wider range of people, it might as well exclude a large range of proportion of the population from care altogether. Questions with regard to who has access, who is excluded and whether those in need are actually served and get adequate care, require careful analysis and justification, already during the development of such technologies. Some of these questions are not new as mHealth is perpetuating existing injustices of problems with new means. However, digital health, including mHealth, also brings about new ways of exploitation and commodification of data. Many mHealth services have an ambivalent status between lifestyle/wellbeing gadgets and health-related products [30], making it opaque how these services should be governed. Data shared on social media, online patient platforms or sold to third parties require ethical scrutiny, not only for privacy reasons, but also to protect vulnerable groups from harm and discrimination. Finally, as mentioned above while changing the ways in which health care is offered, mHealth affects the relationship between health care experts and patients, as well as people's understandings of self-care and management. The meanings of mHealth services for individuals and collectives should be explored both empirically and conceptually. Bioethicists are exceptionally placed to bring these more conceptual and empirical issues into the public debate and extend the current discourse beyond questions of effectiveness and safety of mHealth.

⁵ See for example <https://ec.europa.eu/digital-single-market/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality>

Conclusions

mHealth is rapidly entering institutional healthcare settings, and our private spaces, and is surrounded with shiny promise of revolutionising medicine, but very little is known about their actual use and harms, which is important for the ethical assessment of such innovations. mHealth brings about new challenges and magnifies old challenges by its portability, the changing role of the patient and its market orientation. These changes have moral impact and have to be carefully scrutinised in order to develop suitable solutions. The visions, promises and the intended use of such technologies do provide an important basis for the ethical evaluation of such technologies, even when real life evidence is scarce, as these often conceal hidden normativities. But in order to provide ethical guidance, these promises should also be compared to actual uses and practices. Because the enthusiastic promises may not all come true, and most likely, not for everyone, ethical reflection upon mHealth development, promises and practices helps in providing orientation towards desirable pathways and required governance structures.

Our paper has indicated that mHealth technologies pose challenges for our ethical reflection. Our analysis has pointed out that we need to carefully reflect upon the possible benefits of mHealth of empowering users, being beneficial to patients, reaching rural areas and providing affordable care infrastructure, as these promises show only one side of the coin. mHealth is a container-concept featuring many different objects, with a diverse set of functions and potential uses, by a variety of users in different contexts. Such diversity is extremely important for the ethical assessment of such devices. To develop the potential of mHealth to the fullest and implement it in an ethically sound way, ethical reflection should be involved since the early development stages of these devices. This would allow us to learn step by step from mistakes, inaccuracy, gaps between intended and actual use, and the situated use of such technologies.

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