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Digital Health: The Wearable Devices and the Internet of Things

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Abstract: Wearable devices have recently received considerable interest due to their potential to greatly impact health. They may stimulate a broad population to pursue life-long health enhancing physical activity, fitness and improve individual performance. A wide range of mobile devices are being developed for real-time non-invasive monitoring, for example heart rate, blood pressure, electroencephalogram. Here we review recent biomedical research utilizing wearable technology in the context of the principal areas of medicine (cardiovascular, diabetes and neurology) and some areas requiring further considerations by the field will be discussed. The doctors and the nurses must be prepared to manage the relationship with patients who more and more often will submit the mobile devices data obtained, running thus the risk of being overwhelmed by an enormous mass of information and new responsibilities in a context of greater uncertainty and confusion. Moreover, there is also the possibility that the patients excessively rely on self-monitoring and the mantra of "do-it-yourself" diagnoses, actually not very reliable and in any case not easily inferrable simply from the data analysis. In fact, there are still many uncertainties relating for example to the accuracy of the obtainable data, the treatment criteria and the actual value in terms of improvement of clinical results compared to traditional therapy.

Keywords: Wearable-Device, Non Invasive, Biosensors

1. Introduction

The main tools of digital medicine, in addition to electronic folder technology, online services (consultation of diagnostic or specialist reports) and tools used for patient interaction (e-mail, sms, social network) are all wearable devices (WD) consisting of one or more biosensors, inset in clothing items such as watches (smartwatch), T-shirts, shoes, pants, belts, bands (smart clothing), glasses (smart glasses), which can detect and measure different biological parameters (heart rate, respiration, oxygen saturation, body temperature, blood pressure, glucose, sweat, breath, brain waves) and provide information on lifestyle (physical activity, sleeping, feeding, calorie consumption).

WDs can send an initial feedback to those who wears them, usually through smartphone applications, hence to the cloud service of competence, where they are organized through algorithms to be available and interpretable by the user or by other figures, i.e. doctor or his team.

WDs are a high growth potential category. In the United States only 2-4% of people have one, but it is estimated that 115 million units will be purchased this year with a total proceeds of 50 billion dollars [1].

The growth of these devices is fueled by various factors, i.e. the ever-lower costs, technological improvements and even the fact that devices are sometimes considered out-and-out status symbol. Technology has allowed to miniaturize the electronic components making the devices so light and small to be wearable or integrated into the clothing.

2. Areas of Usage...Wearable...but Where

Leaving out the basic questions here on the highly ambivalent relationship between digitalisation and democratization, it appears clear enough the potential of a technology that makes it possible to perform diagnostic tests and to monitor individual bodily functions both in the context of care and remotely (*Point-of -Care Testing*).

The "sensorisation" is now part of the daily lives of many people, especially for "healthy" users who trust in a life management as a measurable phenomenon through specific tools. An example of this is the development, within a broad cultural movement, of a global network of enthusiasts called quantified self, whose slogan is "self-knowledge through numbers" [2].

More specifically here the attention is focused on the "practical" applications of new technologies usage in a more strictly clinical context.

2.1. The Most Classic Areas: Cardiovascular, Diabetes and Neurology

Wearable sensors, not placed on the classic bracelets, based on photopletismography and radar technology, for example can measure continuously and non-invasively the arterial pressure (AP), evaluating the variations according to the patient's activities on a day by day basis, minute for minute, in addition to the classic night-day circadian trajectories. The pressure data can be aggregated and displayed on the smartphone, in an instantaneous way, to obtain a direct feedback for the user. In the near future, the use of voice assistants is foreseen through the machine learning to analyze the trends of the single individual along with other covariates such as sleep, physical activity, weight, diet, co-morbidity, therapies in place, and that activate graduated, personalized therapeutic approaches aimed at the patient or the carer.

