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Digital Technologies in healthcare: promises and challenges

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Abstract. Digital technology holds promise and has the potential to revolutionize healthcare and drug development by changing the way we collect, process and visualize health data. The potential uses are diverse, have applications in many therapeutic areas, and are likely to develop rapidly. The ultimate goal should be a better understanding of disease variability, response to treatment, and lower health care costs and more efficient clinical research. In addition, the introduction of new ways of collecting data remotely can provide new treatments and care management for all patients in need. The challenges associated with the adoption of digital technologies are significant. The scientific community will benefit from frequent exchange of information to share results and lessons learned; this will facilitate the development and implementation of best practices for technology deployment, data collection, analysis and interpretation.

Key words:digital thechnology, smartphones, wearables, digital therapeutics.

1. Introduction

Digital technologies are powerful tools that hold promise in clinical medicine and healthcare. However, their successful implementation will require assistance: well-trained and qualified specialists with the necessary medical and statistical knowledge. Discussions among stakeholders in academia, industry and health authorities, as well as the development of new statistical methodologies for the design and analysis of clinical research using wearable devices and digital medicine products, will be inevitable to make progress in this direction.

It is not that innovative technologies for measuring treatment outcomes using digital or electronic means are particularly new. In the early 1960s, a Holter monitor became available for use to measure cardiac ECG activity. At first, these devices were not digital or even portable. But today a Holter monitor is clearly a digital device that can be used to monitor your ECG, but can also be used to record ECG endpoints. Is a Holter monitor the first digital medical device? If not, then it is in use. However, we can say for sure that it will not be the last.

Time goes by and you start to see that Fit Bits are in vogue. People record steps, vital signs, and other things to keep track of their health. It doesn't take long to realize that if a person can do this using a telephone, then we should be able to easily collect such information for clinical purposes. Why is it important? Well, that could mean fewer or shorter patient visits. Continuous 24-hour monitoring has become more affordable. All sorts of possibilities appeared. But more exciting is that there may be subtle ideas that could revolutionize medicine. Improved data quality and improved assessment of clinical outcomes can have major implications for clinical trials - improved accuracy, reduced need for clinic visits, shift from treatment to prevention, simplified clinical decision-making, etc. However, these promises are necessarily challenging - more data does not always mean more accurate data, and data analysis must be done properly for results to be convincing.

This article attempts to unlock the potential of smart digital devices in clinical medicine and healthcare to facilitate the development and implementation of best practices for technology adoption, data collection, analysis, and interpretation.

2. The use of smartphones and their components as part of emerging imaging, sensing, and diagnostics tools

These emerging advanced mobile measurement capabilities supported by smartphones will be of great benefit to professionals in various fields, including, for example, microbiology, telemedicine, epidemiology and others. Some important examples of this have been demonstrated by various researchers over the past decade [1].

One of the most important factors behind all of these important advances is economies of scale. According to the International Telecommunication Union (ITU), by the end of June 2017, there were approximately 7.7 billion mobile cellular phone subscriptions worldwide. About 10% of these subscribers are located in the least developed countries, whose resources are extremely limited.

Another key factor in using smartphones for advanced measurements is that they are equipped with at least one high quality complementary metal oxide semiconductor (CMOS) image sensor. These image sensors are associated with camera applications that provide various adjustable settings including, for example, exposure time, frame rate, white balance, and focus. It is even possible to capture images in raw format using smartphones, allowing more advanced computational image processing techniques, including holography, for example, to be implemented on a mobile device. This is also ensured by another key attribute of smartphones: they also serve as personal handheld computers where reconstruction and image processing algorithms can be integrated into specially designed mobile applications, and the results can be obtained locally without the need for data transfer, which is useful for medical applications of care in places with limited resources.
A key benefit of using smartphones as biomedical sensors, imaging devices and diagnostic tools is that smartphones enable ubiquitous data transmission and spatiotemporal labeling and exchange of received information such as sensing or diagnostic data. This simple butvery important feature can be used to detect and monitor outbreaks by collecting and using large datasets generated with mobile phone measurement tools from regions and communities affected by, for example, infectious diseases. This data and analysis can be shared with public health authorities to coordinate staff, prevent transmission of disease to other communities, and manage public health crises and emergencies.
Today, thousands of smartphone applications have been developed for practitioners and patients, which help mainly in daily clinical practice, communication with patients, education and access to electronic health records. Some of these apps are used for prescribing drugs, which helps reduce prescription errors and provides information on drug guides, drug formularies, and drug dosage calculations. Another valuable use of the connectivity and ubiquity of smartphones in medical diagnostics is to monitor the physical parameters of people using wearable technology or peripherals via smartphone apps. Smartphones are used as one of the main platforms for collecting, displaying and/or sharing biomedical data from wearable devices.
There are also several connected or monitored smartphone sensors that have received US Food and Drug Administration (FDA) approval. For example, Dario is an FDA-approved platform consisting of a smartphone app and a blood glucose meter. Another example, among others, is a Wi-Fi-enabled thermometer that uses 16 infrared sensors to measure the heat emitted from a person's head, and the results are synced to a smartphone via a mobile app. In addition to optical imaging and sensing instruments, Philips has demonstrated a smartphone-based ultrasound scanner. It uses a portable ultrasound sensor that is connected to and controlled by a smartphone (via a specially designed mobile app) to acquire images of deeper parts of the human body (e.g. kidney, aorta).
These and other innovative applications of ubiquitous mobile phone-based measuring instruments are opening up new possibilities for point-of-care, telemedicine and other applications.

