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CONNECTED HEALTH

FROM E-HEALTH TO CONNECTED HEALTH

Recommendations of the French Medical Council

ORDRE NATIONAL DES MEDECINS
Conseil National de l'Ordre

(1) *CNOM: French Medical Council*

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WHY THIS WHITE PAPER?

Currently, the market for applications and connected health devices is undergoing exponential growth. Growth fed by true enthusiasm for digital health services accessible at all times and in all places, enhanced by the ingenuity of designers of solutions and maintained by investments of "big tech".

Doctors, just as all healthcare professionals, cannot ignore this emerging world nor seek to distance themselves from it. In the same manner as the CNOM had invited them to use web health[2] tools, currently it heightens their commitment in accompanying the deployment of the "digital world" applied to health and to adopt the useful and beneficial aspects of it in their medical practice.

At all times of history, doctors have adapted to the progress of science and technology, by integrating the latter to improve the practice of their art.

And yet, this does not mean giving in to technological fascination to the point of not recognising threats which may result for individual and community freedoms.

Today, the majority of players are demanding regulation – even if they do not use similar requirements – and are convinced that connected health will not have a future without an environment of trust. Others persist in believing that the pre-requisites of regulation are vain because, in their opinion, this will be "community intelligence", the result of uses which this regulation will make spontaneously.

The CNOM, for its part, has taken a stand in favour of regulation which requires informing the user so that the latter can retain his/her freedom in this "connected world" and which ensures the reliability of technologies and protection of personal data.

The CNOM observes with satisfaction that this debate has opened to the CNIL[3], in circles of reflection dedicated to digital applications and in the European Commission.

The objective of this white paper is to contribute to it.

It does not provide ready-made solutions, but it contains ethical and deontological questions in the forefront in accompaniment of the progression of our societies and therefore, in this brave new digital world of health.

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(2) White paper on web Ethics, December 2011
(3) CNIL: French National Commission for Data Processing and Freedom

1 RECOMMENDATIONS OF THE CNOM

1. TO DEFINE PROPER USE OF MOBILE HEALTHCARE FOR THE SERVICE OF THE DOCTOR-PATIENT RELATIONSHIP

2. TO PROMOTE APPROPRIATE, GRADUATED EUROPEAN REGULATION

3. TO CONTINUE SCIENTIFIC EVALUATION

4. TO EXERCISE CARE IN MONITORING THE ETHICAL USE OF CONNECTED HEALTH TECHNOLOGIES

5. TO DEVELOP DIGITAL LITERACY

6. COMMITTING A NATIONAL STRATEGY ON E-HEALTH

1. TO DEFINE PROPER USE OF MOBILE HEALTHCARE FOR THE SERVICE OF THE DOCTOR-PATIENT RELATIONSHIP

Healthcare applications and connected devices can comprise additional useful tools in management of patients. They can support and reinforce the doctor-patient relationship. M-health devices, provided that they are reliable, can contribute to improve patient compliance with advice on prevention, lifestyle and healthcare protocols, by facilitating contacts between doctors and patients. Moreover, patients say that they await advice in this area from their doctors.
It will be necessary to define a framework of proper use of m-health tools when they have been integrated into the field of healthcare. The CNOM will contribute by its publications to this definition of proper use and naturally will be associated with the HAS, since this setting for recommendation is part of its mission and expertise.

2. TO PROMOTE APPROPRIATE, GRADUATED EUROPEAN REGULATION

All solutions of m-health do not have the aim of entering into the process of healthcare, but essential requirements in applying them, whatever their use, are based on clear, faithful and detailed information on their functional aspects and conditions for use.
In order that the marketing of m-health tools contain guarantees, the CNOM considers that they must be the subject of declaration of conformity with a certain number of standards.

Such a statement must contain 3 parts: -confidentiality and protection of data collected, -computer, software and material security, - and health safety.
A monitoring system must be set up in order to facilitate reporting of dysfunctions. For the CNOM, it appears essential that regulation take on a European-wide dimension, as is already the case with all existing conditions.

3. TO CONTINUE SCIENTIFIC EVALUATION

The CNOM considers that it is necessary to develop, beyond the sole statement of conformity, a scientific evaluation of solutions which fall within the healthcare course and in the practice of telemedicine, a neutral evaluation conducted by experts with no conflict of interest with suppliers.
Once the evaluation of applications and connected devices in fact would be recognised for their benefits for individual and/or community health, it then would be logical to plan that they be reimbursed by the community.

4. TO EXERCISE CARE IN MONITORING THE ETHICAL USE OF CONNECTED HEALTH TECHNOLOGIES

The development of connected health technologies is going to be accompanied by important major changes and will raise questions of ethical practice that the CNOM considers essential to discuss in the setting of an open public debate. The nascent uses of m-health have already led to occurrence of the first threats to social solidarity and integration, the surveillance and dependence of persons. The CNOM wants to warn all of us about the consequences of the economic model which underlies connected health and is based on valuation of data.

5. TO DEVELOP DIGITAL LITERACY

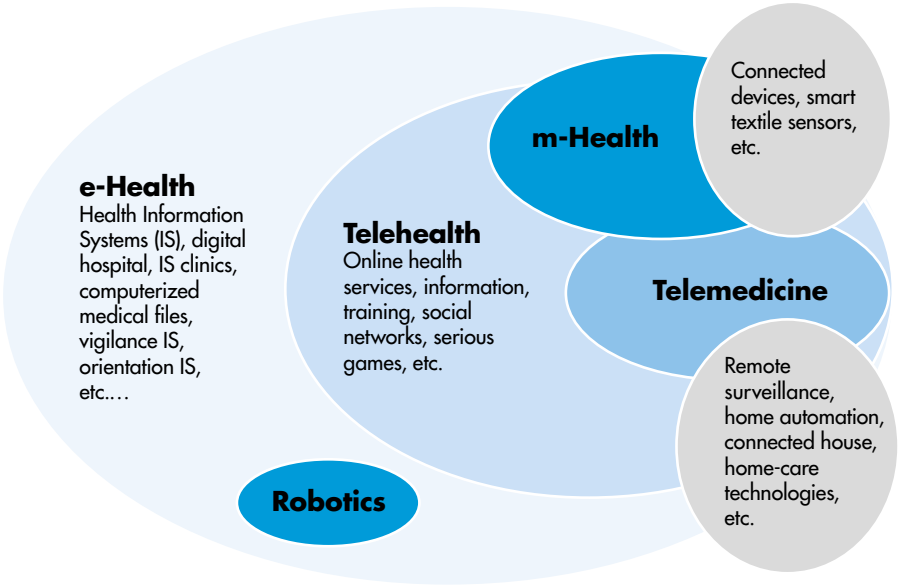
Digital information is doing its best to be part of our daily lives, but it frequently remains opaque. The use of devices appears intuitive, but the true control of their functional aspects, in particular, those relating to confidentiality and protection of personal data, safety of communications, is complex. Education in terms of digital information, in the eyes of CNOM, is everyone's concern: ordinary citizens, of course, for responsible and autonomous use, but also entrepreneurs, who tend to fail to recognise or to overlook frameworks, both legal (regulation), as well as technical (interoperability) in which their innovations fall.

6. COMMITTING A NATIONAL STRATEGY ON E-HEALTH

E-health – and now m-health – must be considered not as an end, but as collection of means, enabling to improve access to healthcare, the quality of management and self-sufficiency of patients. Their deployment must be based on a strategy shared by all of the players. As the CNOM regularly reminds us, a strategic national advisory session placed under ministerial authority would make it possible to clarify the governance of e-health and to uphold the basic principles attached to the deployment, in particular, of ethical requirements to provide information to the patient, to obtain his/her consent in sharing of his/her personal data and respect of confidentiality.

“E-health – and now m-health – must be considered not as an end, but as collection of means, enabling to improve access to healthcare, the quality of management and self-sufficiency of patients.”

2 FROM E-HEALTH TO CONNECTED HEALTH



The boundaries are increasingly blurred in this connected healthcare world and it is becoming difficult or even haphazard to make an absolute distinction between devices, applications (apps) and connected devices used in the field of well-being, of health and in the practice of medicine. However, the debate which opens up in terms of regulation of mobile health apps requires defining its different components and of reminding us of which activities are already subject to regulation.

In 15 years, the application of information and communication technologies to the field of health has led to a rich glossary which regularly borrows from a mix of French and English and designates activities which, although they often intersect, nevertheless are not synonymous.
The use of the words e-health, telehealth and telemedicine continue to cause confusion, as noted by the French National Authority for Health (HAS) in its report issued in July 2013 dedicated to "the efficiency of telemedicine".
This is so, while the World Health Organisation (WHO) starting from 1998, has recommended differentiating the terms telemedicine and telehealth by reserving the term telemedicine "solely for the clinical and curative actions of medicine using telecommunications systems".

WHAT ARE WE TALKING ABOUT?

• e-health

The term e-Health may have been created in late 1999 in the presentation of an Australian study at the 7th international congress of telemedicine. Its author, John Mitchell, then defined it as "the combined use of the internet and of information technologies for clinical, educational and administrative purposes, both locally and at a distance". Its translation into French, e-santé, has rapidly been adopted in metropolitan France starting in 2000, the first calls for a project from the hospital directorate, in the Ministry of Health, to deploy TIC[4], were called e-health.
Since then, the term has entered the vernacular to qualify everything which contributes to the digital transformation of the healthcare system or beyond the sole health sector, the medico-social sector. It has spread by analogy to e-commerce, for example, which has taken the lead during the same period in defining business commercial activities since they then had become dematerialised.
The concept of e-health and this reference to the emergence of a new "business" has been all the more readily retained internationally since, at the time, we were in a period of technological euphoria (the internet "bubble" at the start of the 2000s) from which health did not escape scrutiny. About fifteen years later, we now can observe that a similar frenzy was created from the process of "apps", of connected devices and of the internet for devices. Comparable enthusiasm was found in it by private contractors, with the multiplication of start-up firms and sometimes with inordinate fundraising.

