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ВНЕДРЕНИЕ МОБИЛЬНОГО ЗДРАВООХРАНЕНИЯ И ЕГО ПОЛЬЗА В УСЛОВИЯХ ПАНДЕМИИ COVID-19

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РЕЗЮМЕ

Пандемия COVID-19 привела к неожиданному ускорению развития мобильного здравоохранения (*m-Health*) с внедрением телемедицины, удаленного мониторинга и ряда других цифровых подходов. Эти изменения произошли быстро, за несколько недель, и, вероятно, сохранятся даже после завершения пандемии. Таким образом, инструменты мобильного здравоохранения, дистанционной медицины и носимые устройства могут заменить или по меньшей мере дополнить традиционный личный контакт между врачом и пациентом. Это особенно верно в отношении сердечно-сосудистых заболеваний, поскольку теперь существует техническая возможность удаленно собирать широкий спектр данных, таких как артериальное давление, частота сердечных сокращений, регулярность сердечного ритма, тоны сердца, масса тела, уровни сахара и холестерина, электрокардиограмма, частота дыхания, в дополнение к симптоматике. Однако все еще остается много сложных и нерешенных аспектов. Необходимо изменить принципы возмещения затрат, чтобы в равной степени поддержать цифровую трансформацию. Вопросы, касающиеся конфиденциальности данных, ответственности, нормативно-правового соответствия и проведения исследований, должны решаться справедливо и четко как для врачей, так и для разработчиков технологий. В настоящее время все эти аспекты создают препятствия для внедрения мобильного здравоохранения. Правительства должны повышать уровень информированности и знаний медицинских работников и населения (особенно старшего возраста) в области мобильного здравоохранения, чтобы поддержать цифровую революцию. Необходимо признать проблему «цифрового разрыва» и уменьшить его, чтобы люди с низким доходом, плохим доступом к высокоскоростному интернету или персональным компьютерам могли воспользоваться преимуществами мобильного здравоохранения.

Обо всем этом пойдет речь в настоящей статье. В начале статьи дано определение понятию «мобильное здравоохранение», далее рассматриваются преимущества и недостатки мобильного здравоохранения в общих чертах и в контексте пандемии COVID-19. В завершение приводится утверждение о том, что необходимо обеспечить более конкретное участие и объединить усилия множества заинтересованных сторон системы здравоохранения для оценки, улучшения и управления мобильным здравоохранением и цифровым будущим.

Ключевые слова: мобильное здравоохранение, телемедицина, удаленный мониторинг, цифровое здравоохранение, электронная медицинская карта.

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THE INVASION OF M-HEALTH AND ITS UTILITY IN COVID-19 PANDEMIC

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ABSTRACT

The COVID-19 pandemic has led an unexpected acceleration of mobile-health (*m-Health*) with the adoption of telemedicine, remote monitoring, and several other digital approaches. These changes occurred rapidly in a few weeks and are likely to remain even when the emergency will be over. Thus, *m*-health tools, wearables, and remote medicine may replace or, at least, support the traditional face-to-face contact between patients and clinicians. This is particularly true in the area of cardiovascular diseases as it is now technically possible to collect remotely a vast range of data, such as blood pressure, heart rate and its regularity, heart sounds, body weight, sugar and cholesterol levels, electrocardiogram, respiratory rate in addition to symptoms. Several aspects, however, are still a challenge and need to be resolved. Reimbursement has to be changed in order to equally support the digital transformation. Aspects related to privacy, liability, regulatory issues, and even research need to be addressed in a fair and

firm way for both clinicians and technology developers. At present, these are still barriers to the implementation of *m*-health. Governments should provide more education on *m*-health to support healthcare professionals and citizens (*especially the elderly*) with the digitalisation revolution. A "*Digital divide*" for those with poor income or poor access to high-speed internet or personal computers should also be recognised and improved to avoid to be excluded from the benefits of *m*-health.

The present review article is about all this. First, we define what *m*-health is, then we consider the good and bad of *m*-health in general terms and in the context of COVID-19 pandemic. Finally, we argue that more concrete involvement and effort is needed by the multi-stakeholders of healthcare system to evaluate, improve, and govern *m*-health and the digital future.