All of this research and development is helping us democratize cutting-edge instrumentation that is usually limited for use in well-resourced settings and will continue to create transformative opportunities for improving medical practice, especially in resource-limited settings. Equally interesting are the many possibilities that smartphone-based tools open up for cost-effective learning and teaching for future generations through hands-on, experimental training programs.

3. Using wearables in healthcare

The development of innovative wearable technologies has generated great interest in new data collection tools in medical and biopharmaceutical research and development. Wearable devices have been found to have many uses in a number of therapeutic areas; however,researchers face many challenges in the clinic, including scientific methodology as well as regulatory, legal and operational obstacles.

Wearable devices can collect data on a 24/7 basis, in a natural environment as people perform their daily duties at home and at work. Data collection can be improved with digital diaries that capture key personal health and lifestyle characteristics. The best-known wearable devices are commercial fitness trackers that collect mobility data and some vital signs data [2]. Such wearable devices cannot be marketed as medical devices unless the characteristics of the device have been determined prior to being marketed. This is a big improvement over traditional health-related data collection tools. For example, basic physiological data such as vital signs and telemetry are traditionally collected only during doctor visits or as part of clinical trials for a medical product. These data represent a very limited snapshot of human phenotype and physiology. Conclusions about human health are made on the basis of extrapolating such a picture over long periods of time, perhaps weeks and months.

This extrapolation is also based on patients' recollections of incidents prior to the office visit. Decisions about a patient's health, disease status, and treatment are made by comparing data collected from doctor's offices with population averages, which may or may not be relevant to an individual. In addition, there are well-known problems associated with the measurement of vital signs in the clinic, including white coat hypertension [3]. There is growing recognition that population values need to be adjusted for factors such as age, gender, medication status, demographics, and other factors [4]. These adjustments can be made if data are available for specific subpopulations of interest. It can also be done using the patient's own baseline data collected over long periods of time, allowing for a precision medicine approach. Data, often collected over extended periods of time, can provide a deeper understanding of disease variability, which is likely to be an important factor in treatment response variability. Having larger, denser datasets will help characterize variability within and between patients.

In addition, there is growing evidence that replacing paper diaries with electronic versions can significantly improve the quality of subjectively reported outcome data [5-7], such as pain and functional status, by ensuring compliance, timely data collection, and exclusion of secondary data.

input errors and reduced administrative burden [7]. The replacement of paper diaries and patient memories with electronic means of data collection is likely to continue and expand as technology advances in the future. Moreover, wearable data, when combined with other data such as genomics or other high-performance technologies, can create a comprehensive, multi-layered picture of human health and can deepen our understanding of how to combine genotyping with deep phenotyping.

In theory, wearable devices can be widely used in therapeutic fields for deep phenotyping, detection and interpretation of adverse events, quality of life assessment, and performance measurement. Wearable and digital approaches can provide signal detection for conditions such as depression by measuring increased sleep or decreased activity, signs associated with depression. For example, it has recently been proposed to use wearable devices to detect early signs of Lyme disease [6]. Any therapeutic intervention that can affect quality of life can benefit from movement measurements or, in some cases, when a patient diary is required. One example is the collaboration between PatientsLikeMe and Biogen to more accurately characterize patients with multiple sclerosis, where activity and mobility are clearly linked to quality of life. Some therapeutic areas may not require the use of wearables, but rather simple mobile phone applications such as the Apple ResearchKit.

