Presidenza del Consiglio dei Ministri

Mobile Health Apps: bioethical aspects

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Overview

The phenomenon of 'mobile-health' or the collection of 'mobile' technologies, wireless communications (phones and smartphones, tablets, digital devices, with or without wearable sensors), applied in areas related to health arises within the context of the 'mobile revolution' and transformation of new information and communication technologies.

The development of such technologies is fast and constantly growing, inasmuch as it is difficult to offer a concise overview of the new technologies available. These are technologies that promote strong innovation and open up new opportunities: including, the promotion of a healthy life style of its users, facilitation of communication between doctor/patient, improved efficiency of the health care system, the speeding up of the collection of data, the expansion of access to care, etc..

At the same time there are some controversial aspects involved and discussed in ethical terms, with respect to safety and efficacy, privacy, informed consent, technological dependency and vulnerability, health self-management and the technological divide.

In the light of the ethical analysis the Committee has made some recommendations, with placing particular emphasis on the classification of the applications based on the risks, the promotion of interdisciplinary research between computer experts, programmers and doctors, along with ethicists, and experts in cognitive and social sciences, during the stages of development, testing and evaluation of applications, encouraging industries to create apps which are actually useful for the health of citizens and identifying company responsibilities in building apps as part of the profiles of safety and privacy.

The Committee calls for the establishment of an observatory to monitor apps and the setting up of scientifically accredited sites and/or portals, the promotion of an appropriate information sheet and clear communication for the user whenever using the app, paying specific attention to minors and fostering studies on the impact of the use of apps, particularly as regards personal identity and relationships. The goal is to promote the acquisition of a critical awareness on the part of society of new health applications, avoiding excessive forms of health fanaticism and medicalization. A concise overview of the current major international and national regulations is appended to the document.

The text was written by Professor Laura Palazzani who benefited from the critical notes and written contributions by Profs. Lorenzo d'Avack, Salvatore Amato, Silvio Garattini, Demetrio Neri, Carlo Petrini. The text also took into account the remarks and additions made by Professor Roberta Siliquini, professor of public health at the University of Turin and President of the Superior Council of Health.

During the discussions on the topic the NBC invited for auditions Prof. Claudio Conti, Director of the Institute of Complex Systems of the CNR; Dr. Allen Francis Farrelly, CNR researcher and developer of health applications; Prof. Riccardo Pietrabissa, member of the General Scientific Council of the CNR, Acting Director of

the ICT Department of the CNR, Full Professor of Industrial bioengineering at the Polytechnic University of Milan.

The document was unanimously approved at the plenary session on 29 May 2015 by those present: Profs. Luisella Battaglia, Stefano Canestrari, Carlo Casonato, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Carlo Flamigni, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Massimo Sargiacomo, Lucetta Scaraffia, Monica Toraldo Di Francia, Grazia Zuffa. The advisory members: Dr. Maurizio Benato, Carla Bernasconi, Carlo Petrini also espressed their endorsement to the document.

The Opinion was later endorsed by the following members of the Committee, absent during the plenary meeting: Profs. Salvatore Amato, Carlo Caltagirone, Cinzia Caporale, Rosaria Conte, Bruno Dallapiccola, Riccardo Di Segni, Paola Frati, Silvio Garattini, Anna Teresa Palamara, Rodolfo Proietti, Giancarlo Umani Ronchi.

1. Definition

The term ‘mobile-health' or 'm-health' generally means the collection of 'mobile' technologies, i.e. the use of wireless communication (phones and smartphones, tablets, digital devices, with or without wearable sensors), applied in the medical-healthcare field or in related fields of health[1].

There is talk of 'mobile revolution' as a pervasive phenomenon in the society we live in, even in the healthcare sector: information is transmitted to anyone, it is received, and stored everywhere, at anytime, with any device. Ubiquity, globality, and instantaneity constitute intrinsic elements in the digitalized networked society.

2. Diffusion of the phenomenon and context of development

A recent study in 2013[2] noted that on the market there are about 97,000 apps, distributed on different platforms; about 70% of these are related to the health and well-being of the consumer, while 30% is dedicated to consultation and monitoring of the patient, diagnostic imaging, pharmaceutical information etc..

Some statistics[3] foresee that in 2016 there will be 3 million patients monitored with such technology and that by 2017 about 3.4 billion people worldwide will have smartphones using applications for health. It is estimated that in 2018 there will be 1.7 billion users worldwide. We are moving from Internet 2.0, the Internet of communication through the proliferation of social networks, to Internet 3.0, the "so what" Internet, "something" that will form an integral part of our life, "something which we can-not do without"[4] In this step the body and, by reflex, health will be subject to a multitude of potential points of observation and monitoring of movements, sounds, lights, electric potential, temperature, humidity, location, voice, face, heart rate, changes of thermal and electric energy of the skin, volume of blood flow, the contraction of muscles[5]. There are at least 100,000 applications available on the market in the category "Health & Fitness", with a steady growth over the years.

The transformative potential of this new technology in a growing market has and will always have greater implications on different levels, with a rapid pace of evolution we can now only imagine the economic and organizational developments (for the provision of services) and on a cultural level, the international and national effects.

On the one hand the likely increase in health care costs both due to the increase in the elderly population and chronic, multifactorial diseases and to the personalization of health (the so-called ‘precision medicine’) which demands and will increasingly require the use of technologically innovative organizational models, in order to redesign services, multi-professional and multidisciplinary interventions, at

[1] "The delivery of healthcare services via mobile communication devices" (2010 mHealth Summit FNIH). Applies to both software and hardware, "Healthcare delivered wirelessly".

[2] Research2Guidance (2013), *“The mobile health global market report 2013-2017: the commercialisation of mHealth apps”* (Vol. 3).

[3] *Ibidem.*

[4] For a comprehensive view of the phenomenon WHO, mHealth, Report 2011, *New horizons for health through mobile technologies*.

[5] M. Swan, *Sensor Mania! The Internet of Things, Wearable Computing, Objective Metrics, and the Quantified Self 2.0,* “Journal of Sensor and Actuator Networks”, 2012, 1, p. 219.

different times and places. On the other hand there is talk about increasing the active participation of citizens, ever more willing to manage their own health and well-being and to seek, through information and communications technology (ICT), service excellence.