Key words: digital health, electronic medical records, *m*-health, remote monitoring, telemedicine.

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INTRODUCTION

The COVID-19 pandemic has driven an unprecedented acceleration and adoption of digital patient care interactions. Patients have become engaged of their own health via video, telemedicine visits, remote monitoring, use of "*touchpoints*" such as mobile-health (*m-Health*) tools and wearables, phone calls, portal messages as well as sharing of the remote data. Just in the United States, the number of messages sent to patients' portals and of telemedicine's consultation has increased at the beginning of the lockdown of about 40% as compared with the pre-pandemic levels [1]. These "*forced*" changes occurred very rapidly, almost overnight [2]. In a few weeks, digital medicine replaced the traditional face-to-face relationships between patients and clinicians. It is unclear whether these changes in healthcare delivery are temporary or whether and to which extent when the pandemic is over, patients will go back to the traditional face-to-face system. Although the changes were motivated by a urgent necessity, it seems that neither patients nor clinicians are aiming to go back to the old days of in person visits [3]. Such a digital shift can be considered as an opportunity to share a better system with the possibility to choose among in person or video visits or asynchronous messages or digital touchpoints. These last options might be welcomed by patients and the population in general. Telemedicine, for instance, can be provided at a more convenient time and avoid travelling. More frequent and shorter interactions than traditional visits such as weekly checks using portal messaging may also be useful (*even for the outcome*) especially for chronic illnesses and reduce hospitalisations [4].

As a consequence, the area of digital and *m*-health, which was already expanding rapidly, has been sped up by the current situation. *m*-health is now the third largest industry in the European health sector, after pharmaceuticals and medical devices. This is not surprising. The interest on *m*-health started long before the occurrence of the pandemic for several reasons. On one hand, the limited healthcare budget, the lack of responsible workers (*especially in remote areas of low-income countries*) and the ever-increasing health problems, (*as dramatically spotted by the COVID-19 emergency*), are challenging the national healthcare systems and there is the need to find more efficient solutions. On the other hand, smartphones, tablet computers, and their applications have become ubiquitous in modern life across the world and are part of the new actual healthcare [5]. Today, there is the need and the hope to deliver reliable healthcare by using *m*-health innovations and all stakeholders need to be involved in shaping the future of *m*-health as the choices made now will last for generations.

The purpose of the present review is: 1) to define *m*-health; 2) to discuss the "*good*" and the "*less good*" of *m*-health, the reasons why *m*-health has been so far under-delivered and to highlight the challenges and the opportunities; 3) to consider the specific role of *m*-health to manage the current COVID-19 emergency; 4) to call for action and encourage health professionals, technology developers, regulators, reimbursement authorities, and citizens to take a more active role in the use of *m*-health.

Let's start by defining the terminology related to *m*-health.

DEFINITIONS

• ***m*-Health:** *m* stands for mobile. Although there is no precise definition for *m*-Health, the terminology is used for the practice of medicine and public health support by mobile devices. It is a part of and often a synonymous of e-Health and relates to provision of health-related services via a mobile device. It comprises multidimensional elements including providers, patients, and administrative applications. The term is normally used in reference to the adoption of mobile communication devices such as mobile phones, computers, tablets, televisions, telephones, communication satellites but also wearable devices like smart watches, different sensors, and intelligent pacemakers for health services, information, and data collection. It follows that *m*-Health has enormous possibilities of application, including consumer education and behaviour change, disease and population registries through wearable sensors, point of care diagnosis, electronic health records, decision support, professional education, conduction of pragmatic-virtual trials, and, eventually, full healthcare management [6]. Part of *m*-Health are several other (*and even increasing*) sub-domains, the most popular being:

– ***Tele-Health:*** Which also includes a broad spectrum of technologies and systems for remote exchange of data between patients and their clinicians to assist diagnosing, monitoring long-term conditions, and treating

– ***Tele-Medicine or Tele-Care*:** which indicates remote care offered using telecommunication and information technologies.

