Apps for Medicine, Health and Home Care – Elements of Safety and Effectiveness

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1 About the Conference and Why Focus on Apps

The number of health apps is growing almost exponentially, and more apps are introduced for special health and wellness purposes every day. The collective entrepreneurial spirit, opportunities to create and to share your strategies to problem solving or self-management given the mobile opportunities comes with a lot of excitement and promise. To open for and invite a broader audience in focused discussions on the opportunities, challenges and potential harms with special purpose apps in health care were a main motivator to invite colleagues to discuss safety and effectiveness of apps for health purposes.

Discussions about the host of questions stemming from and emerging with experiences to use apps for self-management, participation or curative treatment are important for our field. Here are technically oriented, professional as well as very practical questions waiting for answers. The papers featured in this special issue are contribution from the conference "Apps for Medicine, Health, and Home-Care – Elements of Safety and Effectiveness". This is a combined initiative consisting in the Milano's Conference, held on May, 2014, and the present Special Issue. The combination aims at presenting research results focused on the evidence that stakeholders need to understand.

2 Why EFMI Become Sensitive to Problem

For the European Federation for Medical Informatics (EFMI) the discussions around medical apps are examples of important discussions about mHealth activities[1]. This is a continuation of efforts to participate at arenas to exchange knowledge, experiences and exciting insights about the development of health and biomedical informatics. Presenting clinical information through the medical apps offer new and novel opportunities to meet health care providers and their patients' request for more timely access to health information at the point of need. This is important since accumulated information about a person and access to the growing body of research evidence and clinical experiences are an integral for every health care encounter. The specific needs will vary according to focus of an encounter or of a health related activity. Supporting the initiatives allows EFMI to contribute to elaborate on opportunities, uncertainties as well as conditions for wide spread and institutional adoption of important grassroots multi-stakeholder initiatives like the app movement.

2.1 Challenges Discussed in the Meeting

Participating in discussions and common explorations of what some of these mobile opportunities means in terms of challenges and opportunities for the health care system, health care providers and patients or citizens are important. The need to focus on mHealth and medical apps, and give more attention and interest is exemplified by the exploding numbers of apps claiming to assist in specific health, wellness, or self-management activities, available for download from iMedicalApps.com, iTunes, Google store, Microsoft store and the like. When searching for apps in one of the stores, you are operating in a global market. However, the health care you acquire or health and wellness activities you engage in are localized and context bound. If you are interested in a specific self-management challenge, like weight management and diet, the plethora of available apps offered makes the process of selection very challenging for us as average consumers. Core questions like which app to choose', quality and appropriateness in return for efforts it takes of

[1] EU Commission (2014) GREEN PAPER on mobile Health ("mHealth")

the consumer', specific function of the app relative to activity sought support for', privacy of data', credibility of community or person behind the app', communication facilities and data storage', confidentiality', or overall safety', are just a few examples of issues to consider.

The hosts of questions relating to medical apps are indeed multi-facetted. The answers will most likely reflect the perspective of the evaluators. Core issues the health informatics community share with health providers in their professional capacities, and health care facilities alike include quality of service, appropriateness of content, safety and liability when medical apps are part of professional offerings. From the perspective of the patient or citizen/consumer, purpose specific apps offer much in terms of opportunities for information access, registration and accumulation of information for comparison over time or to similar groups elsewhere. Here are unexplored opportunities for individual learning, but also opportunities for the health care system in terms of population health and larger initiatives for prevention or early intervention based on citizen involvement.

A core issue to elaborate on is what is a medical app? Is a medical app a new and exciting tool, only an addition to expanding pool of consumer devices for health monitoring, add-on to well regulated medical devices for health monitoring of some sort, or an information handler offering easier and more appropriate access to health related information and knowledge for judgments, evaluations and decision support?