(4) TIC: telecommunications and computer services

• m-health

Six years after dedication of the term e-Health, that of Mobile Health (mHealth or m-health) appeared in 2005, under the signature of Prof. Robert Istepanian, University of London, to designate "the use of emerging mobile communications in public health".

A world-wide phenomenon, mobile health then did not delay in being defined by the WHO (2009) as covering "medical and public health practices based on mobile devices such as mobile phones, systems for monitoring patients, personal digital assistants (PDA), and other wireless devices".

In terms of uses, its scope ranges from the basic functions of a phone (voice and text or SMS (text messaging)) to the most sophisticated functional aspects using the most recent technologies. For an increasing share of the population world-wide, the Smartphone and the tablet computer have become almost exclusive internet access points.

To facilitate the conduct of a world-analysis, the organisation classified the services of mobile health into 14 categories, from call centres to systems of aid in decision-making, including access to information, aid in compliance, a reminder of the next appointment for a patient, etc. and mobile telemedicine. Its last study, on 114 countries, shows that mobile telemedicine, seen from the angle of communication between healthcare professionals, with call centres, is part of the 4 types of programmes most commonly used in the majority of States interviewed. It can also be noted that the WHO definition integrates the notion of surveillance/monitoring of patients.

• Remote monitoring in the field of telemedicine.

In France, telemedicine is defined by law and by a regulatory framework established by the official decision of 19 October 2010. This text describes the 5 component procedures of telemedicine: tele-consultation, tele-expertise, medical remote monitoring, medical tele-assistance, and medical response provided in the setting of medical regulation.

In terms of telemedicine, the expectations with respect to m-health are expressed mainly in the context of medical remote monitoring, due to the potential of technologies to facilitate the monitoring of clinical parameters and the transmission of alerts.

Medical remote monitoring in fact is described in the Public health code as having the objective of "enabling a medical professional to interpret data remotely, necessary for medical follow-up of a patient, and if applicable, in taking decisions relating to management of this patient.

The recording and transmission of data can be automated or carried out by the patient, him or herself, or by a healthcare professional".

Among the procedures of telemedicine identified in France (DGOS[5] mapping of 331 activities, in late 2012), remote monitoring is still relatively little-developed (22% of projects compared to tele-expertise (65% of projects), or even teleconsultation (49%).

World-wide, it involves about 3 million patients equipped with a monitor, under the control of healthcare professionals who were using home monitoring devices as of the end of 2013.

The Berg Insight Institute of Studies, author of this evaluation, considers that this number is going to skyrocket between now and 2018 and increase to over 19 million, with an annual growth rate of 44.4%. Remote monitoring in terms of its leading application (for two-thirds) involves patients equipped with implantable cardiac devices. 70% of messages sent are still based on conventional solutions (for example, the commutated phone network), but the proportion should

"World-wide, it involves about 3 million patients equipped with a monitor, under the control of healthcare professionals who were using home monitoring devices as of the end of 2013."

MARVELLOUS FIGURES

APPLICATIONS

- The world-wide volume of mobile health applications (in the broad sense) has risen from **6,000** in 2010, to **20,000** in 2012 and reached **100,000** in 2013.
- All functions combined, a store such as the AppStore records **500** new applications each month.
- In France, in monitoring of **4,000** health/well-being applications (performed by DMD [7]), it observed that **60%** are designed for the general public and **40%** for healthcare professionals. However, this trend may be on the verge of reversing itself.

THE DEVICES

- Currently **15** billion connected devices exist world-wide and **80** to **100** billion are expected between now and 2020.
- **3** million were purchased in France in 2013, with consolidated sales amounting to **64** million euros (GFK study): scales, watches, wristbands, etc.
- in France, **23%** of persons state that they use a connected device (according to a survey by BVA /Syntec digital), and **11%** may already use them in the setting of health/well-being.

become reversed within the next 4 years to the benefit of mobile technologies.

• Telehealth

This term generally has replaced the term "health telematics" in French-speaking countries, when the latter started to become out of date, in the age of the Internet.
In France, it was the term dedicated by the Lasbordes report ("Tele-santé": a novel asset in the service of our well-being), named after the member of Parliament who was given the task by Roselyne Bachelot, French minister of Health at the time (2009), to identify the perspectives opened up by TIC in health and in the medico-social field, as well as conditions for their surge. Although a good part of his 15 recommendations have come to nought, the Lasbordes mission did however contribute to adoption of an amendment in the PLFSS[6] 2010 making it possible to remove two legal obstacles to deployment of telemedicine: the principle of prohibition of sharing procedures and that of reimbursement reserved for procedures performed in the (physical) presence of the patient.
The Lasbordes report also outlined for the first time what the vast scope of telehealth comprises. "Telehealth is the use of tools of production, transmission, management and of sharing of digital information for the benefit of both medical, as well as medico-social practices". A few examples of application: information, vigilance, monitoring, collaboration, butler services, moderating, training, and dematerialised (paperless) prescription.

• Health/well-being mobile applications

"Appli" in French, or "app" in English, is software specifically designed to operate on equipment such as a smartphone or a tablet computer. Online applications are downloaded from computer online "stores", separate platforms depending on the type of system used (iOS, Android, BlackBerry, etc.).
Boosted by the surge in sales of smartphones and tablet computers, this market has developed considerably over the last few years to become a decisive factor in deployment of mobile health (see the following figures).
The debate in the legal setting to be developed for these applications concerns mainly two questions: to what extent can they be considered as medical devices; and is it necessary to plan specific rules on protection of the collected data?
In the USA, the FDA has authorised about one hundred apps considered as medical devices, about forty of which during the last two years alone.
In Europe, the integration of software into the scope of medical devices (MD) goes back to the year 2007, under the reservation that they have a medical purpose. There is no regulation setting out the respective scope of MD and of applications (this is one of the objectives of the consultation initiated in April by the European Commission). However, guidelines published in January 2012, have helped manufacturers and publishers to clarify the status of their products and services.

• Health/well-being connected devices

It's a real tidal wave! The new industrial Eldorado! Wristbands made to "track" physical activity or sleep quality, scales, tooth brushes, table forks, pill boxes, etc. By means of integration of inexpensive sensors, devices which only yesterday seemed ordinary can now provide unrivalled services because of their ability for measurement and connection.
Certainly such devices have long been used by athletes. What is new today involves two changes: first, access by the general public to all such equipment, now distributed under the most traditional brand names and, in addition, the "medicalisation" of

(5) DGOS: General Directorate of Health care supply
(6) PLFSS: Social Security Finance Bill
(7) DMD: website opinion survey

connected devices, or in any case the claim of a health benefit…which sometimes resembles certain health claims which the food and agricultural industry had already presented to us. Sphygmomanometers, blood glucose monitors, heart rate monitors, etc. thus are side-by-side in the display cases of the connected device, which continues to be a type of gadget. Devices implanted in the human body are starting to appear, such as for example, contact lens which measure sugar levels in the blood or an electronic patch grafted under the skin which analyses the body's vital signs.
It is obvious that these trends are stimulating the appetite of high tech major players, one after the other, that are well-positioned in this market, as seen during the year 2014, by announcing a range of products and proposed platforms.

• The quantified self

A marginal practice or a precursor of transformation of society? Having long remained confidential during its first years in the community of geeks, the movement of quantified self took on an international scale in 2011 at a conference held in California. Initiated by two reporters from the magazine Wired, it also has its followers in France with the author of the "Practical Guide on the Quantified Self". Emmanuel Gadenne has defined it in his introduction: the quantified self "generically combines the tools, principles and methods that enable each of us to better understand ourselves, to measure parameters relating to our body, our health, our general condition or to the objectives that we set for ourselves". It can be added that the principal original aspect of this practice lies in its dimension for sharing or of comparison between followers.

• From self-measurement to ubimedecine

Clearly less publicised by the media or a "trend" than the previous event, self-measurement is no less widespread. "It can be considered that it goes back to the XIXth century with the entry of scales and thermometers into the patient's home", as we are reminded by its principal sponsor in France, Dr. Nicolas Postel-Vinay, founder of automesure.com in 1999. "The novelty of quantified self therefore does not lie in self-measurement, but in the connection", he stipulates. Convinced of the potential offered by m-health, he proposes to conceptualise "ubimedecine" which places the "individual directly in touch with an aid in computerised decision-making".

• And the intelligent house?