– ***Wearable Sensors*:** As it is intuitive, the term means sensors in contact with the body that are integrated into wearable objects (*watches, jewellery, rings, t-shirts, shoes, etc.*). Sensors can be directly applied to or in the body to monitor health by providing clinical relevant data. There are millions of sensors, often able to provide and connect many different information on an ongoing basis, and to upload the data immediately to the cloud, so that the doctor can make diagnosis, or adjustment to medication or treatment plan accordingly.

– **Internet of medical things:** It refers to the several connected systems of medical devices and applications which collect data that are then provided to healthcare internet systems through computer networks. When connected to internet, ordinary medical devices or sensors can collect additional data and, importantly, can integrate each data in the actual context (*either biochemical, genetic, environmental, or even administrative*) thus enriching the level of information.

– **Genomics:** It is an inter-disciplinary field of biology that focuses on the structure, evolution, functions, mapping, and editing of genome which, in turn, is the complete set of DNA and includes all the genes of the organism.

• **Digital Health:** It is a rather broad term, which means the convergence of digital technologies (*including genomics*) with health, healthcare, living, and society to enhance the efficiency of healthcare delivery and make medicine more available, personalised and precise (*7*). The World Health Organisation (*WHO*) provides a classification of digital health interventions defined as "*discrete function of digital technology to achieve health sector objectives*" [8]. The wording "*digital health*" comprises several other terminologies, often confounding. Here, we report the most relevant ones:

• **Information and Communication Technology (*ICT*):** It refers to technologies that provide access to and dissemination of information (*not necessarily related to health and healthcare*). ICT covers any product that stores, retrieves, manipulates, transmits, or receives information electronically in a digital form. Typical examples are personal computers, tablets, telephone lines, wireless signals, digital televisions, emails, robots, etc. In the context of digital health, ICT comprehends communication channels, that facilitate delivery of digital intervention and health content, which, in turn, is any information that is aligned with recommended health practice.

• **Artificial Intelligence (*AI*):** It is a branch of Computer Science that studies the development of intelligent machines, which are able to think and work like the human intelligence. Classical examples are speech recognition, problem-solving, learning, and planning (*i.e. Siri, Cogito, Tesla, etc*). AI is not limited to just *IT* or technology industry. It is extensively used in other areas such as business, law, education, and, indeed, medicine.

• **Machine Learning:** Another umbrella-type of terminology that can be applied to different concepts and techniques. In general, the term refers to enabling a computer to carry out tasks that are typical of human intelligence by itself, without receiving line-by-line instructions to do so. There is no need to pre-specify all the steps necessary to solve the problem because the computer is able to "*learn*" by analysing the details of the data it receives (*input*), and to confront, generalise, organise these details (*algorithms*), and, eventually, to provide new data (*output*). It follows that machine learning is about data, while AI is about cognition. The more accurate data the computer receives, the better the output will be. This technique can and is applied to diagnosis (*especially in the area of imaging)* and treatment of diseases.

m-HEALTH PERCEPTION: *THE GOOD*

The world is in the middle of a digital revolution independently from the epidemic. The use of mobile devices in health coupled with the related technologies promises to literally transform global health delivery by creating new models that can be integrated and even substitute the existing health systems [9]. However, as for every revolution, the perception and its application depends on different angles of observation. Several groups are strong believers that *m*-Health is the future, others, however, are more reluctant. The enthusiasm relies on several reasons.

First, the number of smartphones is predicted to reach more than 6 billion [10]. Just one year ago, 6 million multimedia applications in the app stores, 418,000 of these being *m*-Health apps (*and more as we are writing this article*) with more than 200 added users each day [10]. The commercial wireless signals cover 85% of the world population, extending far beyond the reach of the electrical grid [11]. Given such scale and speed of technological advancement during the past few decades, together with the importance, and the value of the health-market, it is not surprising that different industries are trying to create a more convenient (*and profitable*) healthcare system [11].