Since many wearable devices can easily measure heart rate as well as blood pressure, the cardiovascular therapeutic area is the main focus of wearable devices. Cardiac monitoring in both healthy individuals and specific disease groups allows for 24/7 monitoring of cardiac events and provides more informed care. Areas of cardiovascular disease in which wearable devices have been used or could be used include congestive heart failure, hypertension, and arrhythmias. For example, Zio Patch (iRhythm Technologies, San Francisco, CA) is a single-lead, continuous-recording, ambulatory adhesive tape recently approved by the FDA. In a recent study, 14-day heart rate monitoring of heartbeats gave 57% greater diagnostic value than standard 24-hour Holter monitoring [8].

Neuroscience uses a variety of wearable devices, including monitoring sleep, cognitive and motor impairments. Wearable devices typically measure selected sleep parameters and activity. The use of medical devices for evaluating patients with obstructive sleep apnea outside the laboratory is steadily increasing [9]. IBM Watson Health and the American Sleep Apnea Association launched the SleepHealth app to conduct research to uncover links between sleep habits and health outcomes. This app will record movements and heart rate during sleep and track the relationship between sleep quality and daytime activities, alertness, performance, general health and wellness. It will compile the largest collection of sleep data to date. Parkinson's disease is another area that has shown promising results and understanding with wearable devices and machine learning techniques. Wearable sensors can be paired with mobile phone apps to measure symptoms such as tremor, balance, gait, memory, and certain vocal characteristics.

There are examples of the use of wearable devices in respiratory diseases, immunology and rheumatology. For example, GlaxoSmithKline (GSK Philadelphia, PA) (in collaboration with

Medidata and POSSIBLE Mobile) is starting a rheumatoid arthritis study called PARADE8. It is expected that 300 patients will be assessed using a mobile app that tracks common symptomsof rheumatoid arthritis, such as joint pain and fatigue, and collects this data through a combination of surveys and sensor-assisted tests (such as motion recording with wrist exercises). This trial collects data about the daily lives of people with rheumatoid arthritisto gain insight and learn more about the condition. The WristOx2 from Nonin Medical (Plymouth, Minnesota) is a pulse oximeter that monitors and measures heart rate and blood oxygen levels for people with asthma who are at risk of chronic pulmonary obstruction. Novartis (Hanover, NJ) has launched an observational study with Qualcomm Life (San Diego, CA) collecting biometric data from chronic lung patients in their homes using smartphones connected to Qualcomm's cloud-based 2net Platform.

Another area of therapeutic concern for wearable devices is metabolic disorders, including diabetes and obesity. A recent systematic review of mobile health-related research on diabetes and obesity treatment and management found that more than half of the reported benefits of interventions are based on primary outcomes [10]. Accurate glucose monitoring is currently under development as it is not always available in smartwatches, but several companies are developing prototypes. For example, Dexcom (San Diego, CA) has developed a continuous glucose monitoring application that uses a skin implant with a sensor capable of monitoring blood glucose every 5 minutes, eliminating the need to prick fingers. The Freestyle Libre Flash Glucose Monitoring System from Abbott (Abbott Park, IL) is a wearable skin sensor that has received regulatory approval. A recent pilot study of a patient-centered diabetes care system using smartphones showed that application of the system for 12 weeks in patients with poorly controlled type 2 diabetes resulted in a significant reduction in HbA1c [10].

The promising potential of wearable devices has received tremendous attention, including the initiation of experiments [11], and a number of deals have been announced between biopharmaceutical companies, contract research organizations (CROs) and device manufacturers. However, the significant impact that digital technology is expected to have on biopharmaceutical research and development has not yet occurred [12]. Reasons for the lack of major change include scientific, regulatory, ethical, legal, data management, infrastructure, analysis and security issues.

4. Digital therapeutics represent as a new treatment modality

Digital therapy can be defined as "a medical discipline and treatment option that uses digital and often online healthcare technologies to treat a medical or psychological condition." For example, a digital therapy tool can be a smartphone app that stimulates diet or exercise behavior change, or an app for effective disease management through adherence to medication, which can also help predict exacerbations of the disease and reduce the frequency of symptoms [13]. A key feature of digital therapy is that the individual treatment strategy is “optimized” (for example,by applying machine learning methods to the observed data of the individual), thereby actualizing the principle of personalized medicine.