NIn the future will our house monitor our

FROM SELF-MEASUREMENT TO UBIMEDECINE

Dr Nicolas Postel-Vinay
Georges Pompidou European Hospital (Paris), Founder of the automesure.com website

The marketing to the general public of new connected devices that can measure healthcare parameters outside of a medical context calls our attention to older approaches such as those of self-measurement of some parameters. In other words, the quantified self blurs the limits between the fields of well-being, health and healthcare, and which fall within a continuum between the normal and the abnormal. In light of these new practices, where the patient plays a major part, the doctor probably will have to take a stand at the outset as being for or against. In fact, currently it is too soon to take a clear decision on the advantages and disadvantages of the potential aspects of mobile health devices because of the little scientific data on this subject.
Having formulated this reservation, the novelty of "connected" health at the initiative of healthcare consumers should not lead us to ignore important medical pre-requisites. In particular, this suggests factual data acquired in the fields of self-management, in the management of chronic illnesses, which have at least twenty years follow-up, including in its uses via the tools of the medical internet and telemedicine. Thus, the question of current interest is to determine how to "connect the two": scientific self-measurement, on one hand, and general public consumerism of connected devices, on the other.
To initiate this reflection, we have proposed the term "ubimedecine" in the setting of a seminar at the Collège de France (January 2012). This neologism aims to designate what may be a medical practice based on the receipt and analysis of healthcare data collected at the initiative of the user, at many times and places. Briefly, a practice whose paradigm surpasses the usual medical settings, such as the doctor's office or a hospital room.
Many questions are raised by these emergent practices: reliability, confidentiality, ethics, conflict of interest, etc. Among the responses which will have to be provided, those of scientific expert reports will be crucial. Only the results of evaluations will make it possible to accept – or to reject – statements claiming one or more benefits of a connected device. Studies will have to determine the utility of sensor devices, and also the relevance of software and algorithms associated with them. For the time being, in particular we lack reliable data, such that too many applications resemble "black boxes". This insufficient knowledge must be corrected because connected healthcare has the goal of producing a direct impact on the behaviour and decision-making of users (patients and/or healthcare professionals). Ubiquitous medicine has the potential to revolutionise the contribution of the traditional organisation of healthcare prevention and the dispensing of care; this is why doctors must take control of this dossier.

health? University professors and research centres have been working on this concept for over 10 years (let us mention research conducted by the TIMC-IMAG laboratory in Grenoble, France) and the first model apartments or prototypes already exist. It involves no less placing sensors with all the imaginable functionalities in every room. Therefore, the intelligent house can take on various roles, such as an alarm system, of course, by reporting a change that deserves the attention of the occupant. But also in diagnosis, for example, by measuring signs of cognitive deterioration.
But this "intelligence" contains a defect, that of appearing overly intrusive, and this is what undoubtedly accounts for the fact that the concept has not yet caught on even though many technologies are already available.

IN THE FIELD OF CONNECTED HEALTH, THE CNOM OBSERVES THE FOLLOWING:

1. A three-fold change. Although it is recognised that the term e-health covers the widest possible category, or is even a catchall term, from use of the internet and of communication and information technologies applied to health in the widest sense (from prevention to treatment, including the online sale of health services or products), it can be noted that its scope has considerably expanded over time. The limits of e-health in fact have been pushed back since the end of the 1990s under the influence of uses for the general public, as can be observed with the advent of m-health and, currently, the expression "connected health". The latter illustrates the creation (expected) of a market, the result of a triple change: sociological, marked by the empowerment of patients; technological (with the proliferation of innovations in technology of smartphones, sensors and connected devices), political and economic (with the search for solutions to improve the efficiency of health systems).

2. A necessary debate on regulation. Why differentiate the various components of e-health and seek to define them precisely? The activities carried out under this term are governed by regulations and different legal frameworks; moreover, some of them are not governed at all.
Yet, the debate on regulation has intensified, in France and just about everywhere world-wide, with development of mobile applications dedicated to well-being and to health. The European Commission has published a "Green paper" and in April 2014 opened a public consultation by which, in particular, it is seeking to take a decision on requirements to be applied to mobile health in terms of security and performance of health applications and the security of healthcare data[8]. Also on a European-wide scale, moreover, the Commission has given itself the deadline of the year 2020 to develop a legal framework for telemedicine which can be shared by all Member states. In this context, and even though France already has a legal definition and a regulatory framework for telemedicine, the CNOM and ANTEL have reminded us that there cannot be any confusion or equalisation between clinical telemedicine and e-health.
An analysis signed by Dr. Pierre Simon and Dr. Jacques Lucas explains why telemedicine is not covered by community law on e-commerce[9].
European guidelines on medical devices are still undergoing review.
In the USA, the area of mobile medical applications is controlled by the FDA (Food and Drug Administration) which regularly comes into the forefront of the scenario. After publishing a Guide to guidelines in September 2013, the organisation announced a proposed loosening of regulation in early August 2014.
France too has performed well where the 1CNIL initiated studies in 2014 by organising meetings on the topic "The human body, a new connected device". Objective: to outline the exploratory poles leading to possible regulation.

(8) Contribution of the CNOM to the public consultation of the European Commission [reference insert]
(9) reference insert

3 CONNECTED HEALTH: USES, BENEFITS AND LIMITS

PROFILES OF MOBILE USERS. WHO ARE THEY? HOW DO THEY USE THEIR SMARTPHONES?

Within a short time, use of the smartphone has taken a firm hold in the heart of doctors' daily practice, as it has increasingly done in the daily lives of patients.

DOCTORS AND HEALTHCARE PROFESSIONALS

• All mobile users, or almost.

Three-fourths of doctors have a smartphone, according to the Cessim 2014 opinion survey, and over 9 out of 10 (94%) use them for professional or combined professional and private purposes, according to the 2nd Vidal-CNOM survey on "Digital uses in health" (May 2013). This is true, whether doctors are general practitioners or specialists, in private practice or salaried position, men or women, and whatever their age.
Two-thirds of persons who have a smartphone have chosen an iPhone. There are also an increasing number who purchase a tablet computer (56%) or state that they intend to do so.
A survey by the Isidore association (March-April 2014) has added that over one out of two mobile user healthcare professionals have both a smartphone and a tablet computer, one-third a smartphone only and 5.1% a tablet computer.

• For which applications?

Over one out of two doctors who use a smartphone have down-loaded medical applications, according to the opinion survey of May 2013. Information on medicinal products arrives at the head of list of uses: in almost 9 out of 10 cases, downloads involve medicinal product data bases and in over 7 out of 10 cases, drug-drug interactions.
The Isidore survey has refined these results by indicating the reason for these downloads. In first place: prior knowledge about the application or its environment. In fact, in more than a third of cases, healthcare professionals state that they have downloaded applications which they used on other media (web, paper, etc.); in almost two out of 10 cases, they had been advised to use them; and for 13%, they knew about the publisher or the author. Only 10% of healthcare professionals were directed to them by advertising, and for 24%, after making a random search.
This survey also tells us that continuing medical education (CME) applications, although downloaded little (1.6%), are among those most widely used (14%).
Moreover, 61% of healthcare professionals state that they are ready to pay for a mobile application, both for a drug database, as well as for recommendations on good practice. Among their expectations, they emphasise the utility of software to access patients' dossiers via a mobile phone.

• How do they use them?

The Vidal-CNOM opinion survey reveals that almost 9 out of 10 doctors leave their smartphone on during an office visit, 81% don't hesitate to answer calls and over one out of two doctors gives his/her smartphone number to patients.
However, according to the Isidore survey, only 24% of them state that mobile health applications have become entirely "unavoidable" in their practice and 40% recognise that they are "probably" unavoidable. Moreover, over 90% of responses showed that their use is still infrequent, with use of less than 5 applications at least once per week.

• And the relationship with patients?

8% of doctors who use mobile devices recommend a health application to their patients, according to the survey "Digital uses in health". This proportion was confirmed by the Isidore opinion survey group which states that 9% of healthcare professionals have downloaded a patient application in order to advise them, 25% to see what it contains and over 60% have never done so…or have done so by mistake!

Only 2% of healthcare professionals have downloaded an application involving doctor-patient relationships and only 1% use it. Thus, the warning of the think-tank with respect to risks of a break in use of digital information between healthcare professionals and patients.

THE FRENCH

• Curious but not yet convinced.

France has 7 million mobile users, i.e. web surfers who download information about their health via their mobile phone or tablet computer. But less than 10% use an application daily. In fact, over 40% of users end up by finding them not useful – and of abandoning them – while 21% have downloaded them out of curiosity, with no real intention of using them.

These results were obtained from a panel of web surfers from a CCM Benchmark opinion survey (March 2014) and were confirmed by the IFOP Observatory of m-health (June 2014). 79% of persons interviewed in fact are not familiar with the application m-health and half of respondents show a limited level of trust. Mobile users who are interested in health applications have downloaded 2.7 on average – and over half are content with only one application – mainly, free of charge applications (87%), located via a search of the internet (29%) or an app store (28%). But, 7% have been advised by a healthcare professional. Finally, 88% state that they are satisfied.

• What are their expectations, and their concerns?

First, it can be noted that high numbers of non-users continue to be reluctant, 67% state that they have no intention of downloading an application.

It is true that they are concerned (44%) about inappropriate use of data and they are not convinced of the usefulness of this software (31%).

But what merit are they ready to give them? The main benefits attached to m-health continue to be relatively vague and general, undoubtedly because of a lack of knowledge of its specific functional aspect: in first place, it involves prevention, followed by the possibility of monitoring one's health, of remaining fit, of being encouraged in an effort to facilitate contact with the emergency services.

• In patients with chronic illness,

mobile health is slightly more widespread than in the general population, as underlined by the study entitled "Searching for the e-Patient". Moreover, a laptop computer and e-mail are beginning to be part of the tools of the long-term doctor-patient relationship. Thus, over 20% of them have their doctor's cell phone number and almost as many have his/her e-mail address. The same study teaches us that one out of two patients with a chronic illness present on the web would like to obtain help from his or her doctor in situating himself/herself in e-health. Almost 16% now expect guidance with respect to mobile healthcare applications.

• Connected devices: attraction and doubts.

Contrary to applications, connected devices are better known: the French have already widely heard about them in the health/well-being field (53% of web surfers in the Benchmark CCM panel, March 2014).

Among the top 5 devices which appear of interest: sphygmomanometres, scales, wristband monitors, wrist watches, and pill boxes.

In reality, uses are still limited.

Only 11% of French use a connected device to monitor their health (IFOP survey November 2013), mainly a scale. Among these 11%, two-thirds perform regular monitoring of data thus collected. Almost the same number state that they accept to share them, primarily with…their doctor (29%). Moreover, 38% consider that these devices or these programmes in which they are integrated may, in the future, be considered as separate medical care.

But the majority continue to worry that this connectedness represents a risk of "no longer having a say in one's own health". Paradoxically, even though that this change is presented as a factor that can make the patient responsible? This apprehension undoubtedly is related to the risk of loss of control of one's personal data and of one's privacy.