Second, health assumes or should assume prime interference around the globe as it is becoming a significant indicator of a nation's growth and development. Limited access to healthcare, in fact, creates a major barrier for social and economic development. This is particularly true when nations have to deal with an epidemic like the one of SARS-COV-2. In all, 400 millions of individuals have no access to any form of basic healthcare and 2 billion patients do not have access to required medications [12]. Therefore, more than one-fourth of the world has unmet health needs. It is not surprising that, in low-income countries, the popularity of *m*-Health is increasing as the use of mobile phones/devices is also exponentially increasing even in the illiterate and very low-income citizens. The majority of people, including those leaving in rural areas who are in desperate need of health, have access to mobile phones and are familiar with their function [10]. Today, the industry, together with social institutions, is working to develop *m*-Health applications that are usable by people with very low literacy [11–13]. Therefore, all these low-income countries are welcoming *m*-Health with great enthusiasm [14].

Third, in the most developed countries, the relative success in prolonging the prognosis, particularly in the area of cardiology and oncology, has led to substantial aging of the population and the relative increase of chronic condition poses economical and organisational challenges to almost every health system [15]. While an acute condition can be treated with "*ad hoc*" solutions, chronic conditions need to be managed and contained during a long and expensive journey from onset (*diagnosis*) to the end (*death*), with limited possibilities of recovery. This is particularly true in case of an epidemic when care is not only centralized to these patients requiring intensive care, but mainly to the others that need to be managed at home. The actual pandemic has revealed all the limits of the existing healthcare systems. The emergency of treating COVID-19 patients, as a side effect, has reduced care of patients affected by other pathologies, with consequent more casualties especially for cancer and cardiovascular patients [16]. All of this jeopardises the already insufficient healthcare budgets with the result that healthcare providers as well as institutions, such as national and international scientific societies, including the ESC, which are starting initiatives to welcome *m*-Health with the aim to find reliable and less expensive alternative solutions [17, 18].

Fourth, politicians do strongly believe that *m*-Health might be the solution to all their problems. They believe that ubiquity of mobile devices (*and therefore of m-Health*) in the developed and developing world represent the opportunity to improve health delivery and outcome, to reduce unnecessary and costly hospital visits and stay, thus improving the population wellbeing. They also hope that *m*-Health might replace the lack of medical and health-related workers, especially in remote non-urbanised areas as well as the complicated health delivery in the ever-increasing megalopolis. Therefore, a sizeable proportion of the budget is shifted versus (*promising?*) start-up industry to develop *m*-health projects [19, 20].

Fifth, researchers and regulators are becoming more and more worried about the costs, the effective participation and even the meaning of traditional randomised controlled trials (*RCTs*) [21]. Usually, RCTs are numerically huge with rigid design, slowly and cumbersome realization and increasingly expensive. Majority of the trials are funded by companies, and managed by costly CROs (*Clinical Research Organisations).* Ancillary investigations to answer pathophysiological questions are limited by costs and time and also by the scarce interest of the sponsors and of the researchers [22, 23]. The endpoints are usually composite and often driven by subsidiary components, and the study representativeness and generalizability are always debatable. Co-morbidities remain a major open issue, typically clicked in the database as "physician-reported", without any further information. The old debate on the nature of these and observation trials has recently risen, leading to new experimental digital solutions [24]. This is now possible by the universal digital diffusion, including Electronic

Health Recording (*EHR*) which have provided private and public health settings of networks encompassing hospitals, clinics, and ambulatory services with unified EHR and central data warehouses. In these archives are deposited individual hard events such as hospitalizations and death, which facilitate periodic interim analyses and safety monitoring, also by leveraging, where available, machine learning and advanced language processing. In addition to these technical facilities, two methodological innovations were introduced in trials' designs. First, the adaptive design model used in the largest trials conducted during the COVID-19 epidemic [25, 26]. Second, the very recent virtual or remote trials. All these models of RCTs (large and simple, adaptive, and virtual) are classified as "pragmatic". Thus, both scientists and regulators are looking at *m*-Health as an interesting alternative for clinical research and this is particularly true in the current days. The SARS-COV-2 tsunami, by necessity, has also changed the approach. Adaptive trials, which allow to change during the trial dosages, drugs, and even the endpoint, have been proposed and accepted by the authorities to speed up research and *m*-health is the preferred instrument to run such trials [25, 26].

