Chapter 2
The mHealth

Alessia Paglialonga, Alfonso Mastropietro, Elisa Scalco and Giovanna Rizzo

Abstract The rapid growth and popularity of mobile technology have opened an entirely new area in healthcare. Mobile health (mHealth) encompasses any use of mobile applications and devices for health and is a lively area of development and research. mHealth apps and devices hold great promise in terms of potential benefits for the several actors involved (patients, citizens, and professionals). For example, the promotion of preventive behaviors and health monitoring, enhanced patient-doctor engagement, improved service delivery in resource-limited settings, patient empowerment, and patient-centered care. At the same time, this mobile revolution in healthcare can bring along peculiar challenges and risks that are entirely new and that need to be carefully addressed. For example, the digital divide and related health inequalities, the risk of increased dropout in clinical studies compared, and the issue of guaranteeing evidence base, validation, and in general, quality and effectiveness of mHealth. These challenges push for more and more focused research in the field and for increasing collaboration among researchers, physicians and healthcare professionals, developers, industries, as well as representatives of the target user groups.

A. Paglialonga (✉)
Consiglio Nazionale delle Ricerche (CNR), Istituto di Elettronica e di Ingegneria dell'Informazione e delle Telecomunicazioni (IEIIT), Milan, Italy
e-mail: alessia.paglialonga@ieiit.cnr.it

A. Mastropietro · E. Scalco · G. Rizzo
Consiglio Nazionale delle Ricerche (CNR), Istituto di Bioimmagini e Fisiologia Molecolare (IBFM), Segrate, Milan, Italy
e-mail: alfonso.mastropietro@ibfm.cnr.it

E. Scalco
e-mail: elisa.scalco@ibfm.cnr.it

G. Rizzo
e-mail: giovanna.rizzo@ibfm.cnr.it

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2.1 Introduction

Mobile health (mHealth) is the use of health-related mobile applications (apps), mobile, and wearable devices to deliver medical information, to access or capture data, to provide clinical and personal services, or to support healthcare delivery in clinical and nonclinical settings. Noticeably, the World Bank has defined mHealth as the use of mobile technology to improve the well-being of people around the world [50]. It becomes thus clear that mHealth can be an entirely novel facilitator to address key healthcare challenges such as, for example, access to care, quality of services, affordability of technology, or matching of resources [47]. Mobile apps and devices can be of value to help people manage their own health, to promote healthy living, and to gain access to useful information when and where they need it [20].

In the past few years, we have witnessed a rapid development of mobile apps and devices for healthcare, with increasing penetration into clinical practice and into the daily life of patients and citizens[53]. The characteristics and context of mHealth are largely new compared to conventional eHealth approaches and, thanks to its peculiar characteristics, mHealth can have a significant impact on public health, healthcare services settings, as well as in nonclinical settings, including home use and patient monitoring. The core characteristics, as well as the general context of mHealth, are discussed in Sect. 2.2.

Documented opportunities and benefits of mHealth include, but are not limited to increased patient motivation toward behavior change [65], promotion of preventive behaviors and health monitoring in the general population [32, 28], enhanced patient–doctor engagement [56], recording of patient-reported measures and Ecological Momentary Assessment [14], improved service delivery in resource-limited settings (e.g., [2]), patient empowerment, and patient-centered care [52, 56].

Moreover, the mobile revolution in healthcare brings along entirely novel risks and challenges that are a matter of debate and that need to be carefully addressed. Examples are the so-called "digital divide," which could exacerbate health inequalities among different populations [30]; attrition and increased dropout in clinical studies compared to conventional protocols [51]; and the prominent issue of guaranteeing evidence base, validation, and in general, quality and effectiveness of mobile technology and applications [37, 41, 58]. Some of the most relevant benefits and challenges of mHealth are discussed in Sect. 2.3.

2.2 Core Characteristics and Context

Four core characteristics of mHealth have been conceptualized recently. These characteristics are specific to the field, unforeseen in earlier applications of information and communication technology (ICT) in Health, and essential to the design, implementation, and adoption of mHealth-based solutions [17]:

- penetration into populations, due to communication access to population and subgroups (although with substantial inequalities);
- availability of apps, due to increasing smartphone capabilities, functionality, and sensors integration and due;
- wireless broadband access to the internet thanks to increasing communication speed and device connectivity; and
- technology tethered to individuals due to increasing capability of locating, measuring data, monitoring function, and communicating with others.