It has been pointed out overlapping functions in an app and a medical device in vital sign monitoring for example. Such examples are question generating and contributing to constitute quite grey areas [2] without clear-cut answers. Here are calls for exploration, consolidation and consorted action, and the discussion in this issue is a start to approach them. Many purpose specific medical apps will deal with only one aspect, and will do so well for a while. However, the embedded side effect can be more fragmentation, adding uncertainties and concerns if a sufficient, complete or endorsed set of best evidence and high quality information is what you get. From a user perspective; either as a health provider; e.g., medical doctor, registered nurse, advanced practicing nurse, physiotherapist etc., or as a citizen or patient, the exponentially growing amounts of information and knowledge, available by apps represents a mixed blessing. The availability of information, access to knowledge and engagements with peers allow the active and resourceful to take charge for themselves. However, orientation in, comprehension of and assessment of appropriateness of resources related to the problem at hand is demanding. How to address such growing, unresolved set of questions responsibly opens for further discussions.

[2] http://www.computerworld.com/article/2476087/healthcare-it/when-is-a-mobile-app-a-medical-device--the-future-of-healthcare-may-depend-on-the-answ.html

2.2 Assessments – Preserve Trustworthiness, Confidentiality, Dignity, in New Forms

As we embrace opportunities and sort out how to take advantage of medical apps, demonstrations given at the meeting "Apps for Medicine, Health, and Home Care – Elements of Safety and Effectiveness" specifically tied into global questions of trustworthiness, dignity and confidentiality. These aspects are relevant safety elements embedded in the important to leverage innovative potentials and opportunities ahead. Seeking health care or engaging in self-management involves building or assuming trust and confidence. Health information is important for personal choices and health & illness decisions, and the significance of trust and confidence in exchange and handling of this information is important. The distribution and dissemination of information calls for contributions of multiple stakeholders. Regulation and accreditation can point out issues for jurisdictions, and help communicate carefulness and requirements for security, levels of confidentiality and suggestions for assessments to make more informed choices. Furthermore, approaches like the "One-Shot Pictorial Schema" alluded to by Pinciroli and colleagues[3] and further exemplified in this issue's contributions by Tognola et al. and Albrecht et al. tease out important areas for further scrutiny.

3 Summary of Contributions in the Special Issue

The issues of Effectiveness and Safety of Apps for Medicine, Health and Home-Care is a new challenge for many of the historically settled and widely relevant stakeholders active in the eHealth arena. Stakeholders to be targeted in ways pertaining to their role, is it follows: a) developers; b) caregivers; c) standardization bodies; d) scientific associations; e) patients associations; f) funding agencies; g) health care governance; and h) policy and regulation. They are challenged a specific way, facing needs to find out how new tools are instrumental for the proper accomplishment of their role. Currently it is the app user who takes the direct risks and responsibilities for possible outcomes that may not be perceived, undesired or unknown. Thus there is a compelling need for reports from well-executed studies, which provide accessible and clear descriptions of requirements for effectiveness and safety of apps for medicine, health and home-care. Nevertheless a scope like this is not easy. Performing an exhaustive evaluation of each available app is not affordable by anybody. Even the level of the methods to be used for such evaluations asks for reliable suggestions. As contribution to such evolutionary framework the papers in this Special Issue do the attempt to help, sometime as a vision, some other times at the practical level.

[3] Methods Inf Med. 2014;53(3):208-24. doi: 10.3414/ME13-01-0093. Epub 2014 Apr 14. A pictorial schema for a comprehensive user-oriented identification of medical Apps. Bonacina S1, Marceglia S, Pinciroli F.

The Ackerman's paper results from a governance vision in the US environment. Nevertheless this has broader significance. When he refers to FDA documents, we know they are frequently considered and appreciated also in other Countries. The idea might be that of a label explicating conditions of use to appear anytime we open a "healthcare but-not-Medical-Device" app, saying that "This products is not intended to diagnose, treat, cure or prevent any disease". For most of the general public, such label is easy to be understood.

The Della Mea's et al paper opens by reminding that, in 2007, the European Parliament and Council amended the previous version of its directive on medical devices, by allowing software to be by its own in a medical device, similar to the "learned intermediaries"[4] clause in the US system. They discuss this applicability to mobile apps, and exemplify the medical devices classification rules to a sample of apps. The paper concludes that it seems that a fair amount of present apps could be subject to medical device classification. This pushes for some attention towards common classification, not necessarily in terms of ruling, but at least of clear identification of functions and limitations.