Another promising application of *m*-Health is collecting data in digital form from real world registries and post-marketing surveillance. Pilot experience is going on, particularly for cancer drugs, when treatment may be promising but not proving. The clinical use might be allowed for limited years, while collecting data by means of *m*-Health used by the competent authorities to finally approve or reject the medication under scrutiny [27].

Sixth, beside pragmatic or adaptative clinical and observational trials, research is moving, as it should, to be directly conducted by patients and/or even by healthy people. This is logical as healthcare is about patients or avoiding healthy people to become patients. Up to now, however, patients and the population in general have not been the main stakeholders in healthcare. Things are rapidly changing as there is greater involvement of patients in health issues and their access to health information is facilitated by the digital and *m*-Health revolution. Thus, today, often patients are directly participating to research [28]. This is particularly true for chronic illnesses and also for epidemic diseases, such as CV diseases, that require changes of life-style approach with constant monitoring [29]. Connected devices – *tablets, wearables, hand-held devices* –enable patients to take a more active role in managing their health ("*empowerment*") and to provide their data to increase disease knowledge from a different angle which could be relevant for the others in the same conditions [28]. Therefore, today, as patients become more and more empowered in their health, many of them are spontaneously participating to research by providing their data (*including the genetic ones*) and their relationship with the disease. The data are then processed for global analysis, thus joining the "*Big Data Company*" [29]. The several groups or patients' associations dealing with the sequel of COVID-19, the so-called "*long COVID*" is a classic example.

It follows that, for different reasons, many different categories (*technology industries, big pharma, managers, suppliers, governments, patients, scientists, insurance companies, and many others*) have a good perception of *m*-Health and several hopes in its application. The picture, however, is not all rosy and other groups are less enthusiastic, to say the best.

m-HEALTH PERCEPTION: *THE LESS GOOD*

As for the enthusiasm, there are reasons for scepticism.

One is rather historical, with roots extending back to Hippocrates. It is a sort of subliminal pride and/or fair for a drastic change. It is the so-called "*medical professionalism*" which has been challenged through time in many different ways and it is not always appreciated [30]. The changes in healthcare delivery, already adopted in several industrialised countries, threaten the nature and the values of medical profession. Several physicians were and are worried (*and, most probably, correctly so*) about the accuracy and reproducibility of the *m*-Health data which are highly dependent on the reliability of the information delivered and the relative coding.

A **second** scepticism relates to AI. In general doctors believe that AI is not as good as full work-up by them, although they are starting to realise that it may be very useful in solving several problems, particularly in situations of emergency like the present one. Apart from emergencies, a metanalysis of 69 well conducted studies provide 92% specificity for AI deep learning imaging and 90% for healthcare professionals, although reporting is better when is performed by human intelligence [31]. This is an example of clear win-to-win interaction by doctors and AI. However, some clinicians consider *m*-Health and AI a sort of competitor, something that will take away their job and pride, an "*invention that will substitute me* ". On the other hand, the order of magnitude of data that will be produced by *m*-Health will require supplementation of human intelligence. Nevertheless, there are several issues, including ethical aspects, on the use of AI in medicine which should be resolved quickly. So, strangely enough, a category that is less enthusiastic or even sceptical about *m*-health is the one of "*doctors*".

In our opinion, this is a wrong way of thinking. Actually, it is a contradiction to *professionalism* that is the basis of Medicine's contract with the Society. It requires placing the interest of patients above those of physicians, setting and maintaining the standard of competence and integrity, thus providing advice to the Society on health matters [30].

A **third** issue relates to the usefulness of several tools of *m*-Health for clinical management as the majority of them has been designed to capture data but without meaningful clinical engagement and, therefore, useless.