M-health fits into this context of technological evolution - the transition from substitution technology to control technology - and the transformation of health, giving rise to increased accessibility (even economically), efficiency of services and a growing involvement of the subject/user, who by using mobile devices or sensors for the collection of clinical data plays an increasingly important role in his/her own health. Firstly, as a matter of fact, the user is active in the search for relevant information about his/her health. Secondly the user is a source of valuable data, contributing to fuelling the pool of information on which to draw from in order to respond to his/her personal queries. As is typical of Web 2.0, the user is a prosumer, producer-consumer of resources. In this case, of information.

3. Some preliminary remarks

The development of such technologies is rapid in continuous growth, inasmuch as it is difficult to provide an overview and understanding of the new technologies available; any attempt to do so would be doomed to grow old quickly, given the speed and dynamism of innovation in this field. It is useful at the outset, to introduce some preliminary remarks in terms of technologies applied to health, their purposes, and the subjects involved.

a) Regarding technology we need to distinguish:

- mobile platforms which, while not emerging from a medical context, turn into medical devices or extension of medical devices that collect, analyze, transmit data or images relating to health[6].

- Accessories (video-camera, microphones, sensors[7], physiological parameter detectors) providing support or assistance to devices.

b) Regarding health-related[8] purposes a distinction must be made:

- Applications for well-being (wellness-fitness): counting calories, steps and movement; monitoring of emotional state, etc.[9].

- medical applications for health in the framework of prevention (devices to record physiological functions such as heartbeat, breathing, pressure, temperature, brain

[6] If the software has a medical purpose (diagnostically or therapeutically) and is used in a smartphone - which is not a medical device - the question arises as to which software can be a medical device. Sofware in itself (stand alone software) can be a medical device, if it has medical functions.

[7] E.g. bracelets, watches.

[8] There are also non-medical applications, e.g. administrative procedures such as booking tours, remembering appointments, managing resources.

[9] Examples of such applications are: `iFood` as a daily agenda for nutrition, 'caffeine areas' for the measurement of caffeine ingested, etc . F. Bert, M. Giacometti, MR Gualano, R. Siliquini, *Smartphones and health promotion: a review of the evidence, "*J. Med Syst.", Jan 2014; 38 (1): p. 9995; M. Giacometti, M.R. Gualano, Bert F., R. Siliquini, *Public health accessible to all: use of smartphones in the context of healthcare in Italy*, "Ig. Sanita Publ., "2013 Mar-Apr; 69 (2): pp. 249-59.

activity etc.)[10], diagnosis (e.g. diagnosis of melanoma), in the treatment of diseases (e.g. medical remainder to improve adhesion to treatment, calculating the dosage of the medication, monitoring of metabolic diseases), for assistance (e.g. care for disabled with limited mobility).

c) Regarding the subjects potentially involved: citizens/patients; doctors; health facilities; in some respects closely related to well-being, physical therapists and personal trainers; providers; app manufacturers or developers or designers (developers; sellers; pharmaceutical industries).

4. New opportunities for health

The Committee believes that these are technologies and innovations with enormous potential for the improvement of public health and personal health. Among the positive factors of these new technologies, already present in our society, we will briefly recall some aspects:

a) promotion of a healthy lifestyle; improving awareness, active participation and motivation of individuals as concerns health;

b) facilitation and speeding up of doctor/patient communication; personalization of treatments; Increased autonomy and safety of the patient who can be controlled and localized at a distance;

c) improving the efficiency of the healthcare system: reduction of costs for care and hospitalization, analysis by the use of remote monitoring and telemedicine, speeding up and enhancing communication of information to the patient by the healthcare facility;

d) the contribution to research: facilitating individual data collection and environmental data collection, useful for the individual as well as the community (especially epidemiological research, the study of the correlation between certain medical and environmental conditions, etc.);

e) expansion of access to treatment, with the ability to reach users who would otherwise not have medical care;

f) stimulating the transfer of research, to production and to innovation, even through the creation of specialized start-up companies;

g) the potential also for the possibility of sharing clinical cases and requesting a second opinion in real-time for physicians.

5. Elements of ethical problematicality

Given these positive data of great interest for scientific and technological progress, the Committee believes, however, that the ethical problematicality of some

[10] Examples of medical applications for health: 'Welp' to detect the paralysis often characterizing seizures; applications for preventing falling of older people; applications to identify the first signs of Parkinson's disease; applications to manage certain diseases (HIV, diabetes, chronic conditions).

emerging aspects should be highlighted[11]. It is important to reflect on these elements, certainly not with the aim of curbing this field of technological development, but rather to make it compatible with the protection of the rights, safety and well-being of users.

5.1 Safety and efficacy

The fundamental ethical aspect regards the protection of health of the user or safety.

A first essential element is the determination of criteria for the distinction of m-health applications that come under medical devices and the applications which do not come under medical devices.

According to the Italian legislation a medical device "means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, which does not achieve its principal action in or on the human body that is targeted by pharmacological, immunological or metabolic means but whose function may be assisted by such means".

This distinction is important because in the first case the applications on health, before being allowed on the market, must comply with European regulations and certification requirements: the rules governing how the devices should be used, by whom, and which their applications are; certification guarantees safety, meaning not being dangerous, but it does not refer to efficacy. In the second case - that is, when the applications for health are excluded as medical devices - there is no specific regulation, but only the general protection of the consumer.

The Community Directives[12] regulating uniformly in all the countries of the European Union the medical device industry delegated to the Competent Authority (CA) in each Member State the designation of Notified Bodies, which evaluate, monitor and verify medical devices. The Notified Body, in fact, is a public or private entity authorized by the Competent Authorities to issue the “CE” marking.

Reference is made to the risk level of the device, according to a precise classification: Class I (low risk, e.g. corrective glasses); Class IIa (e.g. contact lenses); Class IIb (medium to high risk, e.g. X-ray machines); Class III (high risk, e.g. coronary stents); active implantable devices whose risk is equated to the class III (e.g. pacemakers). When at high risk (because, e.g., it comes into contact with the cardiovascular or neurological system) the evaluation is entrusted to the Notified

[11] It is a bioethical topic connected, in some ways, to issues previously dealt with by the NBC. See. *Ethics, health and new information technologies,* April 21, 2006*; The identification of the human body: bioethical aspects of biometrics,* November 26, 2010*.*

[12] Cf. *Directive 93/42/EEC on medical devices, Directive 98/79/EC in vitro diagnostic medical devices, Directive 90/385/EEC on active implantable medical device.* See Appendix.

Body; when at low risk it is the actual manufacturer that identifies the presence/absence of the requirements for classification. This is probably the reason why there has been a greater diffusion on the market towards more applications that fall into the category of wellness and fitness, not classified as medical devices.