PROMISES, LIMITS AND RISKS

Hundreds of m-health projects have been produced to date world-wide, but it continues to be difficult to differentiate those which have a real impact, and which deserve to continue or to be copied.

In its study of 114 countries, the WHO has noted that only 12% of them feel concerned in evaluating the impact of their initiatives in m-health. However, the WHO reports several case studies and their benefits: public health campaigns (for example, vaccination) conducted via SMS in Bangladesh, a communication network between healthcare professionals in Ghana, an epidemiological study in Senegal, nursing follow-up of isolated populations in Saskatchewan, etc. It also shows that in the rich countries, mobile health is motivated by reduction of healthcare expenditures, while the developing countries, in particular, await new possibilities to improve access to primary care.

Nevertheless, the medical benefit provided to patients by mobile health is the subject of over …26,000 published reports! But only 42 studies have been chosen, in the setting of four recent reviews of the literature, for the good quality of their methodological criteria and their scientific objectives. Dr. Pierre Simon, chairman of the SFT-ANTEL (French Society of telemedicine) has written a synthesis of it in March 2013 (see following).
Currently, the utility for m-health remains largely a question of being convinced.

PROMISES, EXPECTATIONS

Countless benefits have already have been attributed to m-health which, in particular, provide matter for discussion in reports and seminars. In its green paper, the European Commission has chosen mainly three potential benefits in terms of healthcare: improvement in prevention and better quality of life, more efficient and more durable healthcare systems and more responsible patients.
There is no doubt that mobile healthcare tools contribute mainly to healthcare education by supplementing or even improving access to services already available online. Similarly, by facilitating the consultation of databases and communication between healthcare professionals, the tools of m-health represent true personal assistants in medical or paramedical practice.
New expectations are arising which involve the utility of m-health in the context of development of telemedicine: transmission of data (imaging) in the setting of a request for an opinion (tele-expertise), medical remote monitoring of patients with a chronic illness at home. "The tools of mobile health with their expert systems may become true active medical devices in the healthcare of patients", as underlined by Dr. Pierre Simon. The first demonstrations are starting to be shown in the management of diabetes or arterial hypertension. Nevertheless, it is necessary to continue or even enhance clinical trials and evaluations.

Information and prevention

Currently, the principal field of action of m-health involves the circulation of information and moreover is limited to the adaptation of resources already available online to the mobile format. This is not a negligible task because it is known that an informed patient is active and easier to manage. Yet, the individual increasingly is leaving aside his computer in favour of mobile devices to look for information.
Although relative to the English-speaking world, the analysis of some 24,000 applications "which are related to an approach on health care or well-being", performed by the IMS Institute for Healthcare Informatics (with support of 21 doctors), provides an interesting clarification. It has segmented the solutions that circulate via the Apple Store in 2013, based on their functional aspect. What are the results? 69% of the apps studied are aimed at consumers and patients, and it is

observed that two-thirds of them focus on the supply of information. 36%, in addition, provide some type of education for patients; 31% make it possible to collect data and 14% display it; 9% provide the service of advice and 8% the service of an alert and of a reminder; 2.4% make it possible to communicate with a doctor or with other patients. Less than 1% (i.e. 159 apps at the time) take advantage of the existence of a sensor device, primarily in monitoring of their weight. The experts at the Institute have also classified these applications according to their place in the course of healthcare. 62% involved prevention and promotion of a healthy lifestyle; 2% are aimed at establishment of a diagnosis (and therefore must receive FDA certification); 7% involved identification of a doctor or of a healthcare institution (location, opinion, setting of an appointment); 4% concerned medical information once the diagnosis was established; 1% concerned the purchase and use of medicinal products (location of a pharmacy, etc.); 2% concerned compliance with prescriptions.
This study confirmed the current position of the majority of m-health solutions, aimed at information, prevention, or coaching or accompaniment. This explains why we are still far from being able to demonstrate its clinical benefits.

What medical service is provided?

Dr. Pierre Simon, chairman of the SFT-ANTEL, in an article published in March 2013, noted that "the majority of trials analysed up until the end of 2011 did not demonstrate any significant impact of such mobile technologies on the health or behaviour of patients and of healthcare professionals". This conclusion summarised his presentation of four reviews of the literature which, to date, have contributed a "state-of-the-art assessment" based on scientific criteria. However, he sought to qualify this observation: in fact, although no (published) significant impact was observed on health, a few results, although contrasted, can be expected in terms of change to behaviours. We can mention the examples of intervention by text messaging (SMS) as a support for treatment in patients with asthma or to improve compliance with anti-platelet therapy after stent implantation (department of cardiology of La Timone hospital AP-HM[10]).
From the standpoint of healthcare professionals, the benefit provided by the use of applications as an aid to diagnosis can also be noted.
Moreover, Pierre Simon considers himself optimistic for two reasons. First, he reminds us that significant new trials

THE MIRAGE OF NEW CONCEPTS TO CHANGE OUR HEALTHCARE BEHAVIOURS

Dr Pierre Simon
Chairman, French Society of Telemedicine (SFT-ANTEL)

Telemedicine, E-health, M-health, connected Health… This flurry of new terms over the last 15 years, progressively with the development of the digital age in our healthcare system, may be surprising. What do these terms signify? Even though telemedicine, i.e. the use of information technologies to provide healthcare at a distance, has not changed in its definition in almost 30 years and currently is increasingly used by persons who seek a direct relation with their doctors, albeit a virtual one, the other terms, created for the clearly defined purpose of developing a market for the digital healthcare industry, can pose a challenge. How can these innovative approaches be reconciled? To date, the impact of these novel approaches in healthcare remains to be demonstrated. Acting on human personal behaviour for marketing purposes can be an ethically controversial subject. These novel concepts should not be confused with the practice of medicine whose nature does not change and for which, currently, the practice of medicine is based on scientific evidence (evidence-based medicine).
Nevertheless, it is no less true that telemedicine is beginning to choose methods, among this vast array of digital tools in m-health, in order to better follow patients with chronic illnesses. Several examples can illustrate this concept. The « Diabeo » system (smartphone with application software to aid in treatment) enables patients with complicated diabetes to better adjust their dose of insulin. A tablet computer, used in the « Domoplaies » study, allows homecare nurses to show an expert doctor via a teleconsultation, the condition of a chronic wound and In return to receive healthcare advice in real time. A smartphone fitted with a dermatoscope enables the general practitioner to send the image of a skin tumour to a dermatologist for advice in diagnosis. A tablet computer used in the Telegraft study enabled patients who underwent organ transplantation to enter a teleconsultation with the specialist doctor who performed the transplant. In this latter application, a recent medical thesis* studied the cost/benefit ratio of such a practice via « the discrete choice method ». This method is based on the study of patient preferences. It demonstrated for the first time that patients concerned prefer teleconsultations compared to face-to-face consultations, and consider that this type of follow-up is safer and less costly and that follow-up is more flexible compared to scheduled appointments. This pharmaco-economic approach, based on patient preferences, better corresponds to telemedicine, which is a new type of medical practice and is not a novel therapy, as some health economist believe, in recommending the conduct of a cost-effectiveness study.

**Houdart-Brunet Solène. Follow-up of transplant patients with telemedicine : a study of their individual preferences by the discrete choice method. Thesis for the Doctor of Medicine (MD) degree, specialty degree in Public Health and Social medicine, 20 October 2014, University of Nantes, France).*

are ongoing and their publication soon may start to demonstrate the utility of m-health. Furthermore, he emphasises that the impact of m-health undoubtedly will be more demonstrable in cases where its uses are integrated in the structured organisation of healthcare by telemedicine. He provides as an example, the promising results of the Telediab1 study in France, currently supplemented by the Telesage[11] study.
Verbatim Pierre Simon
Dr. Nicolas Postel-Vinay, director of the automesure.com website, adds that "several telemedicine studies already support the utility of the connection between patients and expert systems. Thus, it was demonstrated that remote monitoring of patients with hypertension, who were asked to measure their blood pressures themselves (self-measurement) and to receive instructions on changes to make to their treatment (self-titration), enables better control of arterial hypertension than conventional management, which limits the exchange of information solely to the visit to the doctor's office. This stricter control of blood pressure is obtained by a two-fold action on the behaviour of doctors and of patients, by fighting against two weaknesses in clinical management: patient compliance and doctor's inertia in terms of treatment. Correction of these two events results in increased use of anti-hypertensive medicinal products and therefore better control of blood pressure. Moreover, in other cases, but still in the cardiovascular field, it was shown that interaction between smokers and expert systems that deliver text messages (SMS) on mobile phones of patients contribute favourably to smoking cessation. Other studies are investigating this type of process in weight reduction in subjects who are obese."

The impact of electronic coaching

M-health entrepreneurs of course are initiating their own studies, following the example of My Mobile Health, an operation organised by the IDS Health firm, with the support of the Fitbit firm. An experience presented as unique in the sense that it has gathered over 500 volunteers selected in 4 cities in France in order to analyse the effect of an activity sensor during 7 months.
The first conclusions were announced at the end of June 2014: regular use of an "electronic coach" leads patients to take 2,000 more steps per day, on average, and contributes to weight loss. Certainly, the principal bias of this study lies in the fact that participants were volunteers. Moreover, it can be noted that their "commitment" is stronger – and that their results improved – when they accepted to share their personal data.
But My Mobile Health has the utility of providing the first few items in the evaluation that the Quantified Self Institute of Groningen, The Netherlands, plans to refine.

Healthcare first line players

Healthcare professionals and health institutions themselves are sensitive to the utility that these solutions can offer, so much so as to imagine the design. Apart from the example – the one most widely covered by the media – of the Diabeo system, imagined over ten years ago in the setting of collaboration between diabetologists (Dr. Guillaume Charpentier as the lead investigator) and engineers, innovations which arose from needs observed in healthcare institutions or by healthcare professionals are multiply-ing. Here are two recent illustrations.
In Le Mans, France, an oncologist at the Victor Hugo clinic and a researcher in the CNRS[12], in collaboration with

> "the impact of m-health undoubtedly will be more demonstrable in cases where its uses are integrated in the structured organisation of healthcare by telemedicine."