Fourthly, reimbursement is a critical and not easy to be solved task. Actually, it is an obstacle to the delivery of *m*-Health. The classical fee-for-service scheme forces physicians to return to the in-person visits instead of navigate among often complex rules to determine which digital services are reimbursable and which not as well as the size of reimbursement. Regulatory authorities are in a difficult situation. For sure, they are aiming to facilitate *m*-Health innovations but at reasonable costs [32]. Technology industries also expect a reimbursement based just on proof of functionality, but without proper ad hoc studies showing clear added value. Billing for digital intervention is not easy [33]. In the US, for example, medicare reimburse an e-visit only if the visit was initiated by the patient, when patients' written consent was obtained and a clinical decision was made [34]. All this will increase administrative costs for both the physicians and the administration that has to pay.

A **fifth** obstacle is related to regulatory and liability issues. Maintenance of privacy is difficult, if not impossible, in a digital world. The same applies to the consent of the use of data. There is urgent need of establishing clear rules for delivery of *m*-Health as regulatory and liability are often a barrier for *m*-Health and digital tools in absence of an ad hoc legislation [35]. The pandemic, however, has shown that these barriers can be overcome when there is a clear need, but once the emergency is over, particularly liability controversies will explore.

Despite all these scepticisms, staying away or remaining sceptical about *m*-Health is anachronistic. It should be recognised that future is going to be digital. *m*-Health is just a tool, which can facilitate rather than substitute everybody's/everyday work, not only for physicians but also for all the allied medical professions. It is a duty of medical professionalism and, in particular, of national and international medical societies to drive the development and to incorporate *m*-Health into everyday practice. This means a common and synergic approach from all stake holders to move forward and strategically plan how *m*-Health should be developed, how to evaluate a concrete added value, and when, where, and how it should be applied.

Nothing, however, will really improve without the enthusiasm of the medical professionals. An ESC survey in 2019 reported that cardiologists are "fairly" familiar with digital tools but not with *m*-Health. They claim that they are too busy and do not have enough time to dedicate to *m*-Health, apart from using, in a rather passive way, basic functions of smartphones to communicate with their patients by short messaging or voice calls [35]. As a result, and this is the **sixth** obstacle, there is the tendency to produce over-engineered solutions, detached by contextual medical factors and by the complexity of the problem that often needs to be solved. The majority of the apps are not fully professional, thus physicians use only few of them. Most downloads are never opened and consistent continuous use is rare. This is true also for allied professionals, such as nurses, technicians, and students. Not surprisingly, the most visited apps by physicians are those related to conferences (*i.e. those that follow a conference providing proceedings*), diagnosis and treatment as well as those linked to guidelines. The apps related to education, monitoring, motivation, nutrition, lifestyle, etc. are more visited by patients. Unfortunately, these lasts are mostly detached from the diseases, focusing mainly on behaviour changes and are not integrated with the medical system. The underlying scope of the producers is to reach a rather large audience and not the specific stakeholders. This is wrong because the inability to address specific problems and to be connected with the entire health system results in early abandonment and scepticism in the entire technology. A proper development of *m*-Health involves a multidisciplinary collaboration among researchers, clinicians, non-health-specialists, engineers, patients, anthropologists, psychologists, communicators, ethics experts, etc. which will provide a user-centre approach instead of over-engineering solutions. Once again, all of this needs a precise methodological approach, proper time and dedication. The lead must come from the medical arena, which represents the expertise and has the data. Indeed, it is not the work or the enthusiasm of one doctor, but the vision of large medical national and international societies as well as that in Europe, at least, of the European Parliament.

ROLE OF *m*-HEALTH IN THE CONTEST OF THE COVID-19 EPIDEMIC

The unexpected and abrupt spreading of COVID-19 infection has found the world totally unprepared. Great concerns were immediately raised about the readiness and capacity of health systems to respond to the pan-

demic. This has speed up interest and appreciation for the use of *m*-health in several areas [36].