In consensus documents highlighted the potential of IDs in the recognition and monitoring of atrial fibrillation (AF) [3], although the accuracy of the signal - good in arrhythmia detection - is not always adequate in monitoring heart rate. Promising results have been obtained above all through the use of sensors equipped with both photoplethysmographic and ECGraphic technology.

As for the diabetes management, although the prospects are fascinating, especially with regard to non-invasive enzymatic methods such as contact lenses for tears [4], the improvement of wearable devices is still under development.

Several studies evaluated with encouraging results emerging technologies for the long-term monitoring of EEG in epileptic patients in various contexts and especially for a possible use in the home environment [5].

WDs can allow predictive diagnoses highlighting early symptoms, for example in Parkinson's disease, also by means of voice analysis tools [6, 7]. In Parkinson's disease advanced motor disorders such as gait abnormalities, *freezing*, balance disorders have also been studied especially in situations that are difficult to be explored, for example during the night. This could be useful to evaluate the effectiveness of therapy more accurately. However, at the moment, the clinical benefits for the patient are not precisely highlighted.

The EEG detection was also used to quantify the sensation of pain through specific algorithms, obtaining useful information such as objectifing the duration of action of analgesics. Studies are underway to compare this information with those of the common subjective scales [8].

2.2. IoT (Internet of Things)

The integration among connection technologies between smartphone and biosensing and the availability of the so-called home utilities is specifically transforming "where" the care will be provided in the years to come, especially for patients suffering from chronic diseases and hardly transportable from their own home to the hospital. The so-called Internet of Things (IoT) has the goal of creating the smart medical home, characterized by the development of floor level and wearables sensors, cameras and infrared devices, which can assess the risk of falling and the walking condition in general, or else recognizing the fall by warning signs for remote care givers or reference centers. In the smart home AP, HR, body weight, urine and feces can be analyzed when the patient sits on the toilet. Sensors are also available placed between the mattress and the sheets, able to automatically record the data relating to sleep and send them via a bluetooth connection to an app on a smartphone or tablet. The sensor recognizes when the patient lies down and automatically starts monitoring, collecting and analyzing the duration and effectiveness of sleep, the HR, breathing, movement, snoring, temperature and humidity in the room.

Machine learning algorithms would be able to identify and analyze the introduction of food and combine that information with the passively monitored weight variation, at floor or toilet level, to realize individualized diet plans also taking into account caloric consumption. The accuracy of the food introduction is however difficult to assure. For example, it may be difficult for the common user to identify and quantify the individual components of complex foods [9].

The FDA (Food and Drug Administration) approved the first "digital" drug, an aripiprazole pill, called *Abilify MyCite*. It contains a sensor that when in contact with gastric juices generates an electrical signal transmitted to a patch placed on the patient's abdomen. The patch receives the signal and transmits it to the smartphone that will be able to record the actual intake of the drug [10].

Sensors of facial recognition, video, mirrors-video that can analyze the swallowing itself of the drug are being developed. Devices able to trace the breathed air with inhalers are already available for patients with asthma and COPD [11].

3. Wearable... but...for Whom, and How Much “Able”

It is to be underlined the prevalence of studies on the feasibility of sensing: no large-scale trials have shown a positive impact on clinical outcomes [12]. The technological possibilities are still under development, many doubts remain regarding reliability and validity, security and privacy. The possible "recording artefacts", the lack of standardization and calibration of the devices, the non-optimal estimation for instance of physical activity and energy consumption are still to be resolved [13].

As a rule, studies on the use of WD involve small numbers, are short-lived, often conducted by their developers or structures with direct financial interests hence not by independent researchers. Not rarely they are based on the results of reported experiences and they are not conducted in the real world settings. No possible negative effects data are available. Studies against the placebo are missing, so given the close relationship between people and their smartphones, it is believed that part of the positive responses depend on a "digital placebo effect". No definitive analysis on the cost/effectiveness ratio are available in the practice and about the actual ability/willingness of people to take care of their own health. Acquiring data for the elders presents difficulties, or at least problems such as not to allow intensive monitoring.