What becomes apparent today is that there is an extremely efficient system of control by the operators of the store or online sales office of health apps. However, these operators are not scientific bodies and are interested in entering the health market, but not to sell "medical devices" that would require the "developer" to accept rules and very strict conditions within the territory in which they are produced and are intended to be distributed. A lengthy, burdensome and expensive procedure, with repercussions related to legal liability. There is a tendency, therefore, to circumvent this by presenting as a simple method for verifying well-being what in actual fact is a genuine medical device. Therefore, there is an ambiguity in the supply of health applications. On the one hand Google and Apple keep their "distance" from medical applications in the strict sense, but on the other hand they are "close" to health, placing on the market applications which, while not being classified as medical, are increasingly numerous and always more related to medicine.

As part of the dissemination of information and communication technologies what tends to prevail in the market for health apps is the opinion of people who have downloaded and tried them, instead of expert assessment. This is the criteria of evaluation in this area, in which everything changes very rapidly: what has a real impact is what the users see as being reliable, judging from the number of downloads and the views expressed on the network. In this sense what drives users to install an app is not so much scientific validation rather than the approval ranging on the network expressed by consumers.

What often emerges is the absence or deficiency of adequate scientific validation of the applications with regards to safety and efficacy.

While the testing of medical devices is subject to very precise regulation, there is no regulatory requirement for testing apps not classified as devices, but it is ethically desirable that the developers at the time of proposing a prototype, submit it to validation or evaluation of the risks and benefits. Considering that the general information related to health and well-being must be accurate and reliable, because critical decisions regarding the health of the subject may be based on it.

Certain studies have shown that there are few applications for health and well-being that have been adequately tested[13]. Some applications on the market can jeopardize the health of the patient and are potentially dangerous for clinical use. Especially, e.g., some apps for the dosage of opioids, the prediction of cardio-vascular risk or the diagnosis of melanoma have proved to be inaccurate[14].

[13] G. Eysenbach, *mHealth and Mobile Medical Apps: a Framework to assess risk and promote safer use,* “Journal of Medical Internet Research”, Sept 2014, 16 (9), e210; S. Misra, T.L. Lewis, T.D. Aungst, *Medical application use and the need for further research and assessment in clinical practice: creation and integration of standards for best practice to alleviate poor application design*, “JAMA Dermatol.”, 2013 Jun, 149 (6), pp. 661-662.

[14] On these issues, there is already a wide-ranging debate: M. McCartney, *How do we know whether medical apps work ?,* "BMJ", 2013, 346, pp. 181; A.W. Buijink, B.J. Visser, L. Marshall, *Medical apps for smartphones: lack of evidence undermines quality and safety,* "Evid. Based Med. ", 2013 Jun, 18

In this regard - given the lack of adequate testing - it may be necessary to check the variables that can affect risk in the use of apps, distinguishing the internal risks of the apps (e.g. the display) and external risks (the context of use). Internal risks could be reduced with proper regulation; external and contextual risks through suitably educating doctors (if the use is clinical) and/or the users, to make them aware of proper use.

However it has been shown that some health related applications with clinical use do not provide training for doctors using them and that they do not involve doctors in the design and development process[15], Often the designer has great technological knowledge but a lack of medical expertise; the doctor, in turn, is familiar with the scope of application, but knows little about technology; the user, ultimately, tends to rely on technology, often without being adequately informed about the limits of safety and the possible risks.

5.2 Use of data and privacy

The considerable amount of data collected and analyzed by users (data on health and medical data, personal data, biometric data, social data, environmental data) and the ubiquity and continuity of the process of communication in the so-called “mobile ecosystem” (including providers, manufacturers, vendors and users) raise many relevant issues regarding privacy[16].

It generates a huge amount of complex, heterogeneous data, rapidly and continuously accumulated through the monitoring of physiological parameters that are collected, studied, interpreted and correlated with algorithmic models. This explosion of information raises some controversial aspects regarding privacy in relation to their use by parties unrelated to the therapeutic relationship or for non-therapeutic purposes.

The problem of the "third party request" is becoming ever more crucial within the use of the network. As the NBC has emphasized in the document *The identification of the human body: bioethical aspects of biometrics*, any information may be relevant and become discriminatory when connected to others and used to make "profiles" of individual users. The collection of data relating to health, or even just regarding requests for healthcare information, may give rise to elements of relevance for the

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(3), pp. 90-92; F. Haffey, R.R. Brady, S. Maxwell, *A comparison of the reliability of smartphone apps for opioid conversion,* "Drug Saf", in February 2013, 36 (2), 111-117; J.A. Wolf, J.F. Moreau, O. Akilov, T. Patton, J. C. Inglese, J. Ho, L.K. Ferris, *Diagnostic inaccuracy of smartphone applications for melanoma detection, "*JAMA Dermatol", April 2013, 149 (4), pp. 422-426. The problem that remains open on the practical level concerns the fact that the exponential rate of designing new apps, makes it difficult to carry out the evaluation of the risk / benefit. Medical apps are not designed to function in a particular device, but can work with different operating systems: Given the versatility of operating systems (current and future), it is not possible to test them all for safety.

[15] E.g. some applications for asthma, food diary for diabetics, my recovery applied to preparation management for operations and after surgery, for rehabilitation; use of games to control panic attacks; -home HIV testing, sexual diseases, streptococcus.

[16] As part of the processing of sensitive data: *Directive 95/46 / EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data; Directive 2002/58 / EC concerning the processing of personal data and the protection of privacy in the electronic communications sector.* See Appendix.

market of pharmaceuticals, medical services, insurance and labour. Without appropriate regulation and a rigid system of restrictions and controls (such as through the clear separation between search engines and search sites) it is difficult to prevent serious phenomena from occurring - in some areas - marginalization and discrimination, linked to the profiling system (how is it possible to prevent, for example, those visiting sites or purchasing apps for heart problems, from being classified as possible cardiopaths and subsequently prevent this information from reaching the labour market or the insurance market?). These phenomena become even more serious in so far as they occur without the person's knowledge and may call for forms of protection or the defense of one's rights.

The problem not only affects health and medical data, but also the data obtained from apps for wellness and lifestyles. This data is called "raw" (raw data) even if they are not directly medical, combined with other data, they may have a medical importance and allow for the definition of a health profile of the user, with reference to health and to the risks for health[17]. Caution should be taken because, despite being health data, they are currently treated as personal information, therefore with a lower level of protection[18].