(10) AP-HM: Public assistance Hospitals-Marseille
(11) The TeleDiab 1 French study demonstrated the utility of a smartphone in follow-up of patients with type 1 diabetes. The results at 6 months of this randomised, controlled trial showed a significant decrease in HbA1c in the group which received this mobile technology. Considering these results, it is being extended for two years in patients with insulin-dependent type 1 and type 2 diabetes (Telesage).
(12) CNRS: French National Centres for scientific research

> Generally, mobile applications are little transparent in terms of processing of data collected and they provide little protection of privacy.

a physicist from Rouen University, developed an application that can detect relapses of lung cancer. Each week the patient provides information on ten symptoms which are analysed by an algorithm that can produce an alert which, if necessary, can lead to summon the patient to a visit earlier than in conventional follow-up.
Insofar as results of a first study have shown a 25% benefit in terms of one-year survival in patients using this application compared to conventional follow-up, a phase II, randomised, multi-centre clinical trial has been initiated.
The Saint-Jean Healthcare unit, in Cagnes-sur-Mer, France, has developed a programme entitled "my treatment" in order to prevent the risk of drug-related errors. The application, which is free of charge, and is compatible with all smartphones, enables the patient to enter his/her prescription, and generates an automatic alert and sends information by e-mail to the doctor of his/her choice. It also offers an interactive directory of the healthcare professionals in the clinic in order to set an appointment online.
Downloaded by almost 1,600 persons and used by 180 doctors in private practice in the unit, during a one-year pilot phase, in fact it has demonstrated the evidence of its utility.

B-2-RISKS

The problems which can arise with development of uses in m-health are of a highly varied nature and do not all have the same degree of seriousness. Risks associated with connected solutions, in fact, range from incomplete information or of an absent functional aspect, although displayed, to an error in calculation or in guidance to diagnosis, etc.
They concern the following:

- protection of personal data, healthcare data and confidentiality
- the lack of clinical validation for a solution which could be likened to a medical device, fraud in terms of the end purpose of an application
- the dysfunction of products and software, lack of reliability of sensors
- vulnerability, defects in the security of products and software

Questions raised by these risks are developed in the following chapter (The challenges).
But we can already note here that they are far from being theoretical and, moreover, are starting to be documented.

• Protection of personal data, healthcare data and confidentiality

Generally, mobile applications are little transparent in terms of processing of data collected and they provide little protection of privacy.
The CNIL and 26 of its counterparts world-wide, in May 2014, measured in a common operation (Sweep day) conducted simultaneously online over 1,200 mobile applications, all sectors of activity combined, from video games to quantified self, including healthcare. The common findings: the collection of personal data has become generalised, but it is still not justified by the purpose of the application; yet, only a fourth of applications provide satisfactory information on their use of personal data.
Regarding France, where 121 of the most popular applications were examined, 15% of them do not provide any information on the processing of data collected; and when the information exists, the CNIL observed that it is difficult to access or even incomprehensible.
Similar observations are published regularly. Thus, an investigation in the British newspaper Financial Times in September 2013, revealed that "9 out of 20 of the most widely used healthcare applications transfer data to one of the principal firms that collect information on the use that people make of mobile phones", as stated with regret by the Green paper by the European Commission.

"IT IS UP TO THE PATIENT TO DECIDE ON HOW HIS OR HER DATA CAN BE USED"

Gilles Babinet
Multi-tasking private contractor, author of "The digital era, a new age for humanity"

Couldn't data provide an opportunity for a potential comparable to the discovery of antibiotics in medicine?
This concept probably can be summarised approximately as follows: the opportunity to create less traumatic, preventive, personalised and much less extravagant medicine. Several initiatives enable us to hope for this. By analysing the path of healthcare data that could be generated with new sensor devices now commercially available, it may be possible to obtain a better understanding of the course of precursor indicators in the occurrence of all types of diseases. Epidemiological studies using big data would also make it possible to detect precursor signals for which currently we probably have no idea about. Lastly, the continuing decrease in the cost of DNA sequencing may allow us to plan the systematic use of the precious information that it can reveal, which can also be correlated with other subjects.
The change in the paradigm is more significant. From pharmacologically-based post-traumatic medicine, we could progress to preventive and personalised medicine. Although the stakes are high, the conditions to achieve this goal also are. It involves no less reworking our healthcare system and of placing data at the heart of it, while respecting the basic rights of the patient's private life. In this model, epidemiology will become an essential field and new types of sensor devices must be certified by the healthcare system. It will no longer be possible to keep all data processing in the healthcare system, as is the case currently. Start-up firms, that bring innovation and break with the status quo, should be able to perform processing of personal data and accessing of anonymised big data in order to conduct research studies on the correlation with big data. This does not involve an ideological, "liberal" statement, but the observation of a need: there are many so players active in innovation, outside of the official public health system, that they cannot simply be ignored.
Nevertheless, the CNAM* has not taken the least major initiative to facilitate access to data by outside players, in order to perform epidemiological research studies and the potential inherent in data, generally is not perceived in its proper dimension by players in the public sector.
Yet, the means exist which would make it possible to ensure a high level of security of healthcare data: giving its use to patients, similar to the strategy that the US Blue button** initiative has provided. In this way, it is patient who decides on the use which can be made of such data, which in turn solves a number of problems regarding the respect of the patient's private life that an overly open approach would have been created.
It is imperative to review our approach in this regard. Not acting would mean that Google, Facebook, Apple, and others would be free to do as they please. Already, the former are perfecting their weapons to attack a market which offers limitless or almost unlimited opportunities. The risk within the next few years would be a two-tier healthcare system: one, public, out of date, more or less free of charge, but little efficient. The other, private and based on a fee-for-service system, probably remarkable effective.

**CNAM: French National Health Insurance fund*
***US Veterans Affairs (VA) Blue button program*

In the USA, when the Federal Trade Commission (FTC) studied 12 healthcare and mobile fitness applications in the spring of 2014, it observed that they circulate data to no less than 76 third party firms! Based on a study published in the JAMA, in August 2014, less than one-third of 600 healthcare applications among the most widely used and downloaded by iTunes or Google Play, have policies on confidentiality. Furthermore, when they are available, they are not explicit and detailed concerning the application itself.
Yet, the risks which weigh on confidentiality and protection of health personal data of users are higher with mobile devices compared to use of a computer. In particular, we are reminded by the G29 (Article 29 Working Party) in its opinion in February 2013 "on applications intended for intelligent devices", an opinion which above all is aimed at developers. Their close interaction with the system of utilisation in fact enables applications to access much more data than a conventional internet browser. Yet, developers most often are unaware of the existence of obligations in terms of confidentiality and tend to maximise the collection of information without relevance regarding the purpose of the service and in the absence of explicit consent from the user.
In addition, the activity of data brokers should be added, which is undergoing major expansion. These firms specialise in the collection of information on consumer use, from sources online and without consumers being aware of this, to sell this information to firms, banks, or insurance companies for marketing and targeted advertisement purposes.

• a defect in clinical validation for a solution which may not be likened to a medical device, fraud in terms of purpose of an application

In the same manner as we have seen excessive health claims by the food and agriculture industry flourish in a certain period, the consumer runs the risk of increasingly being confronted with undue therapeutic claims by the 'connected' health industry.
However, few studies as yet have been

undertaken to verify the reliability of applications.
A team in the department of dermatology in the University of Pittsburgh (USA) tested four applications in 2013 that propose screening of skin lesions by using the functionality of smartphone photography. Conclusion: the 3 applications which are based on automatic image analysis may not be reliable in 30% of cases; they classify images of melanoma as being "not of concern" which were circulated online. Certainly, they are presented by their sponsors as having a purely "educational" role, but researchers are sounding the alarm on the absence of evaluation of such devices which are not certified by the healthcare authorities. In fact, they risk giving the user a false sense of security which may be translated by loss of chance and/or of a delay in seeking medical care.
Another article published in the Journal of Cancer Education concerns a study of applications available in oncology and reveals that almost half are based on data that are not scientifically validated.
Another example, in the field of vascular disease, only one-third of applications analysed had received the involvement of a healthcare professional, which would make it possible to call into question the reliability of two-thirds of them, according to the author of the report (in the medical journal, Annals of vascular surgery).

The US specialised website, iMedicalApps, known for the soundness of its assessments with respect to healthcare applications, recently warned users of the fact that some developers believe that they are exempt from all regulatory requirements, i.e. FDA certification. In fact, in July 2014, its editor-in-chief identified an app that he considered dangerous for patients because it proposed to measure blood pressure simply by using one's iPhone with the microphone placed over your heart and your finger placed in front of the lens of the camera.
Yet, this app was listed among the Top 10 most downloaded applications… and users had even spent almost 4 dollars (USD), persuaded that in this way they could manage their hypertension, as confirmed by comments collected in the appstore. On the contrary, the editor considered it wise to decline all responsibility by specifying that this application was for recreational use only, of course in very tiny printing. Three years later, iMedicalApps issued an alert concerning an app which offered to treat acne by using the screen brightness of the phone. Ultimately, it was withdrawn from the market by the FTC.
A few weeks after publication of the article on iMedicalApps, the mobihealthnews website added that it observed that this exemption of liability was very commonly used, including by firms which have a foothold in the healthcare sector and even in cases where the sentence formulated borders on the ridiculous. "Where is there a recreational aspect in an application of a medical calculator which helps you to evaluate a patient's acute tubular necrosis", notes its editor-in-chief ironically.

