

Health & Wellness Apps: what do we really know about them?

Pier Angelo Sottile

UNI/CT 527 Informatica Medica UNINFO



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Digital Health and Care



TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- ⌘ Ageing population and chronic diseases putting pressure on health budgets
- ⌘ Unequal quality and access to healthcare services
- ⌘ Shortage of health professionals

Potential of digital applications and data to improve health

- ✂ Efficient and integrated healthcare systems
- ✂ Personalised health research, diagnosis and treatment
- ✂ Prevention and citizen-centred health services

What EU citizens expect...

- 90% agree** To access their own health data (requiring interoperable and quality health data)
- 80% agree** To share their health data (if privacy and security are ensured)
- 80% agree** To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data



Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.



2 Health data pooled for research and personalised medicine



Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.



3 Digital tools and data for citizen empowerment and person-centred healthcare



Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

Many Examples of Apps in the Medical, Health & Fitness fields

- Businesses, public administrations and individuals continually make new digital services available to users through APPS.
- **BIG numbers**, as last seen in June 2018 f.e. on appbrain.com!
 - Apps on Google Store: 3.297.926, of which 99.995 regarding Medical, Health & Fitness Medical topics
 - Similar numbers can be found regarding Apps on Apple store

Obsession and/or alibi: “User Experience”

- The desire to make ICT and especially apps increasingly "easy to use" should not at all be underestimated. There's a trend to eliminate any kind of action (or friction) that could increase the difficulties or the time required to obtain data and/or results.
- This has become one of the obsessions of the industry, supported by various categories of users who complain about the limited time available to work on IT tools, ***but it generates further (great) risks on the security front.***

Issues around Apps in Healthcare

- So, regarding the App, what about:
 - documentation (technical, about the provider, promoter, testing, and correct use)?
 - quality and safety (risks)?
 - data protection?
 - integration of App data with other patient/person data?
 - scientific/expert review of the app?
 - accreditation of the apps?
 - regulatory aspects?
 - usage in health organisations?
 - ...



UNI/TR 11708 Background & Need

- What does the user really know about an app just acquired, often for free, from the online store?
- Maybe she/he is informed that the App will require the use of the camera, but not informed about who (private or public) has sponsored the development/distribution of the App nor if her/his personal data will be distributed and used for purposes other than those expected!
- Apps rarely ask the user for confirmation before sending the (hopefully anonymized) data to third parties or social networks, with the excuse that a further authorization request would increase the number of "points of user friction" and consequently the time of interaction/use of the App itself, worsening the so-called "user experience".
["Your Apps Know Where You Were Last Night, and They're Not Keeping It Secret", 10/12/2018, https://www.nytimes.com/interactive/2018/12/10/business/location-data-Policy-apps.html](https://www.nytimes.com/interactive/2018/12/10/business/location-data-Policy-apps.html)
- *«Delete all your apps - It's not just about Facebook: the Android and iOS app stores favor an economy where free apps earn money by selling your personal data and geolocation history to advertisers [and/or...] . »*
<https://motherboard.vice.com/it/article/i5zap3/inchiesta-new-york-times-app-ios-e-android-tracciano-utenti-privacy-cancella-app>
- Therefore, there is a need to have more information on Apps, to be included in a **quality reference framework**:
 - explain advantages and/or risks in the use of the app;
 - reduce any difficulties in understanding the functions made available to the user;
 - reduce concerns related to the misuse of personal information, even without the knowledge of users.
- The 11708 technical report wants to give an answer to this need, although this should be really considered as a first step to be explored/refined also at a European level: **UNI/TR 11708 IS IT!!!**

UNI TR 11708 “Characterization (in terms of information) of the App in the context of health and wellness”

- UNI/TR 11708 concerns the “characterization (in terms of information) of the App in the context of health and wellness”. It was conceived in order to provide producers, users,... with a guide on the quality features of the App in the health and wellness sectors.
- It proposes evaluation and usage elements valid also for different application domains. The TR 11708 wants to stimulate the various parties involved to have a responsible attitude in compliance with the relevant technical standards of the sector, especially in cases where the Apps can have consequences on the health of users
- The report is intended as a reference to:
 - identify the main information accompanying the app;
 - allow the user to know the features of the app;
 - allow systematic monitoring by regulatory bodies and other relevant/interested bodies;
 - allow developers, manufacturers and manufacturers, suppliers and distributors to comply with the proposed references
- In summary, the goal is to allow the user to make an informed and conscious choice regarding which Apps to use. For this reason it is necessary to provide information that allows the evaluation of the product from different points of view, including health risks, and the further usage of any data collected by the supplier/distributor or third parties

UNI TR 11708 Requested characterization

- The App should report information about the response it provides with respect to the following quality factors:
 - functionality, providing indications on the data processed with regard to accuracy, precision, completeness, consistency, timeliness, credibility and compliance with the legal-regulatory framework
 - efficiency;
 - compatibility;
 - usability and accessibility (Law 4/2004 "Provisions to facilitate access for disabled people to IT tools);
 - risk assessment;
 - security and privacy;
 - maintainability;
 - portability.
- The App should contain general information including, for example, beyond its name:
 - logo and name of the developer/producer/supplier/distributor/sponsor/promoter;
 - operating system;
 - type;
 - CE mark (in the case of a medical device);
 - possible number of the notifying body;
 - version;
 - cost;
 - supported languages;
 - presence of advertising;
 - minimum hardware and software requirements;
 - reference website for specific information and insights.
- The App should also include specific information, such as:
 - Intended recipients of the App;
 - intended use;
 - usage limits;
 - health problems for which the App is eventually targeted;
 - indication of the disability to which it is addressed;
 - age range.



CEN & ISO Initiative: define a Technical Specification for Quality and Reliability Requirements for Health & Wellness Apps

- Stemming from this activity, the work of many other national initiatives, and building upon the existing specifications for Health Software in ISO and IEC, the European Commission is supporting a project to develop a Technical Specification for Quality and Reliability Requirements for Health and Wellness Apps. The work is being led by the European Committee for Standardization (CEN), working with the International Standards Organization (ISO), the International Electrotechnical Commission (IEC), and the European Committee for Electrotechnical Standardization (CENELEC).
- The specification is intended to apply to any app that is being promoted explicitly to improve health and wellness, building on the definition of health from the World Health Organization (WHO) “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.



eHealth can contribute to the country's economy by figures similar to that of a financial maneuver.

The objective of this document is to analyze and describe what a group of the eHealth industry experts wants to tell public decision makers, top health managers and policy makers.

"Digital Health: from doing to treating" moves the target and also the interest towards the evolution of the system. It's not just "telemedicine": today we are talking about Digital Health, eHealth, Digital Health and Care!

There are many new and emerging innovative technologies/methodologies and there are new strategic aspects arising from what has been done to date.

Thus, the next decisive step is to actually move from doing to treating, modifying the health service's processes, according to a model that has established itself as "Business 4.0" and, by analogy, "Health 4.0".

For information about the book, contact:
m.pantaloni@cdti.org