What also emerges is the concern that the use of apps leads to maximizing the use of medical/personal data without any appropriate knowledge, or rather with indifference or even for recreational purposes, especially among young people.

To be noted therefore, are the following problematical elements related to privacy:

a) a lack of transparent information to users, before downloading the application of data, on what and how much data is used for possible research (for scientific, epidemiological or commercial purposes, or in any case used for purposes that are not necessarily in the interest of subject); who the data is used and managed by (data controllers); where the data is stored (data repository); a lack of information as to whether the data is to be combined with other data from which health-related information can “reasonably” be inferable;

b) absence of information on the possibility of withdrawal of consent, rectification and destruction/erasure of data;

c) the absence of information on the risk of identification, when partial anonymization is not possible or guaranteed[19];

d) a lack of information on the risks of data access by third parties (insurance companies, employers, etc.) and the possibility that those who store data may 'sell' it to form research databases (commercial/scientific). In some cases it is stated that the data will be used for commercial purposes, but often in special sections of the app

[17] E.g. if one collects data of the counting of the number of steps taken once only, such data reasonably will not lead to any inference. These are not data in a medical context and are not correlated with other data, therefore not relevant for research. But if they are systematically collected and combined with other data (e.g. gender difference, age, habits) they can become important for research.

[18] See note art. 29 Working Party. C.f. Appendix.

[19] There may be user authentication systems based on biometrics, tokens, technical log tracking, similar to the banking sector (*digipass, SMS authentication*).

this is not readily available for those who do not have adequate computer skills. In some cases this information is relegated to third party websites and therefore is not present within the app.

An interesting aspect that is emerging in the ethical debate is that the very construction of applications is based on the requirement of “privacy by design” as a condition of the very legitimacy of the app. It is an expression that indicates the possibility that the issue of privacy is already considered at the design stage of the application, for example through the construction of applications that have *a priori* determined the manner and limits of access to personal data, the possibility of control over who has access, from manufacturers and users, the request only for the data required for the app functioning, the effective revocation of data on demand[20].

5.3 Informed consent

From the above, the NBC, although it is well aware of the difficulty of realizing informed consent and protecting the privacy of users in this new field of application, nevertheless, it hopes there will be the possibility of giving appropriate information and a transparent communication at the time of using the app so as to achieve informed consent.

But, how should the patient be informed about the issues relating to security and privacy?

The Warsaw Declaration on the “appification of society” (September, 2013), in the context of the meeting of the Data Protection and Privacy Commissioners, 35th annual international conference, proposed the so-called "granular consent" [21] indicating that the consent must be given for each type of information. The subject should therefore express different consent: general consent to download the app and a separate consent for the specific purpose of the app. Each type of consent should be preceded by separate information[22].

This solution has several problematic elements. Firstly, there is so much digital information written in small characters to display on smartphones; sometimes the real alternative of dissent or change of choice is absent. There has already been concern that the informed consent displayed on screen and not on paper, leads to clicking in

[20] Art. 17 Directive 95/46/EU, art. 14.3 Directive 1999/5/EC and 23 of the Proposal for the Regulation on data protection “the controller shall implement appropriate technical and organizational measures and procedures in such a way that the processing will (…) ensure the protection of the rights of the data subject”.

[21] See Paragraph 6: “individuals can finely (specifically) control which personal data processing functions are offered by the app they want to activate”.

[22] This is the line of thought based on the interpretation of paragraph 107 of the Explanatory Memorandum *Recommendation N° (97) 5 on the protection of medical data*: “But even in cases where his/her consent is not required - that is, when the collection and processing of medical data follow an obligation under the law or under a contract, are provided for or authorised by law, or when the consent requirement is dispensed with - the recommendation provides that the data subject is entitled to relevant information”. Also Article 29 Working Party has recently published a document "*On apps on smart devices*", which emphasizes the need to inform in a clear and unambiguous way the way in which the data is used (data type, purpose, period) before installation of the app. The right to be informed is also expressed in art. 10 Directive 95/46 / EC; art. 5.3 of the ePrivacy Directive 2002/58/EC.

an immediate way without sufficient time for making an informed choice and without the possibility of ascertaining actual voluntariness. Furthermore, the multiplication of consent may lead to irritating the user or often to giving consent just in order to speed up the procedure, without - here as well - adequate awareness. In this way the meaning of informed consent would be undermined[23].

This need to inform users and receive their consent becomes even more complex when the apps are used by children, as occurs with great frequency, both medical and non-medical apps. So what are the precautions to consider before a teenager or older minor downloads a health app?

Obtaining informed consent in the medical field presupposes symmetrical and reciprocal communication. Communication is symmetrical when individuals are equally powerful in the interaction and it is reciprocal when the positions between those giving the information and those receiving the information take place in the recognition of their respective autonomy. If this already appears hardly feasible to ensure with regard to an adult in the use of medical apps, where the relational context is missing, it is even less so for teenagers whose elements of competency, such as the ability to decide, the reasoning of decisions, the prediction of outcomes, involve a balance between these elements that is established only progressively during the stages of development.

One must also consider that it is legally debatable that such consent could nevertheless be given merely by the child: since these matters concern the child's health, they must necessarily fall under the responsibility of the parents or legal representative. And if the risks associated with these medical devices are consciously undertaken by an adult, the same can-not apply for a minor, as his best interests in the context of care is still represented by traditional use of the patient-doctor relationship. Particularly since the most downloaded apps by users, as mentioned above, request access to a large amount of data, without even adequately explaining the purposes for which this information would be used and the possible personal data that will be collected and the purpose of this.

However, it is difficult to know whether the use of the medical app is carried out by an adult or a minor. This is a problem that, even in the field of ICT, should be highlighted: thought should be given to providing specific additional guarantees for minors, by identifying, for example, information technology requirements and mechanisms to verify the age of the purchaser of an online health application. It also follows that there is a need to provide, precisely for minors, simple, and concise information that also includes educational references which encourage awareness of the issues, using suitable language. The education of minors, active users of these new technologies, is particularly urgent and relevant in terms of bioethics: an education enhancing the instruments of self-defense of the young in the context of the use of technology. It should also be the role of parents, the buyers for their

[23] E. Mantovani, P. Quinn, B. Guihen, A. Habbig, P. Hert, *eHealth to mHealth – A Journey Precariously Dependent Upon Apps?*, "European Journal of ePractice", vol. 20, November 2013; M. Parker, *Ethical considerations related to mobile technology use in medical research*, "Journal of Mobile Technology in Medicine", 2012, 1, 3, pp. 50-52; M.J. Siòlberman, L. Clark, *M-Health: the union of technology and healthcare regulations*, Greenbranch publishing, 2012.

children of mobile technologies, to make use of control systems (parental control) for accessing the app which should be included in the system by the manufacturer.