The Albrecht's et al. paper presents an e-health grounded, academic approach to the apps safety and effectiveness. Its founding observation is the conflict between the "too-long some-years-period" any historically settled standardization body needs to deliver a standard, and the evolution speed of the interactive and technological nest where the apps come from. As a resolution, these authors suggest something in between doing standards and doing nothing. Doing nothing is not an option but at the same time, acknowledging that respected associations and public stakeholders never will have the power needed for testing each of the close to 100.000 medical apps already available (by end of 2014). The more pragmatic "something in between" would belong to the family of "somehow guided and trustworthy" descriptions, where the templates' components could be recommended by public bodies and the contents remain a responsibility of the description's signer. Such signature would be a mandatory part of the template.

The Bertini's at al. paper comes from a developer approach. They discuss the complementing contributions in more or less occasional meeting between two building block of knowledge, the ICT side and the medical side, each doing its own job: the developer the former, and the ispirator and verifier the latter. When each side holds the properly high reputation in its side, the result is a useful app. As such, the Bertini's paper can be a remarkable example of a mutually interacting cooperation for the benefit of the envisaged final-user.

The Tognola's et al. paper opens for an entire eHealth4Hearing paradigm, to which the apps world can provide significant building blocks, in favor of a higher adherence of systems to patient needs. Hearing Care System do not have all the human resources to support implementation of the requested actions, calling for self-managed efforts. Starting from a needs assessment, perceived by patients with hearing disabilities, they formulate the new "eHealth4Hearing" paradigm and provide practical examples on its application. Mobile app technology makes it feasible to easily use a mix of sensory channels; audio, video and graphics, text, to deliver health knowledge to the subject, perform do-it-yourself tests, as well as provide technological solutions suited to hearing and communication skills.

The Fiorini's et al. paper does the attempt of providing a vision of the potential benefits of applying "Internet of Medical Devices" (IoMD) to solve the cost problem and improve patient safety. While the medical industry is quickly adopting mobile technology (mHealth) to connect lay users with medical professionals, the current apps can be quite fragile to unexpected event and trends. Unpredictable changes can be very disorienting specific stakeholders. We need more resilient and robust application to prepare for next generation systems, seen as anti-fragile self-organizing and self-regulating system. Health Information community can take advantage of a new HICT Natural Framework proposal. It can be used in advanced modeling for healthcare application and organization (HO) and in high reliability organization (HRO) in general.

4 Recommendations

The two coordinated EFMI initiatives – i.e. the Milano's Conference and this Special Issue – opened for more in-depth discussions to understand safety and effectiveness related to the on-going, exciting development. In particular we realize that recommendation or suggestion should care about some key elements. Given the evolution of the apps market segment, regulatory actions from any historically settled standardization body would take too long time to materialize, and professional and patient associations can by no means mobilize manpower for exhaustive tracking or consistent classification of the huge quantity of already available and still coming apps for Medicine, Health and Home-Care. In this "a few euro" for the apps, future actions imposed to any app before making it available on the market should not deny to circulate the app for doing business, provided that there are no risks when the app is used.

Major suggestions and recommendations would include the following, 1) any app offered for sale at any online or physical shop should be accompanied by an essential and clear ID. Its contents, visualization, monitored effectiveness and envisaged signature should be included in a mandatory self-declaration. 2) The Health Informatics Community should promote and cooperate through their associations with various stakeholders to reach a consensual definition of the self-declaration. 3) It is highly welcome if Funding Agencies activate specific funding to properly support definition of the items in the self-declaration, and assist in efforts to make applications effective to avoid risks, in particular from the patient's safety perspective.

[4] Koppel, R., & Kreda, D. (2009). Health Care Information Technology Vendors' Hold Harmless' Clause: Implications for Patients and Clinicians. JAMA: the Journal of the American Medical Association, 301(12), 12761278. doi:10.1001/jama.2009.398