With respect to the general objectives and context of mHealth, the US Federal Communications Commission [19] emphasized that mHealth can use mobile networks and devices in supporting e-care, leveraging health-focused applications on general-purpose tools such as mobile phones to drive active health participation by consumers and clinicians. Nowadays, mHealth apps and devices are used with proven success in several medical specialties, as well as in general health management and disease prevention. The fast increasing availability of mobile applications dedicated to health prevention and care supports management of chronic conditions and risk factors, medicines uptake, as well as the achievement of lifestyle/health objectives as obtained using ICT for personalization and real-time feedback. Unprecedented opportunities arise thanks to personal devices connected to mobile phones such as, for example, smartwatches, wristbands, and wearable sensors. Unique, innovative capabilities provided by the combined use of apps and wearable devices include, e.g., blood pressure monitors, pulse oximeters, blood glucose meters, environmental exposure measures (e.g., for asthma), single lead electrocardiogram (ECG), and sleep monitors [17].

The range of uses of mobile applications and devices is large and supported by growing evidence. In terms of categories, mHealth solutions can be classified into: general solutions for medical providers (physicians, nurses, and assistants), for example drug-referencing tools, clinical decision-support tools, electronic health-record system access and medical education materials; apps for medical education, teaching, and learning; tools for telemedicine and tele-healthcare; apps/wearables for patients and the general public over a wide array of functions; and specialty- or disease-specific apps [12]. Several examples can be found in the literature, related to a variety of specialties and disease groups such as, e.g., asthma risk management [27], cardiology [34], diabetes care [24], emergency medicine [61], nutrition [6], mental health [23]; sensory systems healthcare [54, 48], or infectious diseases monitoring [46].

2.3 Benefits and Challenges

Of the several documented benefits of mHealth, this Section discusses the opportunities offered by mHealth in terms of Ecological Momentary Assessment (EMA), patient empowerment and engagement, and service delivery in undeserved settings.

On the other hand, among the potential risks and challenges related to mHealth use, this section outlines the problem of health inequalities related to the digital divide, the issue of potentially increased dropout in clinical/research studies, the need for robust validation and evidence base in mHealth and the open debate on how to assess quality in mHealth.

2.3.1 Ecological Momentary Assessment (EMA)

The huge potential of mHealth approaches can have an enormous impact on surveillance, epidemiological, and intervention studies in both social and health sciences. Most of these studies were typically based on static retrospective self-report methods [22] that can be vulnerable to reporting errors and recall biases [4]. EMA has been widely proposed as a valuable alternative to overcome bias and errors coming from the traditional approaches.

EMA is referred to a group of techniques and methodologies allowing the subjects to self-report on detailed information about their status, activity, and experience (e.g., symptoms, feelings, behaviors, and cognitions) in real-time. This information is usually acquired many times through the course of their normal daily life in a natural environment [57]. Since the 80s, just after its introduction, EMA was usually carried out in the form of a daily diary. Nowadays, thanks to the progress of mobile, electronic, and wearable sensors technology, new approaches to EMA have become possible. The feasibility of frequent self-assessment sessions and real-time monitoring, based on non-obtrusive monitoring of mHealth apps and devices, makes it easier to monitor the individual's health status and self-reported measures.

A recent paper [14] has addressed the necessary steps and the related challenges to plan and prepare a longitudinal study using mobile technology to administer EMA. The paper was based on the EMPOWER project aimed to examine the triggers of lapses and relapse following intentional weight loss in adults. The adherence to completing EMA surveys was high, ranging from 88.3 to 90%. The EMPOWER infrastructure can be used as an example showing the technological solutions adopted (smartphones, apps, web server, database server, IoT approach, and Wi-Fi communication) and their interactions.

