

NBC paper explores bioethics concerns posed by mHealth

On 28 May, the Italian National Bioethics Committee ('NBC') published a paper entitled 'Mobile Health Apps: bio-ethical aspects.' The paper presents a survey of several bioethics problems involving mobile health ('mHealth') and identifies possible solutions, as Silvia Stefanelli of Stefanelli & Stefanelli Law Firm explains.

The NBC's recent paper¹ highlights the positive benefits of mHealth such as improving awareness and the active participation of individuals in personal healthcare, facilitating communication between doctors and patients, improving the efficiency of the health system by reducing costs, and widening access to treatment. The NBC also highlights several important legal and ethical issues.

App legal framework and patient safety

The NBC points out how the legal classification and legislative framework regarding mobile apps can have an impact on patient health and safety². An app classified as a medical device has to comply with Directive 93/42/EEC (or similar authorisation, depending on the country), passing through a special clinical evaluation - Annex X. This process results in more strict regulations when compared to related wellness apps, which are not classified as a medical device, and are only required to comply with Directive 2001/95/EEC.

To avoid complex medical device regulation, many apps are released as intended for 'no medical use.' However lacking medical device safety controls, a lot of these apps may impact patient health³. Thus the NBC recommends developing international classification criteria to draw a distinct line between

health applications (classified as medical devices) and wellness applications.

App reliability and monitoring

The legal framework applicable to a given app is deeply linked to its reliability. The NBC acknowledges that a consumer most frequently uses other users' comments and statistics concerning downloads as the criteria to decide whether to download an app. Whilst using the app, usually patients are not able to evaluate the associated health risks or how their personal data is protected. The NBC therefore suggests establishing a committee to monitor medical apps, track potential risks, and observe the need for regulation revision. It also suggests creating scientifically accredited websites and/or internet portals to classify and analyse the most popular health apps, and alert patients about risks associated with app usage.

Data protection and industry

Owing to the potential for the misuse, or commercial use, of data by unintended parties, data protection is emerging as one of the critical issues concerning app use⁴. The most critical aspects are:

- a lack of transparent information for users;
- a lack of information on data withdrawing possibilities;
- a lack of information on identification risks, where data can't be anonymous; and
- a lack of information on the access risk by third parties.

Addressing the criticisms listed above, the NBC suggests that companies address privacy issues throughout the engineering process ('privacy by design'), before the new Regulation on data protection is enforced⁵. The NBC asks for safety and minimisation of data collection, and - wherever possible - for 'anonymisation of the

data' to be considered.

Data protection and consent

Obtaining consent while processing personal information and health data is very complex, especially for health apps. The Warsaw declaration on the 'appification' of society⁶ proposed so-called 'granular consent',⁷ in which separate information and separate consents have to be given for any kind of information. For example a general consensus to download the app is given first, followed by consent for the specific purposes. However, according to the NBC, this solution may present several critical concerns, for example too much information for small screens, the lack of a real alternative to dissent, and the tendency to click without reading all the information, etc. These problems seem even more relevant when apps are downloaded by young users, who often lack knowledge and awareness of the associated risks.

To accomplish the Warsaw declaration's aims, the NBC proposes the provision of one set of general information to clarify the health and privacy risks, highlighting the legal possibilities of consent withdrawal and data destruction. Regarding children and active users of technology that are particularly vulnerable, the NBC suggests that a tool is included that enables parental control and/or 'online age verification' in order to prepare appropriate and adequate information measures.

App addiction

The NBC paper outlines a number of interesting thoughts about the risk of app addiction:

- a) Individual addiction consists of an obsessive attention to one's physical condition, that may turn into a psychological pathology: this

phenomenon is called the 'Quantified Self';⁸ an expression meaning the tendency to incorporate technology into our own life, by constantly measuring the calories eaten, miles walked, calories burned etc.

b) Social addiction relates to developing standard behaviour, which, being socially approved, might push people towards a 'mandatory' health consciousness, and towards heavy consumerism of health products (for example the abuse of food supplements to improve physical capacity).

c) Political addiction could arise when the use of technology becomes compulsory in certain practices (for example health or life insurance that provides advantageous conditions for patients using technology, thus excluding patients who lack such skills because of their age and/or incapability).

d) Economic addiction might appear as app prices could increase significantly with growth in demand and wide usage.

The NBC fears that the compulsive use of apps might lead to disorders similar to addictions to gambling or video gaming. For these reasons, the NBC proposals push towards:

- promoting studies on the impact of app use, with specific attention paid to all implications regarding personal identity and relationships, in order to avoid addiction problems;

- supervision and proper education of vulnerable groups in order to avoid misuse and discrimination; and

- social promotion regarding the correct use of medical and wellness apps, to avoid the risk of health-shape obsession.

Interdisciplinary work and new training

These are presented by the NBC as

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essential to reach eHealth and mHealth targets, not only for clinicians but also for patients.

Transitioning from a traditional healthcare system to an eHealth system involves a cultural leap, which concerns everyone associated with the eHealth sector: healthcare managers, clinicians, the medical industry, clinical engineers, lawyers, and patients.

Relevant research in this field has to be interdisciplinary to achieve optimal results. For example, app designers often have technological skills without the medical expertise, therefore their apps might be suboptimal because the designer may not be aware of the real situations in which the apps will be used. Conversely, clinicians often know the 'scope' of technology, but not how to use it properly. Often medical apps do not provide doctors with the necessary training, so apps may be used without completely understanding all of the operation modes; this situation presents risks relating to possible health damage and medical liability, but also inhibits the doctors' ability to explain the uses and limitations of the technology to patients.

Lastly, patients often tend to rely faithfully on technology, without being properly aware of the risks; this might further lead to technical or legal complications.

To summarise, the NBC paper advocates:

- the promotion of interdisciplinary research between computer scientists, engineers, and doctors, along with ethicists and social experts, during the design, testing and evaluation of apps, to protect patients' health, privacy and autonomy;

- the development of doctors' training and education in mHealth, in order to acquire new models for patient control, reducing concerns they may have

about losing their professional role and interpersonal relationship with the patient; and

- the education of patients about technology utilisation.

Challenges are raised as new technology is embraced by diverse groups of healthcare providers, encompassing both the public and private sectors. For a smooth transition into the effective use and implementation of eHealth services, a concerted effort will be required from all - including but not limited to the government, process designers, doctors, patients, and legal services. A progressive change in working methodologies will be critical, where different disciplines with complementary skills and expertise cooperate to find solutions to new problems under a unified vision.

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1. <http://www.governo.it/bioetica/eng/index.html>
2. For an overview see www.who.int/ent/ity/goe/publications/ehealth_series_vol3/en/
3. G. Eysenbach, 'mHealth and Mobile Medical Apps: a Framework to assess risk and promote safer use,' *Journal of Medical Internet Research*, September 2014, 16 (9), e210.
4. For e.g., http://europa.eu/about-eu/institutions-bodies/edps/index_en.htm
5. 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, http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf
6. https://www.priv.gc.ca/information/conn2013/declaration_e.asp
7. 'Interpretation of Explanatory Memorandum Recommendation N° (97) 5 on the protection of medical data,' September 2013, par. 107, <https://www1.umn.edu/humanrts/instree/coerecr97-5.html>
8. 'The body, new connected object, the self has quantified m-health, the new territories of the world data layout,' the National Commission for Computing and Liberties, May 2014.