The most relevant use of *m*-health was and still is for **instantaneous contact tracing** [37]. The current virus is less virulent but more infectious than previous coronaviruses with high tendency to mutate. As a result, SARS-COV-2 has a greater epidemic potential because the spread is fuel by mild or asymptomatic cases making difficult to trace pre-symptomatic infections. This seems to be true also in vaccinated people who can be asymptomatic but still infectious as vaccines do not conferee total immunity. Therefore, precaution, such as social distancing and, when necessary, quarantine as well as decontamination, wearing masks, and hygiene measures are still, in absence of specific drugs (*which could be available soon*), a way to limit virus spread. To implement the most drastic measures at the right time (*the earlier, the better*), it is critical to understand routes and timings of the infection transmission, i.e. instantaneous contact tracing [38]. Digital contact tracing, especially if widely developed, seems to be more effective than traditional methods of contact tracing. Several COVID-19 apps are available and have been successfully used by governments. These applications have been developed using different mathematical models for infectiousness to estimate the basic reproductive R0 and to quantify the weight of different transmission routes [39]. Not surprisingly, privacy concerns have been raised, especially about systems that are based on tracking the geographical location of the app users. Less intrusive alternatives have been developed, including the use of Bluetooth signals to detect users' proximity to other mobile phones. Google and Apple have integrated the functions to support such Bluetooth-based applications directly to their operating systems. They have also produced specifications of the core technologies based on a combination of Bluetooth low energy and private preserving cryptography [40]. Although there are small differences among the applications, the basic principle is the following: the contacts of an individual using the app, are traced using GPS co-localisations with other app users. Then, when and if any individual linked by the app requests a SARS-COV-2 test (*using the same app*) and the test results positive, the app immediately triggers a notification to all the individuals who have been in close contact as well as to the relevant health providers. One of the problems is inevitably related to false positive results, which would trigger unnecessary worries and reactions. Another problem is the potential lack of effectiveness if the system is limited to a small fraction of the population. Data ownership, privacy, and ethics are the other issues, particularly once the threat has passed. A set of principles and conditions have been provided and approved by several governments to overcome those problems [38]. Apple and Google have agreed to remove the tracing mechanisms from their operating systems once it is no longer needed [39]. Another way to avoid these problems is to use a centralised network tracing location instead of apps, eliminating the need of download the app and the risk of tracking information other than those related to the infection.

In view of the possible spread of the virus, despite vaccines, it would be useful to have a worldwide accepted system able to trace the pandemic across the world without any border. We are far from this; there are not even central repositories of meaningful data and follow-up of the pandemic situation. Governments are making decisions just from incomplete, constantly changing data spread out by a wide range of sources, not always trustable. This is the reason why ***COVID* Tracing Tracker** has been developed, a database to capture details of every automated contact tracing app around the world. It is far from being a database of infected people but, at least, it provides a list of automated contact tracing up backed by local governments with details on who the producer of the algorithm is, which technology is used, the level of penetration, whether the system is voluntary or not, and, importantly, when the data will be destroyed, and whether are used for purposes other than public health.

Another obvious use of *m*-health, when fighting the epidemic, is to **expand home medical services** [9]. Patients with mild symptoms and without chronic comorbidities may and should be cared remotely, at home. It is essential to establish easy and continuous communication with healthcare providers so that they can check on patients' conditions via *m*-health, telephone or digital solutions. Remote monitoring and telemedicine will help to provide drugs prescription and information on possible side effects, to monitor their effective use and efficacy as well as to observe the progression of the patients' conditions and intervene in person when necessary. Primary care database can be used in digitalised health systems to identify the patient, provide the data to central authorities and public health organisations, tag the patients for follow-up and, importantly, use the digital data for research as still little is known about the novel virus.

Thus, **remote monitoring** has been often used, and still is, during the pandemic, particularly for patients with CVD in whom was not difficult to measure digitally basic parameters such as blood pressure, heart rate, rhythm, etc. [9]. Today, actually, it is technically possible to remotely monitor symptoms, electrocardiograms, heart rate, blood pressure, regularity of heart rate, weight, heart sound, respiratory rate, lung water accumulation, etc. This is helping to maintain a line of

contact and to provide care to CV patients often reluctant or unable to reach for the regular check-up busy hospitals with COVID-19 patients.

During the immediate and acute phase of the pandemic, it was also important to establish **a line of communication** and reassurance even with healthy people, a sort of informative first-point of contact by means of a centralised hotline using online platforms. In China and in several Western European countries, for people at risk or with COVID-19 suspicion or even with symptoms, the first contact with the health system was through an online platform with clear, simple algorithms, to alleviate tension and provide instructions on what to do or not to do, if necessary. This approach was important to protect healthcare workers in primary care centres, to avoid unnecessary hospital or first aid admission, and to reassure the population that was not left alone.