Furthermore, it is also hoped that the medical app, which contains data and treatments aimed at minors, should be designed, supported and endorsed by scientific companies or health institutions specialized in diagnosis and pediatric care. The same proposal on the market should be diversified in relation to target recipients (adults or minors).

5.4 Dependency and technological vulnerability

A simple "touch", just one "touch", is all that is needed to enter the world of infinite potential that mobile-health offers to health protection and the construction of individual identity via continuous comparison with one's own body, even in its most hidden and impalpable aspects, such as change in blood glucose levels or cardiac arrhythmia. Is one "touch" sufficient even to pull through? At what stage does an increasingly pervasive supply of medical and therapeutic indications end up becoming obsessive, deeply affecting an individual's existence and patterns of coexistence?

As already pointed out, various forms of addiction both individual as well as social and political may develop.

'Personal dependency' is expressed through attention to the single changes in one's physical and psychological condition, which could lead to a genuine health consciousness pathology, exacerbating the fear of disease and morbid attention to the most insignificant details and consequent medicalization, the phenomenon of the so-called 'quantified self'[24]. This expression indicates a tendency to incorporate technology in everyday life with the recording and comparison of real-time data on human activity: measurement of food consumed, number of kilometers covered, control of the calories consumed, the quality of the air breathed, registration or the emotional state of physical and mental performance[25].

This trend is part of a wider context in which prevention is increasingly understood in an individualistic sense, devaluing the collective dimension of health, the importance of which is specifically mentioned in our Constitution; it results in the induction of specific lifestyles, in emphasis on control, self-management of health and individual responsibility for one's own health. A similar trend may contribute to exacerbate forms of health fanaticism and the medicalization of life, as well as even

[24] 'Quantified self' is a movement of thought that was born in the scientific field (in San Francisco in 2007) and has become a 'philosophy of life', summed up in the slogan "I quantify, therefore I am". On the topic see *Le corps, nouvel objet connecté, du quantified self a la m-santé, les nouveaux territoires de la mise en données du monde*, Commission National de l'Informatique et des Libertés, May 2014.

[25] This phenomenon has been interpreted as the application of the scientific method to the personal sphere, with the aim of biometrically quantifying oneself and data sharing through ICT. The urge to quantify oneself and 'datify one's corporeal and psychical functions can arise from the desire of self-control: by measuring one feels able to exercise power over themselves. Keeping tabs on what you can do gives the feeling of being masters of one's own destiny in an era like ours, marked by uncertainty. The difficulty or impossibility to control the world and what is happening around us urges to fill with a sort of 'compensatory mechanism' such a lack with the will to control what becomes technologically controllable.

the capillary government of people's lives, putting a particular emphasis on health reductively understood as only physical well-being.

One might also configure a `social dependency` with the creation of `norms of behaviour` that help to continuously redefine and elevate the standard `performance` regarded as normal in society, which ends up imposing itself on others, in a race to health fanaticism as well as consumerism (market pressures to buy new apps or supplements or drugs to improve physical and mental performances), medicalization (considering inability to achieve certain objectives, as an illness which creates discomfort)[26]. A condition that can lead to the expropriation of one's autonomy by the market, but even by oneself. Those who do not use these technologies could be regarded with suspicion and suffer serious limitations in relational life.

One could envisage even scenarios of `political dependency`: the utilization of these technologies could become mandatory, reducing the space for individual autonomy and justifying an increasingly intense intrusion in one's personal sphere. Let us take the possibility that in the near future citizens wanting to take out life insurance and/or health insurance policies could be classified in different `clusters` and be granted more favourable economic conditions, depending on the proven use of such technology packages, with the result that its use would be made "almost obligatory" otherwise the penalty would be exclusion from the groups of policyholders with a lower premium.

It could then give rise, if not already underway, to a form of `economic dependency` so that the price of these technologies, at first negligible, will tend to increase insofar as the demand increases along with their widespread and systematic use. We can-not forget that it is primarily the market that stimulates and fuels the proliferation of mobile-health and therefore it will be the market, without appropriate regulation, to decide on prices and terms of use. Ever more frequent, as mentioned, is the offer of free access to certain benefits in exchange for the waiver of confidentiality in data processing. What and how many other constraints could emerge in time and with use?

Dependency is not a new phenomenon. In many respects our whole existence is built on the needs, desires and passions that make us "dependent" from others and from things. In mobile-health this phenomenon occurs in a variety of ways, through exacerbating the fear of illness or the obsession with health that impelling urge for attention and reputation, that so belongs to social networks. It should not be ruled out that the ease of access, utilization in solitude, compulsiveness waiting for the results may develop pathologies similar to those already found in compulsive gambling.

Alongside regulations and controls there is, therefore, the more general problem of training to use this means of gaining information and relating with one's own body and health. The existence of increasingly complex and refined technology without a corresponding rise in the level of awareness and culture is inconceivable.

[26] The issue was addressed by the NBC in the opinion *Neuroscience and pharmacological cognitive enhancement: bioethical aspects*, 2013.

5.5 *Health self-management*

Is Google now the first doctor for Americans? Will it be even more so with the Apple Watch on the market, the watch designed to ensure the continuous monitoring of our health interconnected with all services offered by the Internet?

New technologies can play a decisive role to fundamentally change the way in which citizens manage their own well-being and health. There is the phenomenon of more active participation by the individual due to improvement in education levels (in technologically advanced countries) and the increasingly pervading availability of ICT as an instrument of knowledge, within the context of changes of a cultural nature that tend to reduce the constitutive asymmetry of information between doctor and patient.

The active participation by citizens in the management of their own health is extremely positive, but it can have negative implications insofar as it is expressed as a desire for self-medication: the citizen/patient may feel able to take care of oneself and be responsible for one's own health, without feeling any need for a doctor. The ability to download independently from the internet ITest/home-testing and IT tools that enable analysis, interpretation and visualization through diagrams with comparative data at any time and place, can lead to self-medication, self-diagnosis, and self treatment[27].

This can have advantages in some respects in the prevention of disease and the maintenance of appropriate lifestyles[28].