A slightly different approach, based on real-time sensor-informed context-sensitive EMA (CS-EMA) was developed to analyze physical activity [18]. CS-EMA is an innovative strategy that automatically triggers survey prompts at opportune times based on detected information from internal or external sensors using a mobile phone app. The average CS-EMA prompt compliance and survey completion rates were 80.5%.

The feasibility and acceptability of using smartphone-based EMA to capture daily functioning and other behaviors were also assessed in HIV + adults [39]. The authors report a high EMA adherence (86.4%) and assert that participants rated their experience with EMA methods positively.

The use of mobile technologies is a promising way to enable and boost EMA applications in research and in clinical practice, as it was already effectively tested in different fields of social and health science. Currently, EMA is mostly based on mobile phones and mobile apps and the use of integrated monitoring sensors can improve the EMA approach including more quantitative data. However, it is important to implement strategies that maximize patient feedback and participation as one relevant risk in EMA and, more generally, in using mobile tools for recording data/measures from patients, is potentially increased dropout compared to face-to-face or PC-based procedures, as discussed in Sect. 2.3.5.

2.3.2 Patient Empowerment and Engagement

mHealth has the potential to empower patients to self-manage their chronic diseases through instant tailored feedbacks [52]. With respect to clinic-based care, mHealth data can be collected much more intensively through a self-management support, allowing more detailed patterns to emerge in the outcomes of interest [56]. Patient empowerment is also reached by a support for decision-making about self-management directly to patients rather than through health care providers [28].

Moreover, mHealth has a potential impact on the patient engagement with treatment, which includes behavioral, affective, and cognitive components that contribute to maximize treatment outcome. In particular, the influence of mHealth intervention on health behavior change is an interesting field of research, showing encouraging results [65]. The use of mobile applications can monitor how engagement changes during treatment and factors associated with changes in the level of engagement [56].

Enhanced patient empowerment and engagement with treatments through the use of smart device-based interventions have demonstrated a clinical and health impact on different chronic conditions. Among these conditions, cardiovascular pathologies and diabetes have been widely studied. For example, it was reported in numerous studies a health improvement in HbAlc control among patients with diabetes [28].

Regarding cardiovascular risk factor control, mHealth has an impact on different situations, from the use of text message reminders to take medications to the application of biosensors that record and transmit blood pressure readings to databases for analysis and feedback [52]. In this field, the management of hypertension through mHealth interventions was extensively evaluated, reporting a high use of text messaging as the preferred instrument to monitor and control blood pressure. For example, a Russian study reported a significantly higher proportion of patients reaching target blood pressure in the intervention group in which regular text message reminders were sent to them to monitor home blood pressure, compared with the control group receiving usual care [29]. In more recent years, mHealth interventions were much more focused on the use of biosensors and mobile phone applications, such as the use of a smartphone-based home service delivery which has improved the uptake, adherence, and completion of cardiac rehabilitation in post-myocardial infarction patients as demonstrated by a randomized control trial [60]. Smartphone apps and wearable technology have demonstrated their potential also in the achievement of lifestyle/health objectives such as smoking cessation [64] and exercise promotion in middle-agers [32].

However, several studies have identified hurdles that challenge wide usage, including poor user interface designs, differing user literacy levels, implementation issues, and organizational structures. To take full advantage of the potential of mHealth as a trigger for behavior change, it is important to consider elements of patient engagement since the design as well as to introduce strategies that are specific to the target users group [16].

2.3.3 Service Delivery in Underserved Areas

The social, economic, and educational level, as well as age, gender, and ethnicity of an individual can strongly affect his health status. In particular, limited income and education affect individuals' health negatively by reducing their capability to access health services and to acquire and understand health information needed to prevent or adequately care pathologies [44].

mHealth technology is potentially a valuable approach to limit the disparities among people as it can effectively strengthen health systems in low-income countries through better access to knowledge and information, improved service delivery and reduced intervention time and cost, thus extending the number of persons who can take advantage of health services [2].