• Dysfunction of products and software, lack of reliability of sensor devices

The fact that Apple has announced that it is going to withdraw blood glucose monitoring from its healthcare management application has called attention to the fact that these solutions are not so harmless and simple to operate as they appear, even by someone experienced in use of the technology. Its teams noticed the risk

> "The consumer runs the risk of increasingly being confronted with undue therapeutic claims by the 'connected' health industry."

of confusion between two units of measurement (milligrams per decilitre, used in a majority of countries and millimoles per litre used in the UK or in Australia).

The first examples of a dysfunction – observed – go back to 2011.
A pharmaceutical firm had to inform its users that the application in a calculator in rheumatology that it had developed gave erroneous scores; it asked users to destroy it. The next year, another pharmaceutical firm had to recall its application for calculation of doses of insulin. These firms, when they venture into the field of publication of applications, in principle, use the appropriate means – and desire – to detect and to correct, the effects that they market.
Yet, this is not the case with the majority of developers of applications. As emphasised in the Green paper of the European commission "this market [mobile healthcare] is dominated by small firms: 30% of the firms which develop mobile applications are one person operations and 34.3% are small firms (2 to 9 employees)".

For their part, wristband monitors of activity provide approximate results and their measurements must be taken relatively, as shown by a team in the "Science & medicine" supplement to the daily newspaper Le Monde when it conducted a few tests whose results it published in February 2014.
Thus, it observed that the difference in measurement provided by three different devices in a day and in about 8,000 steps could reach 25%.
Yet, when "questioned on the accuracy of their devices, the manufacturers responded evasively", as the daily paper criticised.

Other tests involved heart rate metres attached to one's wrist. Conducted by the specialised online magazine Cent, with the collaboration of a cardiologist, they showed the lack of reliability of these devices…unless used while the patient is at rest, which has limited interest!

• Vulnerability, gaps in security of products and software

In the field of connected devices, as in that of applications, younger firms – which comprise the majority of the forces involved in innovation – most often are motivated by the desire to gain an advantage over the competition at the risk of offering products which are not perfected and do not provide an adequate level of safety.
Thus, a recent study conducted by the safety division of a major US high tech firm [HP Fortify] revealed no less than 250 weaknesses in 10 connected devices that are currently the most popular, including scales.
The defects concern mainly lack of protection in processing and transmission of sensitive personal data: unencrypted user authentification, absence of encryption, of requirements in terms of a password, and cross-site scripting[13].
"Connected devices are sieves in terms of security", was the headline in the journal 01net last August calling attention to a report of an analysis published by an internet firm specialising in web security [Symantec]. The defects identified enable a third party to recover data, without the user being aware of this.
For example, almost all wristbands which measure activity can be located by means of their Bluetooth chips and at least 20% of mobile applications used with connected devices to not encrypt their data properly even though they store then in the cloud.

(13) Type of defect which makes it possible to inject content into a page and thus making it possible to produce actions in web browsers visiting the page

4 THE CHALLENGES

CREATING TRUST

Uses in m-health cannot durably secure a place in practices without an environment of trust. The environment assumes that users, patients or healthcare professionals are guided in their choice of solutions and can verify which guarantees of quality and reliability cover the applications and the devices.
The use of applications and healthcare connected devices is not specifically subject to regulation, but this is a gap in appearance only.
In Europe, as in the US, a series of regulatory conditions can now be mobilised to regulate the development of m-health. They involve the protection of personal data, conformity of medical devices and consumer protection. Nevertheless, they are not sufficient or appropriate. This is why many players, both public or private, are exploring **new pathways of regulation**, by recommendation, labelling or certification depending on the device concerned.
In terms of applications and connected devices in the field of m-health, the CNOM for its part, is proposing a pathway of regulation which, at the least, would consist of the **implementation of a statement of conformity** of healthcare solutions connected to switchboards and it recommends that this regulation be adopted on a Europe-wide scale.

IN EUROPE

• Existing regulation

General laws on protection of personal data in countries of the European Union (EU), resulting from directive 95/46/EC, classify health data among the most sensitive data. Processing of these data is prohibited, except in precisely defined cases.
The proposed European regulations related to protection of personal data, currently under discussion, for the first time define data involving health, as "all information relating to the physical or mental health of a person, or to the provision of healthcare service to this person".

A French specific aspect. The harbouring of personal healthcare has been regulated in France since the law of 4 March 2002, in particular, for the purpose of ensuring confidentiality, integrity and availability of patient data. Activity is subject to prior certification by the Minister of health, according to a decision (4 January 2006) which sets conditions for harbouring healthcare data "collected or produced during the activities of prevention, diagnosis or healthcare".

The EU also has legislation on medical devices whose purpose is to make certain that these products offer patients, other users and third parties a high level of protection and that they achieve the objectives attributed to them by their producer. Marketing of medical devices (MD), active implantable medical devices (AIMD) and diagnostic medical devices in vitro (DMDIV) is subordinate to prior CE marking under the responsibility of their manufacturer.
To be allowed to affix this CE marking, the manufacturer must submit the devices to an evaluation procedure in conformity with essential requirements described in European directives.
This regulatory setting currently is under review, with a deadline set for 2018.

The directive relating to consumers' rights (2011/83/CE): although it expressly rules out the field of health, on the contrary, it covers applications relating to lifestyle and well-being.
Its requirements concern essentially information to be delivered in the context of long distance sale (or online downloading, which is similar to it) and regarding the time period for retraction of consent granted to the consumer.

• New pathways…

…in France

- **Recommendation.** The Dmd health firm created (by a psychiatry resident in training) with the objective of evaluating and recommending

> Since September 2011, the CNIL has taken on the mission of delivering labels designed to facilitate the identification of "entities which ensure a high level of protection for personal data.

healthcare mobile applications on the market in France. It then initiated a similar approach concerning healthcare connected devices.
It compiled a grid of 12 criteria and a system of weighting which enables evaluators to grade each application out of a total score of 20. Evaluators are healthcare professionals and unpaid users…who are connected! They examined about 500 applications.
The firm publishes the result of evaluations and the description of apps analysed on a website where the visitor can add his or her own comments. This site facilitates screening of application by filters (professional or general public, field, etc.).
Dmd differentiates applications which have obtained a minimum score of 16 out of 20 in an annual event (Awarding of mobile healthcare trophies).
The firm is supported by activities of advice and development of mobile healthcare applications.
-Another start-up company in France, Medappcare, has also developed its own methodology for evaluation and sells this service both to developers, so that they can prevail in terms of quality approach, and also to players in the industry, who would like to differentiate themselves by offering reliable mobile applications mobiles. Medappcare then positions its service as a "turnkey recommended computer system" but reserves its evaluations to its own clients.

- **The label.** Since September 2011, the CNIL has taken on the mission of delivering labels designed to facilitate the identification of "entities which ensure a high level of protection for personal data". However, in a first phase, it must establish the necessary references. Currently, the Commission is examining the utility of developing a label in terms of e-health and of mobile healthcare applications, as indicated by its chairwoman, Isabelle Falque-Pierrotin, in the public hearing in the French Senate by the Parliamentary office for evaluation of scientific and technological choices (Opecst), on 15 May 2014.

… in the UK

- **Public action.** The National Health Service (NHS) opened a Health Apps Library in March 2013, an online library which contains only applications which have satisfied requirements in terms of security and conformity with rules on data protection. The apps must also be in phase with the editorial rules and requirements of the general public information website on health, NHS Choices.
Referenced applications are classified in three categories: diseases, living in good health, and information for patients.
Each application provides a brief description and invites users to submit their opinion. The online library operates as a website which leads to a store for downloading apps.
Within a year, the evaluators (healthcare professionals and security specialists) have succeeded in selecting about 200 apps, i.e. a drop in the ocean!
Sponsors of the initiative emphasise its experimental nature and state that they may revise the current procedure.

- **A private action.** myhealthapps.net has the original aspect of screening of applications performed from the user's (patient's) standpoint. This portal was launched in November 2013 with a first choice of 307 apps determined by over 450 patient groups. The public is invited to use a system of scoring of 1 to 5 hearts. A heart is attributed (or not) depending on each of the five following criteria: the application

helped you to control your health condition, to remain in good health, is worthy of trust, is easy to use, enables you to enter into relation with people like yourself/who understand you, and can be used regularly.
The portal, which states that it is independent, was initiated by PatientView with the support of European Health Forum Gastein, with the support of 3 pharmaceutical firms and 2 telecom operators. PatientView is defined as a group for research, publication and advice. Founded in 2000, the organisation has the objective of listening to patients and their associations world-wide.
In order to set out its educational mission, PatientView has already published (in 2012) a Directory of applications, and very recently (early October) a guide to use for the general public, "Health Apps—a Toolkit to Help You", of almost 70 pages. The initiative, without a doubt, distinguishes itself as being the first of its kind in Europe.

...in Andalusia

For healthcare players in the area of Spain, the role of regulation in e-health is left up to the public authorities and to the administration. Thus, Andalusia has launched a system of accreditation of healthcare webpages in 2005.
To deal with the development of apps, the ACSA (Andalusian Agency for Health Quality), founded in 2002 in order to carry out missions similar to those entrusted to the French National Authority for Health, started to publish, in September 2012, a Guide on recommendations aimed at all types of audiences: ordinary citizens, healthcare professionals, healthcare organisations and developers.
It consists of 31 recommendations classified in 4 groups and by 14 criteria.
The 4 groups cover the following subjects: design (ergonomics) and relevance; quality and security of information (who is the author of it, on what date…what risk management); service (technical support, advertising and how to deactivate it, if applicable, etc.); protection of data and confidentiality (information on data collected and on the purpose, description of authentification procedures, etc.). It can be noted that this is the 4th group of recommendations and which is proportionally the most well-developed.
The ACSA then developed a programme of labelling, "AppSaludable", based on a two-phase methodology: a first phase of self-evaluation by the publisher of the application (who must follow the guide of recommendations) and an outside evaluation by a multidisciplinary group of experts.
The approach is free of charge and is performed on a voluntary basis.
Officially launched and disseminated in May 2013, currently, it has resulted in a catalogue of 10 apps and about sixty that are under evaluation.
This is very few! Currently, its sponsors are working on a second version of the Guide and ultimately are aiming to certify the applications.