The ethical problem emerges in relation to diagnosis and treatment of pathologies, when the patient does not have sufficient skills and information to make a direct medical assessment by himself. There is, in this context, the problem of medical expertise and computer/digital ability for the safe use of the technical tools available, as well as the reliability/security of the same technologies. The user can have access to data that were once generally mediated by a doctor, while today these may be obtained directly.

In this sense, applications for medical purposes (diagnosis, treatment, care) should require for medical supervision (information at the moment of downloading the app/conditions for downloading the app). It should be the doctor to adequately inform the patient and to make sure the patient is able to use such an instrument, and that it is reliable, to avoid forms of self-management by the patient that would endanger his health.

Even on the part of the doctor the use of m-health can have many advantages, enabling real-time monitoring of the patient at a distance, it is an improvement in care in terms of quantity and quality. But at the same time it can become a form of removal of responsibility from the doctor, and `passing` it to the patient, by increasingly restricting face-to-face appointments and thereby reducing the

[27] To be emphasized regarding the possibility of purchasing drugs and substances online, even dangerous ones, such as opioids, by users without any prescription from the doctor. See in this regard: F. Bert, V. Galis, S. Passi, MR. Gualano, R. Siliquini, *Differences existing between USA and Europe in opioids purchase on Internet: an interpretative review*, "Journal of Substance Use", 2014, Early online: 1-8.

[28] Cf. NBC, *Lifestyles and Health Protection* 2014.

interpersonal relationship (replaced with video-appointments) impoverishing or even eliminating the relationship with the patient.

5.6 The digital divide

The problematicalities detected in the use of technology should not however overshadow its unquestionable importance and the opportunities acquired by our society (cf. § 4).

Insofar as the undoubted advantages of appropriately-used m-health are recognized, the problem of exclusion of those without access to technology emerges, namely the problem of the gap between those who have the tools and skills and those who are marginalized due to a lack of technology or lack of knowledge of the use of technology and/or stimulus for knowledge.

In this sense it is essential to reflect upon a fair distribution of technology resources, on the extension of the right of access to new technologies for all, including disadvantaged and vulnerable groups (the elderly, the disabled, the indigent and those not sufficiently competent to actually use technology).

An essential element is to appropriately educate citizens to use the new technologies for mobile-health, in order to obtain adequate skills for properly using such tools. Non-discrimination should also be guaranteed towards those who can-not or will not be able to access these medical technologies, whilst ensuring the provision of alternative solutions for health treatment.

This problem is known as the "digital divide" which can certainly have among its causes the lack of computer skills and deficiencies in the capacity of interpretation of the information available via the app. However, it should be recalled that this gap can be associated with other reasons such as the cost of mobile devices (smartphones and tablets) therefore a socio-economic gap and the network coverage for the Internet in the area under consideration. These variables can strongly influence equity of access to possible healthcare services offered through m-health.

6. Recommendations

The Committee recognizes the importance, the positiveness and the great scientific relevance of technological progress in this area. While recognizing this importance, given the issues related to health and privacy that are nevertheless present, it highlights certain ethical recommendations. The Committee recommends:

1. drawing up of internationally agreed criteria for classifying software used as medical devices, distinguishing them from those that are not medical devices, specifically differentiating the applications for health in the proper sense and the applications for wellness /fitness;

2. promoting interdisciplinary research between computer experts, engineers doctors, together with ethicists, cognitive and social sciences experts, in the phase of

design, testing and evaluation of the applications as to ensure the protection of health, privacy, and autonomy;

3. encouraging developers and industries to produce apps which are actually useful and reliable for the health of citizens;

4. identifying the responsibility of companies/industries that produce apps, placing as requirements to design the safety and minimization of data collection - as far as possible - making data anonymous;

5. establishing an observatory to monitor health apps in order to devise potential risks and the possible need to revise regulations; it is hoped that scientifically accredited sites and/or portals will be established with guidance on the classification of health applications on the market, continuously updated (at least for the most popular apps), in relation to the risks;

6. promoting an appropriate information sheet and transparent communication for the user whenever using the app with an informed consent form clarifying the risks to health and privacy, specifying the possibility of revocation of consent and the destruction of data; specific attention should be given to minors, particularly vulnerable subjects and active users of technology, identifying IT tools for parental control and/or age verification online in order to prepare, accordingly, appropriate and adequate information;

7. implementing of informing and educating doctors about mobile-health, in order to allow the acquisition of specific expertise enabling them to use the new IT tools to improve the relationship with the patient in terms of control and autonomy, mindful of the need to preserve and not to impoverish the interpersonal relationship;

8. fostering studies on the impact of the use of apps, with specific attention to the implications on personal and relational identity, in order to clearly identify the problems of technological dependency and vulnerability;

9. monitoring an adequate education of particularly vulnerable groups - children, the elderly, the disabled - in order to ensure non-discrimination and enhance inclusion of the advantages in the use of the new technologies;

10. social promotion of a critical use of the new applications for health in the context of a balanced relationship with one's own body and health, avoiding forms of excessive health fanaticism and medicalization, focused on the single dimension of health as well-being.

Appendix: Regulation

At the international level[29]

Guidelines

In the USA, the Food and Drug Administration has developed the Guidelines (2011, 2013, 2015) establishing the criteria for the identification of medical devices, within the context of apps, distinguishing their regulation according to the different categories[30]. According to the FDA, apps are medical devices if they are used as an accessory to a regulated medical device or transformed as a mobile platform in a regulated medical device. If, therefore, a limited number of apps similar to medical devices (about 100), must in some way be regulated or subjected to a certification path, for all other types of apps, not subjected to this path, certification is not required, however the issues of validity, security and respect for privacy are raised. The FDA speaks of 'enforcement discretion', but not regulation. The FDA believes that if the aim of the application is the management of health in everyday life (thereby excluding it as a medical instrument for diagnosis, care and treatment), and if the risk is low, it does not need to be treated as a medical device. According to US regulations, apps are classified as medical devices, when they act on the structure and functioning of the human body ('to affect the structure or any function of the body of man'). However, some 'gray areas' remain which are difficult to assess, with possible diversified uses that could, depending on the context, be classified as medical devices or not. The FDA distinguishes high-risk applications (medical devices), evaluated by a third party and low-risk applications (non- medical devices), validated by the same manufacturer.

A similar approach is followed by the Medicines and Healthcare products Regulatory Agency (MHRA), the agency of the Health Department of the English NHS. This agency has shown a model for classification of clinical apps, which highlights the need to submit to a process of validation only those apps that are in fact similar to medical devices. The National Health Service reports on the website the apps that have passed a review to prove their safety and compliance with the rules of data protection and security from a clinical standpoint.