Safety and Privacy: Data, theoretically owned by the device users, in reality are registered and deposited by the manufacturing industries. Furthermore, data security and anonymity are not generally guaranteed. Subject's "digital traces" such as behaviors, biological parameters and position are detected by means of complex algorithms. Mostly possible information on sensitive areas, at risk of stigma, for example mental disorders, vulnerable targets and sensitive data are easily intercepted and manipulated to discriminate, predict or influence people's choices or to ask for higher insurance premiums [14].

In Europe, apps for diagnosis purpose, treatment and prevention are equated with real medical devices hence subjected to specific regulations. Moreover, there are critical issues regarding quality certification, privacy and bioethical aspects. In fact, wearable sensors accumulate large amounts of sensitive information that can be accessed without the consent of the interested parties. For a summary about the issues related to the privacy of the apps using health data, please refer to the release issued by the Information Commissioner's Office (ICO) of the United Kingdom [15].

4. Discussion and Conclusion

The interaction between device and patient is complex and studies to evaluate the types of subjects that can actually benefit from it are needed. Beyond a focus on clinical efficacy, new types of pragmatic trials using the principles of machine learning and digital interfaces should interact with standard methods of diagnosis, monitoring and treating in order to obtain a real understanding of the data, all of that in a strictly, contextualised and personalized way [16]. The use of Wds pose a problem of effectiveness/efficiency, but also how to change the cultural paradigm and use the new sensorial apparatus: "They are not just tools to calculate the number of steps or the amount of burned calories, but tools by which we are constructing our new idea of human subjectivity" [17].

Industry is investing a lot in new technologies, but in the clash between interests and values it is well-known that the former are destined to prevail. However, the future is not completely determined. We can intervene on its development trying to reintroduce into the culture of medicine an explicit dialectic and a comparison of thoughts, methods and objectives necessary to deep into the merits of the paths, the management of planning and the defense of citizens/patients avoiding a sort of power point logic characterized by "given" communications, fashionable presentations of reality considered in an optimistic and definitive manner.

The General Practitioners and the nurses must be prepared to manage the relationship with patients who more and more often will submit the WD data obtained, running thus the risk of being overwhelmed by an enormous mass of information and new responsibilities for example concerning the expectations in technology. Moreover, there is also the possibility that the patients excessively rely on self-monitoring and "do-it-yourself" diagnoses actually not very reliable and in any case not easily inferrable simply from the data analysis.

Let us not forget that our identity is still fundamentally analogical, even though in an increasingly digital world. In this regard it is interesting to point out that the term digital derives from the English digit (referred in this case to the binary code), which in turn derives from the Latin digitus, "finger" (with the fingers we count the numbers). Despite the etymology, the concept of digital medicine has become in practical use an oxymoron: human touch vs its antithesis, contact vs monitoring, with an ever greater risk of losing the doctor-patient relationship.

Glossary

CT (Information and Communication Technologies): technologies relating to integrated telecommunications systems (wired and wireless communication lines), computers, audio-video technologies and related software, which allow users to create, store and exchange information.

Algorithm: sequence of instructions to be performed to obtain the solution of a given problem

Machine learning or machine learning: subfield of artificial intelligence, study of algorithms that improve with experience, "teach machines how to learn"

Cloud computing: a series of technologies that allow to process, store and store data thanks to the use of hardware and software resources distributed in the network

Internet of Things: a network of objects connected to the Internet that can collect, record, analyze and share health data using sensors and other technologies

Applications (apps) for health: application software designed for mobile devices (smartphones, tablets and smartwatch)

Mobile Health: medical and public health practice supported by mobile devices, patient monitoring devices, personal assistance devices and other wireless tools

Point-of-Care Testing: medical examinations on (or near) the patient's place of care

Digital divide: gap between those who have effective access to the network and who are excluded, partially or totally

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