Digital therapy appears to be eminently suited for the digital delivery of clinical therapies that are otherwise conducted in face-to-face meetings with therapists, such as cognitive behavioral therapy, clinical hypnotherapy, or clinical physiotherapy. The digital delivery of such treatments, for example via a smartphone, tablet, or even a consumer virtual reality headset, can have several important benefits:

1. Digital delivery facilitates access to therapeutic content for users or patients. Many of these treatments include exercise therapy, and accessing them through such exercises on personal mobile devices allows patients to exercise anywhere and anytime they have 15 minutes, as opposed to more stringent time limits and the timing of the appointment with the therapist.
2. In view of the above, behavioral therapy has often been successful in treating mental disorders, and therefore access to therapeutic treatment may be associated with a certain level of stigma. In such cases, it may be more difficult to explain to the immediate personal or professional environment of the patients the need for frequent visits to the therapy room, compared to accessing therapy content in the privacy of the patient's personal time and environment.
3. Moreover, according to our previous definition, a key feature of digital therapy is the personalization of therapy based on observed results, progress or other indicators. Since therapy is now delivered and available digitally, the digital therapy platform can assess individual characteristics, progress, or mastery of specific subjects or topics of therapy at a much more granular level, allowing for even more personalization.
4. It is important to note that the benefits of "personalized therapy" should not be limited to the use of digital therapy tools alone; if digital therapy allows you to track a patient's progress through some kind of dashboard, then when a patient visits a therapist or clinician as part of his/her therapy, the data collected by the digital therapist can be used by the therapist to personalize their therapeutic intervention to a much greater extent than without him. This integration of digital therapy into the overall patient care can be critical to the ultimate treatment success.
5. Finally, when such therapies are delivered face-to-face with therapists, the quality of the intervention can vary greatly [14], while digital delivery of the therapeutic agent ensures consistent quality of the therapeutic intervention.

To highlight one specific example, digital therapy technologies can be used to effectively deliver therapeutic interventions based on cognitive behavioral therapy (CBT). Pear Therapeutics has used CBT to develop a digital therapeutic agent for the treatment of substance usedisorder. Omada Health has developed a digitized version of a proven 16-week CBT program to help patients lose weight and reduce their risk of obesity, hypertension and diabetes [15]. Over the years, CBT has proven to be effective in treating many conditions, including insomnia [16], schizophrenia [17], anxiety and depression [18, 19], obesity [20], non-alcoholic fatty liver disease [21], and many primary indications associated with these conditions, such as chronic obstructive pulmonary disease [22], peripheral arterial disease [23] and psoriasis [24]. Given the operational complexity of providing high-quality face-to-face CBT in clinical practice, we believe that the needs of patients in general may not be adequately met, and that digital therapeutic delivery of CBT can significantly improve treatment outcomes in these many and varied settings.

Another related example of the use of digital therapy technologies is cognitive learning. A large library of cognitive training exercises has been around for decades, but it is the ability of digital therapy technologies to personalize cognitive training on an individual basis and to select exercises of increasing difficulty based on current cognitive functioning that has enabled companies in this space to achieve impressive results. treatment results. For example, Akili Interactive recently reported on the positive effects of video game training on the cognitive control ability of older adults [25]. The gamification of therapies can also hold promise in pediatrics, as children and adolescents generally readily interact with gaming systems.

However, digital therapy does not have to focus only on mental functions. The same platforms can be used to efficiently deliver and personalize physiotherapy treatments that are typically performed in a clinic. Companies such as Jintronix and Reflexion Health have developed platforms that provide, track, and personalize physical therapy using game consoles in the context of postdischarge rehabilitation [26].

Finally, the use of technology to develop digital therapy should not be limited to applications for mobile devices and game consoles; in particular, the use of consumer virtual reality devices seems to support truly immersive therapeutic experiences - sometimes with impressive clinical results.

In the field of bioelectronic medicine, electronic devices are used to modulate the behavior of individual cells, usually by initiating a targeted response in the nervous system. The field itself may have been around for many years, with earlier applications such as the use of transcutaneous electrical nerve stimulation (TENS) for transcutaneous pain relief and the use of electrical stimulation to restore the nervous system [27].

5. Conclusion

Continuous development and miniaturization of digital technologies is a constant driver of innovation. The ubiquitous presence of mobile technology in our daily lives makes it much easier to access any services and content, including those that are of a therapeutic nature. With the advent of the cloud and better data privacy protection, healthcare data can be transferred safely and efficiently between patients and healthcare providers. The gradual miniaturization of sensory technology allows for personalized medical interventions; each new sensor offers a new therapeutic intervention during the course of the disease.

Today science and technology have reached a state where discoveries and advances in medicine and health care will be made much faster. Now we see that digital technologies will be revolutionary and have a great impact on the practice of medicine in the future.

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