A similar initiative in this direction was taken by the "Agencia de Calidad Sanitaria de Andalucia" with a Catalogue for Mobile Health Applications. A number of countries are turning to the use of guidelines. The Therapeutic Goods Administration, Department of Health in Australia (Australian Government) developed guidelines for health care workers in 2013, including apps in the regulation in force for medical devices.

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[29] A.J. Barton, *The regulation of mobile health application*, BMC Medicine, 2012, pp. 10-46.

[30] N.G. Cortez, J.D., I. Glenn Cohen, J.D., A.S. Kesselheim, FDA Regulation of Mobile Health Technologies, "The New England Journal Of Medicine", 2014, 24, pp. 372-379. Mobile medical Applications: Guidance for Industry and Food and Drug Administration Staff, FDA September 2013, http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf., document February 9, 2015.

Regulations/proposals for regulation in Europe

There is no explicit regulation. The applicable regulation in force:

As part of the discipline of medical devices: Directive 93/42/EEC on medical devices, Directive 98/79/EC in vitro diagnostic medical devices, Directive 90/385/EEC on active implantable medical device.

In the context of the processing of sensitive data: Recommendation N° (97) 5 on the protection of medical data, Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, currently being reviewed[31]. Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector, modified by Directive 2009/136/EC. With reference to users also Directive 2011/83/EC on consumers' rights.

With reference to paragraph 38 of the "Explanatory Memorandum"[32] of the Recommendation N° (9) 5 on the protection of medical data, where the link between medical data and non-medical data is highlighted, for example, lifestyles[33]. In this report, paragraph 61, states that the use and analysis of data should be for therapeutic purposes[34]: in this sense there is discussion on the possibility that the data related to lifestyle may be regarded as medical data.

In the context of European initiatives on this topic refer to:

- Guidelines related to the topic:

• Guidelines on the qualification and classification of stand-alone software used in health care within the regulatory framework of medical devices Meddev 2.1/6 January 2012. In these guidelines the definition of medical device means any instrument, apparatus, application, software, material or other article, used alone or in combination, including the software intended by the manufacturer for specific use in diagnosis and/or treatment, prevention, monitoring, treatment, also aims to relieve pain, harm or compensate for disabilities, for research, replacement or modification of the anatomy or physiological process. Stand alone software is software that is not embedded into a medical device at the time of placing on the market. The definition

[31] Commission proposal: http://ec.europa.eu/justice/dataprotection/document/review2012/com_2012_11_en.pdf

[32] Council of Europe - Explanatory Memorandum on the Recommendation on the Protection of Medical Data. Available at: http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)5_EN.pdf

[33] "The drafters of the recommendation further agreed that under the terms of the recommendation, "medical data" should also include any information - unless it is public knowledge - giving a ready idea of an individual's medical situation, for instance for insurance purposes, such as personal behaviour, sexual lifestyle, general lifestyle, drug abuse, abuse of alcohol and nicotine, and consumption of drugs. This was the reason for including in the definition of medical data the words "manifest and close," that is, having a clear and direct impact on the health situation of the individual".

[34] "In practice, this means that the principles are applicable to the collection or the processing of medical data for the purpose of medical treatment, the assessment of the health condition or the fitness of a person".

of 'medical device' is mainly identified in the intention of the manufacturer (manufacturer's 'intended purpose').

• Guidelines on medical devices MedDev 2.7.1 rev 3 Clinical evaluation guides for manufacturer and notified bodies, identifies the documents that a manufacturer must submit to the notified body in the presentation of clinical data that will serve for CE marking and, therefore, all the elements that a notified body itself must take into account when assessing the same clinical data before the CE marking of a medical device. A specific document for the clinical evaluation of coronary stents is attached to Appendix 1 of MEDDEV.

• Guidelines on medical devices MedDev 2.7.2, Guide for Competent authorities in making an assessment of clinical investigation notification (European Commission Enterprise and Industry Directorate General). Lists the documents and the main elements which the competent authorities must take into account during the assessment of clinical investigations notified by the manufacturer.

• Guidelines on medical devices MedDev 2.7.3, Clinical Investigations: serious adverse event reporting (European Commission Enterprise and Industry Directorate General). It specifies how to communicate to the competent authorities any serious adverse events occurring during the conduct of clinical investigations before marketing.

• Guidelines on medical devices MedDev 2.7.4, Guide for clinical investigation-guide for manufacturer and notified bodies (European Commission Enterprise and Industry Directorate General). It specifies the essential elements for the proper planning and performance of clinical investigations of medical devices, as well as providing details of the circumstances in which clinical trials are required.

• Guidelines on medical devices MedDev 2.12/2 rev.2, Post-market clinical follow-up studies-Guide for manufacturer and notified bodies (European Commission Enterprise and Industry Directorate General). It is a guide for the planning and carrying out of post-market studies as part of the plan for follow-up after-sales developed by the manufacturer.

• Guidelines on medical devices MedDev 2.12/1, Medical devices vigilance system (European Commission Enterprise and Industry Directorate General). Illustrates the European system for reporting and evaluation of incidents and corrective actions for security (FSCA) involving devices marked CE, among them those used in clinical investigations after marketing.

- The Warsaw Declaration on the 'appification of society' (September, 2013), in the context of the meeting of the Data Protection and Privacy Commissioners 35th annual international conference, raised forcefully the issue of privacy.

- The European Commission has released a 'Green paper on Mobile Health' (10 April 2014)[35] with the aim of collecting, with extensive consultation of citizens/ patients, health professionals and manufacturers, their respective opinions on the

[35] http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth.

different obstacles that prevent a wider spread. A report on the consultation has also been published[36].

- Recently, the Council of Europe, Directorate General Human Rights and Rule of Law, circulated a questionnaire (15 September 2014) Consultative Committee of the Convention for the Protection of individuals with regard to automatic processing of personal data, data protection and medical technologies issues. A consultation was attended by: the Privacy Authority, Ministry of Health, the National Committee for Bioethics, for ethical aspects. The question of m-health in the context of e-health is treated specifically.