Mobile technologies could assist vulnerable patients who live in rural regions, far away from hospitals, by allowing clinicians to monitor them remotely. This may improve access to quality care, and prevent frequent and costly trips to the urban health care facilities [43]. In addition, the use of mHealth approaches can improve the screening of pathologies in populations that have no access to health services and screening protocols. As an example, a smartphone-based hearing screening system was validated in South Africa to improve healthcare in underserved communities at a primary care level [63] allowing for quality control and remote monitoring for surveillance and follow-up. Using a similar technological approach, individuals who are vulnerable to health disparities were successfully able to use mHealth programs designed to promote colorectal cancer screening [36].

Finally, in low-income areas, where the health literacy of the population can be modest, mobile-assisted health care systems can increase the quality and efficacy of both diagnosis and care by helping health workers, caregivers, and patients to access a higher level medical knowledge (guidelines and manuals) using mobile devices [38]. However, specific efforts are needed to tailor mHealth to the peculiar needs of underserved contexts and disadvantaged populations to try to limit possible drawbacks due to poor access to technology, low digital skills, and low literacy levels, i.e., the so-called digital divide.

2.3.4 *The Digital Divide and Health Inequalities*

While the use of mHealth may bring along several important benefits, indeed mHealth can be effective to the extent that individuals are in a position to use it well. Yet, the “digital divide” along with demographic and socioeconomic inequalities can create a gap between users and nonusers in terms of the improvement of health services, leading to (or exacerbating) health inequalities [30]. Health inequalities can become a prominent issue because they can translate into differences in the prevalence of illness and of illness repercussions, mortality rate, and burden of illness and other health conditions among different population groups [42].

Demographic and socioeconomic inequalities among different population groups (e.g., ethnicity, socioeconomic status, age and gender, literacy, health literacy, and access/affordability of technology) can lead to differences among individuals in terms of skills and ability to use mHealth effectively and this, in turn, can amplify health inequalities [30, 35].

Unequal access to technologies such as computers, smartphones or the Internet is referred to as “primary” digital divide, and is known to influence the utilization of services [33]. This is frequently related to geographical, demographical, and economic disparities. Widespread use of smartphones and other mobile devices and the reduced cost of technology and the Internet can, at least in part, diminish the “primary” digital divide. Yet, gaps still remain, for example, in smartphone adoption for individuals over 65, with less than high school education, with a disability, and living in poverty [31].

However, even though access to technology is a crucial element in the utilization of a technology, this is not sufficient so the primary digital divide accounts only for a part of the potential health inequalities [35]. For example, digital literacy and knowledge related to the utilization of modern technology also have an impact. This gap in digital knowledge between users is called the “secondary” digital divide [7] and pushes for research toward mHealth tools that need to be easy and simple to use for individuals with limited digital skills.

Moreover, a “tertiary” digital divide exists [9]. Much more widespread, the tertiary digital divide refers to the concept of significant (or universal) access encompassing technology, Internet connection, skills development, technical assistance, and appropriate content, i.e., content understandable and useful for disadvantaged populations. This tertiary digital divide is much more difficult to overcome and calls for a common effort of developers, healthcare providers, policymakers, researchers, and industry.

So, although mHealth can, in principle, be a means to bring healthcare closer to people in disadvantaged settings, nevertheless efforts need to be done to ensure that mHealth holds its promise to reduce inequalities among individuals. It is important to bring technology closer to those with reduced digital capabilities and health literacy so to enable any individual along the socioeconomic scale to adopt mHealth technology effectively.

2.3.5 Attrition and Increased Dropout

A common issue in mHealth is the difficulty in recruiting and retaining people for testing the feasibility and the efficacy of new mobile applications and services. A very recent study aimed to evaluate a mHealth application to increase tobacco cessation medication adherence. In this work, the final users had been involved during the development of the mHealth service, thus allowing its optimization from the usability and acceptability point of view. However, high attrition was found due to technical (lost/upgraded phones) issue, insufficient human contact between staff and participants, medication side effects, and enrollment procedures [21], resulting in an eligibility of 42% and a dropout of 43%.

Analogously, another study [26] reported the patient recruitment and engagement, as vulnerable phases in an text message-based trial of mHealth intervention of people with serious mental health problems. In this study, the main factors related to attrition were patients gender, age, vocational education, and employment status, while the need of staff extra support seems necessary to reduce attrition.