CALL FOR ACTION

m-health is rapidly expanding and is a key to the digital transformation of healthcare. Main targets of *m*-health are patients, physicians and organisations. Several issues have to be revised or solved in the field of m-health. Terms related to this topic are broad, carry ambiguity and, particularly, the definition of *m*-health remains challenging. The technologies included in *m*-health, are designed to achieve easier access to health services and research and to optimise the cost medicines. At present, none of these aims has been reached. Several challenges remain, especially in low- and middle-income countries, related to literacy and limited connectivity. Even in the most advanced countries, *m*-health is sporadically used, even for simple and easy tasks, such as blood-glucose and blood pressure monitoring or for cardiac rehabilitation [41]. In more complex situations, such as heart failure or coronary artery diseases, the value of remote monitoring and telemedicine is still controversial [42]. However, COVID-19 has changed the perception. The present limitations are expected to be quickly resolved and the actual improvement of outcome may not be the endpoint of *m*-health. Just less travelling and inconvenience for patients may be sufficient.

There is a lack of properly performed *m*-health driven trials but we are confident that the evidence based utility of *m*-health will grow substantially in the coming years especially if the Scientific Communities and relevant authorities will set rules on how value the results of *m*-health.

Health services, political institutions, and the entire healthcare ecosystem are called to embrace this innovation. There is the need to solve issues related to liability, regulatory rules, and reimbursement for both physicians and technology developers [43]. Privacy and consents to capture and use of data also need to be solved [41]. Beside these technical aspects, support should be provided to allow physicians to be more confident and to encourage their patients to move forward and use *m*-health. As the majority of tools are produced by "*big tech*" and targeted for wealthy customers, the healthy population will be an important stake holder. In this case, it is important to avoid the so-called "*digital divide*". This wording refers to people with low income and/or with poor access for high speed internet, smartphones or personal computers. They would be totally or partially excluded by the benefits of *m*-health. This is the empty part of the glass, the full size is that *m*-health can be of paramount importance in geographical areas with poor access to healthcare. This is facilitated by the fact that young people are confident with smartphones, while older population may be less so.

Thus, there is the need to reconcile uncertainty of costs for this part of the world population. It is also essential that governments will quickly invest on an efficient EHR system, interoperative across hospitals and clinic and, in the future, even among countries [44]. The process is in progress in the US and few European nations but it needs to be expanded to the whole world. As sub-product, this approach could contribute substantially to generate tracking of the routine out-hospital care of chronic patients, thus familiarising them with interconnection via *m*-health. In this way, *m*-health will strongly contribute to research as an efficient EHR is fundamental for pragmatic-virtual clinical trials [45]. Equally, it is hopefully that regulators will determine the proper trial designs, the validity for final drugs or interventions approval, etc. [46]. Only when all this is in place, it will be possible to clearly determine, in terms of objective outcome, the real added value of *m*-health.

CONCLUSIONS

m-health represents a fertile ground of opportunities and not just of challenges. However, there is a strong need of a more enthusiastic involvement of doctors and scientific institutions. The society expects clinicians and healthcare system to govern the changes and to use the available data for diagnosis and treatment. Science may be also essential to produce objective knowledge of "*what works*" and "*what does not*".

In the last years, the COVID-19 pandemic has speeded up an unbelievable change in the delivery of healthcare which has been dormient for decades [46]. *m*-health, during the crisis, has been essential to maintain a line of communication between doctors and patients via telemedicine and remote monitoring. Another major contribution has been the instantaneous contact

tracking. All of this will remain as indicated by the fact that Apple and Google are mobilising huge investments and teams to build up their own system which could be used by millions of people worldwide.

We need to accept that the future will be digital. Unless we move rapidly towards *m*-health models for medicine, the healthcare system will continue to be suboptimal, non-patient centred and unnecessarily costly. But more than anything else, it will be responsible for not capturing the potential of the existing technology around us.

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Conflict of interest

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