- A working group was established (in 2013), Article 29 Working Party on apps (WR29), an advisory body to the European Commission on the topic. In February 2015 the group produced a document which clarifies the definition of healthcare data in the context of applications on lifestyles and well-being. A letter was sent from the Group of European guarantors - addressed to the Commission - on the definition of health data in relation to apps. The annex to the letter reveals some important bioethical reflections. In the annex please note that the use of healthcare data is prohibited by art. 8 of the Data Protection Directive (95/46/EC), with certain exceptions. Healthcare data are qualified as highly sensitive data that require proper restrictive protection: the misuse of data can be irreversible and result in consequences for the individual. Healthcare data are data about the health of the individual; they are medical data originating in a medical context, however also covering a broader context. Even data correlated to health fall within healthcare data (e.g. the data of those who wear glasses or contact lenses; lifestyle habits such as smoking or alcohol use). Healthcare data are not only data collected when one is sick (e.g. the results of blood tests are healthcare data even if one is healthy). One can speak of healthcare data regardless of whether they are the result of tests carried out by doctors or in a medical context. In this sense, the group notes that the core of the regulation on data protection refers to reasonable proportionality in the collection of data (including `data controller` and `data subjects`): Users must be aware of, the collection of data minimized to actual needs, with the identification of those who collect the data and for what purpose (specific, explicit, legitimate). The group points out that it is not clear whether the applications for lifestyles and fitness are covered by that regulation.

- At European level, in October 2013 the first European Directory of Health Apps was issued which includes about 200 mHealth apps on an online platform[37].

[36] https://ec.europa.eu/digital-agenda/en/news/summary-report-public-consultation-green-paper-mobile-health

[37] http://myhealthapps. A further document at European level specific for the health sector is represented by *eHealth Action Plan 2012-2020: Innovative Healthcare in the 21th Century*, whose aim is to remove obstacles to the full use of digital solutions in the European healthcare systems.

Regulation Proposals

Within the European Parliament there is an ongoing review of the regulation on medical devices[38] and the processing of personal data.

The European Parliament on 22 October 2013 adopted a text on the proposal for a regulation Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) N° 178/2002 and Regulation (EC) N° 1223/2009 (COM 2012/0542 - C7 0318/2012 - 2012/0266 COD)[39].

Within the framework of the protection of personal data the regulation is being revised.

European Parliament legislative resolution of 12 March 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)[40].

As the national level

There is a lack of explicit regulation of m-health. The following can be considered regulatory references:

- Code for the protection of personal data: DL June 30, 2003, no. 196. In Article. 122 "Information collected in respect of the contractor or user" refers to the storage of information and the need for consent with simplified procedures (taking into account consumer associations) and the `use of methodologies that ensure the effective awareness of the contractor and user`. For the purpose of the expression of consent computer programs and devices with easy and clear usability should be utilized.

- Decree Law October 18, 2012, no. 179, sec. Agenda and digital identity, sect. 12: electronic health records and surveillance systems in the health sector; art. 7 coding systems of data; safeguards and security measures to be taken in the processing of personal data in the interest of the patient; details of allocation of ID code not allowing for direct identification, interoperability criteria at regional, national and European levels.

- Related Decrees and Circulars:

• Legislative Decree 507/92 and subsequent amendments, art. 7 paragraphs 1 to 6 and paragraphs 8 and 9 and Annexes 6 and 7. Implementation of Directive

[38] http://ec.europa.eu/growth/sectors/medical-devices/documents/revision/index_en.html

[39] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P7-TA-2013-0428+0+DOC+PDF+V0//EN

[40] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN

90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices.

• Legislative Decree 46/97 and subsequent amendments, art. 14 paragraphs 1 through 7 and paragraphs 9 and 10, and attachments viii and x. Directive 93/42/EEC concerning medical devices.

• Legislative Decree n. 37/10. Implementation of Directive 2007/47/EC amending Directives 90/385 / EEC on the approximation of the laws of the Member States relating to active implantable medical devices 93/42/EEC concerning medical devices and Directive 98/8 / EC concerning the placing of biocidal products on the market.

• Ministerial Decree of 2 August 2005. How to submit documentation for notification of clinical investigation with medical devices.

• Circular of the Ministry of Health on August 2, 2011. Clarification on "mode of submission of documentation for notification of clinical investigation with medical devices".

• Legislative Decree 24 June 2003 no. 211 implementation of Directive 2001/20 /EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal product for human use.

• Ministerial Decree of 21 December 2007. Conditions for issuance of the request for authorization to the competent authority for communication of substantial amendments and the declaration of the end of the clinical trial and the request for an opinion to the ethics committee.

• Harmonized technical standard UNI EN ISO 14155 - 2012. Clinical investigation of medical devices for human subjects. Good clinical practice.

• Harmonized technical standard UNI EN ISO 14971 - 2012. Medical devices-application of risk management to medical devices.

• Ministerial Decree of 12 March 2013. Restrictions, conditions and facilities where one can conduct clinical trials of medical devices, in accordance with Article 14 of Legislative Decree 24 February 1997 N° 46, as amended.

- Initiatives of the Ministry of Health: the establishment of the Directorate General of digitization and computerization. Currently being processed and implementation of DL 2012 by the Ministry of Health.

- Guidelines of the Data Protection Authority (currently being processed).

Under the "Privacy Sweep 2014" sponsored by the Global Privacy Enforcement Network (GPEN) 25, the Data Protection Authority launched in May 2014 an investigation into medical and wellness applications, downloadable on smartphones and tablets, aimed at assessing the degree of transparency on the use of personal data, the required permissions before downloading and respect of the Italian legislation on the protection of personal data. The survey results, published September 10, 2014, confirmed how even in our country users are not adequately protected and often are not put in a position to express free and informed consent. 50% of Italian and foreign medical and wellness applications analyzed by the Authority, and randomly chosen among the most downloaded available on various

platforms (Android, iOs, Windows, etc.), in fact, either do not provide users with an informative sheet on the use of data prior to installation, or give general information, or call for excessive data in relation to the features offered. In many cases the privacy policy is not adapted to the reduced size of the monitor, making it difficult to read, or it is placed in sections concerning, for example, the technical characteristics of the smartphone or tablet.

- Code of Medical Ethics (2014).

The Code - in Title XVIII " healthcare computerization and innovation," art. 78 on "Information Technologies" – highlights the requirement of the use of new technologies the acquisition of consent, the protection of confidentiality, the relevance of the data collected and the security of techniques. The doctor is called upon to "guarantee the conscious participation of the patient". The doctor's use of these technologies for the purposes of prevention, diagnosis, treatment, and clinical surveillance, is to adhere to the criteria of "proportionality, appropriateness, efficacy, and security".