Interestingly, a recent study compared the efficacy and the appreciation of a PC-based eHealth physical activity intervention with its mHealth version [51], reporting that the eHealth version resulted in a more effective intervention and better usability and appreciation. This finding suggests that mHealth is not preferable to eHealth in any circumstances and that mobile phone could be per se a distracting factor; a very careful co-design to optimize subject's engagement and appreciation could help in minimizing this aspect.

Noncompliance and nonadherence of the participants to the study are certainly a detrimental factor to the benefits provided by mobile EMA self-assessment. A systematic review and meta-analysis collecting 42 studies involving young people (<18 years old) showed that the weighted average compliance rate was 78.3% [62]. Study design and protocols may affect compliance, whereas including additional wearable devices did not significantly change the participant's adherence.

It is worth to notice, however, that there is a need for new, more robust, experimental studies to investigate the real impact of mobile technologies on participant adherence and engagement.

2.3.6 Need for Methods to Ensure Quality in mHealth

The high number of mHealth apps and devices available on the market is not always demonstrated to be based on documented evidence and/or developed involving all the relevant stakeholders. The number of apps that are validated or tested for evidence base is still very low in several application areas [13, 59]. More scientific-based, controlled, clinical trials are mandatory to increase the quality of mHealth solutions and to fully understand the feasibility and benefits of introducing these solutions into clinical practice before promoting their routine use in healthcare.

The need for methods to characterize and assess mHealth apps and devices is particularly urgent as a means to support physicians and healthcare professionals in the identification of the most appropriate solutions for themselves and for their patients and families. This need has inspired a significant amount of research to try to devise assessment methods to inform potential users of apps and wearable devices that can be accurate and at the same time simple and easy to use. Basically, the main source of information for the end users still remains the web, including not only online markets (app and wearable markets) but also the manufacturer's websites, health-related web portals, expert communities, and voluntary review and evaluation systems [11]. Attempts to develop certification frameworks such as, for example, the Happtique Health App Certification Program (HACP) have failed so far due to security shortcomings [12]. In general, certification and standardization are difficult to achieve due to key market factors such as the number of features, diversity of information, and the very rapid pace of development [15].

The characterization and assessment of mHealth tools is an important area of research in and of itself. The concept of quality of health apps is complex, subjective in nature, and a matter of debate. It includes, for example, elements of safety, trustworthiness, user-oriented quality (e.g., operability, usability, depth of understanding, and quality of experience), effectiveness, and evidence base.

Many examples of methods for the characterization and assessment of mHealth tools have been introduced so far [8, 25]. For example, some classification frameworks have been proposed, based on features such as the type of health management strategies, user engagement approaches, or the potential to influence behavior change and the drivers used [55]. Some other studies in the literature proposed to code mHealth tools not only for the enabling drivers and functions but, also, for their content and features. For example, data analysis capabilities [24], fulfillment of clinical guidelines [1], completeness of information [40], or the degree of medical professional involvement and the availability of evidence-based content [45]. Some studies have tried to develop characterization frameworks in the area of mHealth safety and trustworthiness, but these aspects are difficult to measure [3]. Some other studies introduced methods to address user-oriented attributes that are directly or indirectly related to elements of quality such as, e.g., operability, usability, depth of understanding, and quality of experience. Expert-based evaluations have been suggested [5] as well as to user-oriented, easy-to-use tools to collect meaningful information about a core set of relevant features [10, 49, 58].

Overall, although the literature in this area is ample, the question of how to characterize and assess mHealth is still an open and challenging one.

2.4 Conclusions

The popularity and usage of mobile technology are growing along with the number and variety of mHealth solutions and applications. Increasingly, patients and citizens are inclined to seek health-related guidance from mobile devices due to practicality in communicating, information resourcefulness, portability, affordable costs, and widespread availability. Along with the many opportunities and benefits that mHealth can bring in public health, healthcare service settings, and personal health management, there are also some important potential risks that need to be considered and as far as possible, minimized by design.

The field of mHealth is a lively area of research where scientists, physicians and healthcare professionals, developers, industries and the target user groups should work together toward the common goal of delivering mHealth applications and devices that guarantee evidence base, reliability, effectiveness, and quality and that can be affordable and accessible for everyone.

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