IN THE USA

• Regulation

-The HIPAA federal law (Health Insurance Portability and Accountability Act, 1996) governs the processing of healthcare data. Its scope of application is vast since it involves not only healthcare professionals and health institutions, as well as insurance firms, but also their partners of all types: technology providers and data transmission services, consultants, lawyers, etc.
Under this law, patients must be informed of conditions by which their personal health data are used and protected. It also carries the requirement to make public any gaps in security of healthcare information systems whenever they concern more than 500 persons.
-The FDA (Food and Drug Administration) is in charge of regulation of medical devices, defined as any device or software which has the purpose of diagnosis, treatment or prevention of an illness.
It started by publishing general recommendations on mobile medical applications (July 2011), and then guidelines (September 2013) designed mainly to clarify its scope of expertise.

It examines only apps which satisfy functions identical to those of medical devices and maintains surveillance of health/well-being applications for the general public. It has just proposed again to relax its requirements with respect to apps by eliminating from its scope of action an entire series of devices which are not classified as carrying a risk. But the FDA states that it reserves the right to intervene in case where confirmed risk is detected.
The FDA has authorised the marketing of about a hundred apps since 1997, 40 of which in the last two years alone.
-The FTC (Federal Trade Commission) ensures the protection of consumer affairs in the US, in particular, it verifies that the consumer is properly informed and that he or she consents to collection of his/her personal data. In 2013, it published guidelines relating to protection of personal data in the field of apps, all sectors combined.
It has already proceeded to withdraw from the market a healthcare mobile application, which claimed that the light emitted by the screen of a mobile phone could treat acne. Moreover, it closely monitors the changes to activity of data brokers and is calling for a law to make their activities transparent.

• Private initiatives

Healthcare players themselves have taken the initiative over the last few years to help patients and healthcare professionals in guidance to thousands of available applications. Two characteristic examples: Happtique and iMedicalApps.
-Happtique.com was launched in 2010 by the Hospital Association of Greater New-York with the aim of developing a programme of certification of healthcare apps, an initiative followed with great interest at the time. But its sponsors developed a grid of standard criteria which proved to be too unwieldy and complicated to use.
Only 16 apps were certified at the end of 18 months. Furthermore, the project underwent serious reverses when an expert revealed gaps in security of some of the certified apps! In the end, this programme was suspended in late 2013.
Currently, Happtique develops and markets focused around the activity of classification and selection of apps, software and management services for patients and of their personal data.
Moreover, it can be noted that there now are many healthcare organisations which are involved in publication of web portals whose mission is to inform and to compare apps and connected devices, following the example of the Wellocracy website, an initiative of the Partners HealthCare group, in Massachusetts (USA).
-iMedicalApps.com is an independent, online publication aimed at healthcare professionals, patients and analysts, whenever they are interested in m-health. It now specialises in commenting (or evaluating) mobile applications for healthcare professionals or the general public. This regularly leads to penalise certain "apps" or even contributes to having them withdrawn from the market (see the following, action of the FTC). The seriousness of its team is recognised and its contributors (doctors and medical residents in training) have acquired expert status in many scientific publications. No grid or list of criteria for these experts! They freely draft their assessments which, above all, are based on their experience of medical practice. In the quest for certification, these oppose recommendation, peer review and a search of the literature.

REGULATION: PROPOSALS OF THE CNOM

Experience shows that procedures for certification are unwieldy and complicated to set up, and thus necessarily inappropriate in a context of innovation. Furthermore, applications and connected devices which clearly display the purpose of being medical devices are now well-situated in a regulatory setting of certification, even though the latter currently is undergoing change.
Furthermore, the CNOM underlines that all these solutions do not have the aim of entering into the healthcare system and that the first requirements to apply them, whatever their uses, lie in clear, faithful and detailed information on their functional aspects and conditions for use.
In order for the marketing of m-health tools to contain guarantees for their users, the CNOM estimates that they must at least carry a declaration of conformity with a certain number of standards.

DECLARATION OF CONFORMITY

This statement must necessarily contain detailed descriptive information concerning:
-the publisher, the manufacturer, the distributor,
-the functional aspects, the public for whom the tools and solutions are intended, conditions and restrictions for use.

It must focus on 3 topics:
-confidentiality, protection of data collected and healthcare security. Which data are collected? Where, how and by whom are they used and processed? To what extent has the user consented to this? Etc.
A CNIL label as mentioned in the above may correspond to this declaration of conformity on this item.
-computer software and material security.
Are figures provided on data transmission? Is the integrity of data ensured, as well as accessibility to them by the user? Is user support/a hot line available? Etc.
-healthcare security
What is the source of information used? Is it scientifically validated? Etc.

This statement should be completed by a random, controlled procedure regarding its truthfulness.
This process of user protection should be entrusted to the CNIL involving the chapter on protection of personal data and should carry possible sanctions.
There could also be an added safety device facilitating the reporting of a dysfunction in terms of material and software aspects, following the example of the system already developed by the ANSM (French National agency for the Safety of drugs and health products).
The CNOM does not fail to recognise the non-negligible role played by communities of patients, communities of healthcare professionals and of social networks when they comment, recommend or advise against an application or a connected device. This "community intelligence" is not equivalent to a process of regulation, but nevertheless remains essential to identify and lead to emergence of useful solutions worthy of interest.

> "Applications and connected devices which clearly display the purpose of being medical devices are now well-situated in a regulatory setting of certification."

EUROPEAN-WIDE REGULATION

Of course, France can adopt a system of national regulation and mobilise the expertise of its agencies in terms of safety and scientific evaluation to be conducted on the French market. However, it is obvious that the market for mobile healthcare is not limited to

the area within its borders and it appears essential that regulation take on a European-wide dimension, in the same capacity as the process of certification of medical devices.
The CNOM congratulates the European commission for having launched a consultation on mobile healthcare, which includes its legal framework. In its contribution to this consultation, the CNOM, in particular, reminds us of the need for protection of data collected by a European legislation which imposes obligations not only on EU Member states, but which also may influence that of service providers from non-community States.
It also insists on the requirement to use large volumes of data collected and the cross-checking of data from various sources under the basic law of protection of personal healthcare data as will be the result of the European regulation currently being drafted.
Furthermore, the ongoing reflections of the Commission on telemedicine in Europe will have to integrate the manner in which, and under which conditions, apps and connected devices can be associated with the practice of telemedicine, while remaining legally separate.
According to the CNOM, telemedicine, in fact, requires specific European regulation in order to differentiate it legally from an electronic service and from Directive 2000/31/CE on online commerce.

SCIENTIFIC EVALUATION AND SOCIAL MANAGEMENT

Although the CNOM is convinced that there will be uses which will distinguish what is a gadget from what will go from promise to reality, nevertheless it will be necessary to develop beyond the sole declaration of conformity a scientific evaluation of solutions which fall within the course of healthcare and in the practice of telemedicine, a neutral evaluation conducted by experts with no conflict of interest with suppliers.
For the CNOM, whenever the evaluation of apps and of connected devices, in fact, would have recognised their benefits for individual and/or community health scientifically, it would be consistent that public policies of Member states ensure their social management. This would be the case under the reservation that such management does not enable access by the payer to data processed in the data base of information collected enabling direct identification of the person. The logic of open data – to which the CNOM subscribes and provides its assistance in France – assumes that data are made anonymous and cannot be identified.

“Nevertheless it will be necessary to develop beyond the sole declaration of conformity a scientific evaluation of solutions which fall within the course of healthcare and in the practice of telemedicine, a neutral evaluation conducted by experts with no conflict of interest with suppliers.”

QUESTIONS OF ETHICS

Confronted with the major impending changes in the development of connected health technology, the CNOM reminds us that technologies are produced to serve persons. Resistance to change or fascination with technology then are also inappropriate, the former, as well as the latter.
Hippocrates had removed medicine from the power of the gods: it is not the gods who make persons ill or who punish them with illness. Similarly, today, the Internet or digital applications must not be made divine, but it should be observed that it can contribute to the doctor-patient relationship, but without providing the illusion that it is going to resolve everything.
The CNOM calls for responsible and pragmatic use of connected health. It wants the ethical questions raised by these technologies to give rise to a public debate.

SOLIDARITY, EXCLUSION, DISCRIMINATION

The principle of solidarity, on which the French healthcare system is based, may be called into question by certain practices promoted by connected health.
Even though the adoption of mobile communication equipment is becoming generalised in France, the risk of a "digital fracture" is not ruled out. This corresponds to several lines of division (economic, social, or even geographic) and covers very different realities as shown by the report of the National Council on digital information, "Citizens of a digital society" (October 2013). This report invited everyone to "surpass the digital fracture to believe in e-inclusion for today and tomorrow". It rightly emphases the fact that "the challenges of digital inclusion now concern the entire population and we face a moving target". Example: "A person who currently is at ease with digital information in his family and social universe, tomorrow may be lost when it is necessary to re-invent his digital profession or to care for a disease via a dematerialised device".
It adds: "The persons who are not connected, who have become a minority, moreover are also those who are victims of social, cultural and economic marginalisation, which calls for as many further specific actions in favour of these groups. Believing that inclusion in a digital society requires building policies for all, without losing sight of those who are the most vulnerable and which must remain the priority".
The CNOM naturally endorses these warnings.

The economic model which underlies development of connected healthcare, and which moreover comprises the engine for a good part of the digital economy, is based essentially on collection, processing and valuation of data.
Yet, does the citizen who purchases an application, a connected device, does he or she always know what is really involved? Has he or she truly the means of controlling the use which will be made of his or her personal data? The user often loses all control concerning the potential dissemination of his/her personal data, as shown by many surveys. The asymmetry of information between user and supplier of services is tending to increase.
Furthermore, the capacity of follow-up/coaching offered by connected solutions open the door to new economic opportunities in the world of insurers, in particular. The temptation of correlating the amount of insurance premiums, or that of reimbursements, with the behaviour of the insured party is strong… and is already practiced in some countries such as the USA, South Africa, but also in France. A white paper, published by the Renaissance digital think-tank, gives several examples of this. It is concerned in seeing develop "a bonus-malus system related to an individual's health behaviour". As the CNIL recently called attention to the "scenario in which a health insurance or a supplemental health insurance carrier would correlate the obtainment of a favourable insurance premium with the accomplishment of a certain number of physical activities and with figures to support this" (…). In the years to come, individuals may be asked to provide evidence of healthy behaviour based on the model of "usage-based insurance". These organisations call for a concerted discussion on these topics. The CNOM naturally subscribes to this opinion.
The debate – and the reaffirmation of

the principle of solidarity – in fact is all the more urgent since this evolution is not the sole prerogative of private insurance companies. The public health insurance plan had planned in 2013 to no longer reimburse the treatment of sleep apnoea by CPAP (continuous positive airway pressure) unless the patient adheres to criteria for compliance verified by means of a tele-transmission device. The Council of State then suspended the decision for application of this system of tele-compliance. But the question is going to arise again and will not fail to spread to other fields.
Let us add that this type of practice not only raises a debate in terms of the bonus-malus economic system, but also, more widely, in terms of social integration: tomorrow will it be suspect to refuse the use of connected solutions as if there was something to hide?
On the contrary, the CNOM wants the question of social reimbursement of some of these tools to be processed as soon as their benefits have been scientifically evaluated. If it is confirmed that they have a human and an economic benefit, not only in terms of well-being, but also in the area of prevention, health education, the maintenance of home self-sufficiency, of aid in a disability, the CNOM estimates that public health policy must integrate them upstream of the healthcare system.

MONITORING, DEPENDENCE

By the tracks that we leave during each connection to an online service by the functional aspects of our geographic location that we do not think to deactivate, we are likely to be followed at every moment of our lives! Moreover, debates are all the more intense, and rightly so, concerning the outcome of private life in our digital society.
Yet, connected healthcare technologies are necessarily intrusive and ambivalent. On one hand, for example, they can provide non-negligible assistance to persons followed at a distance, on the other hand, they act together in the advent of a society of generalised surveillance if safeguards are not established.
The first rule to be kept in mind in this area is that of the individual's consent to be followed and to be identified by geographic location (geolocation), without of course overlooking each person's right of disconnection or to non-connection.
Moreover, the debate was opened in 2008 with development of gerontechnologies and the widespread use of electronic wristband monitors for vulnerable persons.
In this regard, the CNOM emphasises the fact that technological responses of course must not be uses as a replacement for human intervention and vigilance.
It reminds us that the CNIL has issued recommendation in mid-2013 on the topic of "systems of electronic monitoring and assistance for elderly or disorientated persons".
Recommendations to which the development of a Charter on use of the devices in geo-location has been added.

Apart from the – well-known – privacy paradox, which designates the propensity to reveal personal data even though there is the expression of wishing to protect one's private life, our societies must be careful to not find themselves confronted with the isolation paradox with patients perfectly monitored at a distance, but socially isolated.
The CNOM also wishes to call attention to the fact that it would be regrettable that the "emancipation of persons" (empowerment) with respect to management of their own health be facilitated by use of connected healthcare tools, while at the same time, they would fall under the dependence of such solutions. Moreover, the French are conscious of this and mention this potential risk as the number one obstacle to adoption of connected devices.
These types of excesses, which are similar to "digital slavery", moreover may be encouraged by the marketing of devices with debateable functionalities. Thus, we have recently seen the development of a proposed connected wristband that can send an electrical shock to its user whenever he or she does not reach his/her goals.

CONNECTED HEALTH AND THE DOCTOR-PATIENT RELATIONSHIP

All surveys indicate that mobile healthcare professional uses by doctors are increasing at a rapid rate. First, the uses by the doctor him or herself in his or her practice are intensifying insofar as the smartphone is a true pocket computer which facilitates access to a set of databases, memory aids, calculators, etc. at all times. Second, in addition an increasing number of doctors (currently about one out of ten) recommend a healthcare application to their patients. Their opinion and recommendations concerning connected devices undoubtedly will follow logically and relatively quickly.
Thus m-health is progressively being integrated into the practice of medicine. According to the CNOM, it is inevitable and has a positive impact. Let us not forget that the practice of medicine, has always used emergent techniques and technologies for the benefit of patients, from the first stethoscope to ionising radiation to ultrasound, to mention only a few technical advance. Currently, this process involves digital tools.

A supplement

Consequently, the CNOM estimates that it must accompany the development of this new technological contribution, not only to ware users with respect to the risks, but also to emphasise their utility.
Apps and connected devices in fact can provide support to the doctor-patient relationship to make it secure and supplement it. A few examples (see also chapter 2): the follow-up of a metabolic disorder such as diabetes, a diet appropriate for a person who is overweight, assistance in therapeutic education, support for maintenance of patient self-sufficiency, monitoring of physical and athletic activity, etc.

Expectations

Let us add that citizens themselves express the expectation of being

"RECONCILE WHAT IS USEFUL AND WHAT IS ENTERTAINING"

Robert Picard
Health Reference Expert to the Ministry of the Economy, member of the Cgeiet (General Council of Economics, Industry, Energy and Technologies), Author of the report "Living well in the digital information age (February 2012)

Alongside the doctor, who in France is the expert of reference for our fellow citizens, the Internet is the principal information media for the citizen-patient on the subject of health and his or her choices, at a time when he/she needs it and in terms of knowledge which he/she has. Furthermore, from now on, the use of mobile devices makes this search accessible everywhere. The term of "m-Health" signifies the extent of this phenomenon. This tool can be a resource in effective cooperation between the patient and his or her doctor, more generally with healthcare professionals who manage it. It can become a factor which makes the patient self-sufficient and contributes to increase his/her attentiveness to his/her health, his/her knowledge of behaviour and of risky behaviour. M-Health attracts the attention of patients (access to healthcare professionals, the economy, the management of one's own health); but healthcare professionals are less enthusiastic: lack of evidence, non-assurance of long-term use, loss of patients, etc.). A few "apps" intended for the general public, however, fall within the category of medical devices. But the majority of them relate to "well-being" and healthcare professionals do not have the time to follow the explosion in the number of applications offered. They are not (yet) appropriate for solutions in the setting of their medical practice. The arrival of new generations can make all the difference. But undoubtedly, time will tell and the effect of this evolution in healthcare and in the economic situation is uncertain, unless a healthcare policy emerges, which gives a clear and recognised place to this new manner of managing the health of populations. Unless successful applications that are the most useful for health and well-being see their concepts adopted and extended to the medical field, with, as a benefit, the conjunction of what is useful and what is recreational, at affordable prices. Unless training of doctors and other healthcare professionals acclimates them and reassures them on the benefits of such solutions, for them and for the patient. These perspectives assume that a two-fold evaluation will be conducted, combining value of use and medico-economic value.

accompanied by their doctors in order to "find their way in e-health", in particular patients with chronic illnesses who wish to be guided in their choice of mobile applications. Furthermore, over one-third of French persons interviewed in an opinion survey consider that connected devices, in the future, can be considered as medical care and state that they are entirely favourable to sharing their personal data on physical activity with healthcare professionals.

Proper use

Then, it will remain to be defined, between doctor and his/her patient, a framework of "good use" of the app or of the connected device and its integration into the field of healthcare and its management. In fact, it is not feasible for the doctor to be constantly available to analyse or to process an alert. This involves a reflection which may be guided by the National Authority for Health and in which the CNOM is ready to provide its contribution. This setting of proper use is comparable to recommendations of good practice which are also required in the area of communication between doctors and patients by e-mail, as has been underlined by the white paper on Ethics on the web[14].

Prescriptions

Whenever apps and connected devices receive scientific validation, doctors will be encouraged to go from simple advice to prescription of solutions, as for example, is already practiced in the UK and in the US. Moreover, guarantees on reliability will support trust granted by prescribing doctors to the information collected by this means; they then can provide added value to computerised medical dossiers.
The CNOM insists on reminding us that integration of m-health in medical practice (like computerisation in general) imposes on doctors the obligations of training and vigilance.

Training

Initial instruction and continuing training of doctors obviously must integrate uses of digital information in health, for which apps and connected devices now are part, as moreover has started in a few medical schools. Training should concern not the tool, but its ethical and deontological integration in medical practice itself to the benefit of the patient; this is all the more so since the handling of many mobile devices and of apps can be discovered intuitively without special training. However, it also appears necessary to develop training in the field of digital information for the attention of all citizens, in particular to promote uses that respect rights and freedoms, confidentiality and of protection of personal data. Technological advances in fact are tending to convert the smartphone into a "black box" whose complete control is becoming complex.

Vigilance

Lastly, the healthcare professional must not overlook the fact that he/she carries a responsibility in using or recommending a digital solution, in particular, when it has not undergone scientific and technical validation. Therefore, he/she must be vigilant, in the same manner that he/she ensures the safety of a treatment that he/she prescribes or of healthcare that he/she dispenses to a patient. Yet, doctors who currently are listed among "early adopters" perhaps overstep their boundaries by excessive of trust! Thus, a survey conducted on members of the Association of interns in oncology and radiotherapy has showed that they widely use medical applications (including the one promoted by the association), but… only 60% of them recognise that they are concerned by the validity of the applications which they use.

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