EJBI 2015 ISSN 1801 - 5603

European Journal for Biomedical Informatics

Volume 11 (2015), Issue 3

Special Topic

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

Editors

Francesco Pinciroli, Anne Moen

An Official Journal of the European Federation for Medical Informatics

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CZ-14000 Praha 4
Czech Republic
EU VAT ID: CZ25666011

Office

EuroMISE s.r.o.
Paprsková 330/15
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[1] Schwartze J, HaarbrandtB, Fortmeier D, Haux R, Seidel C. Authentification systems for securing clinical documentation workflows. Methods Inf Med 2014; 53 (1):3-13.

[2] Kalina J, Seidl L, Zvára K, Grünfeldová H, Slovák D, Zvárová J. Selecting relevant information for medical decision support with application in cardiology. European Journal for Biomedical Informatics 2013; 9 (1): 2-6. Available from: http://www.ejbi.org/img/ejbi/2013/1/Kalina_en.pdf

[3] Hasman A, Blobel B, Zvárová J, editors. Data and Knowledge for Medical Decision Support. Amsterdam: IOS Press; 2013.

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Contents

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

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EJBI 2015; 11(3):en1–en3
published: April 20, 2015

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

Activating Standardization Bodies Around Medical Apps

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Abstract

The accuracy and safety of the information provided by medical and health related apps are of concern to medical and healthcare professionals. In the United States medical and certain health related devices are regulated for safety and accuracy by the U.S. Food and Drug Administration (FDA). Wireless devices, like smart phones, are regulated by the US Federal Communications Commission (FCC). Until now, the approval process was limited to complete devices. An FDA regulated medical device can contain software but the regulatory approval process involves the complete device, not each of its components separately. But what about apps? Apps are software which may turn an otherwise non-medical or non-healthcare device into a medical or healthcare device. Do you regulate the software? It only has value when running on a device. Should you regulate the combination of device and software? It seems that every day a new smart phone is introduced and new apps become available. Do you have to test every combination? This paper will discuss the approach being taken in the United States by the government as well as by private industry.

Keywords

m-Health, Portable Software Apps, Medical Devices, Telemedicine, Mobil Phone

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EJBI 2015; 11(3):en4–en6
received: June 13, 2014
accepted: October 10, 2014
published: April 20, 2015

1 Introduction

Traditionally one judged the content of a book or other reading material by its cover or place of purchase. Then the Web happened and reading material no longer had covers. In a similar sense one judged application software by the developer or the place of purchase. And then apps happened and there is no longer a known developer and sometimes not even a recognized place of purchase. How does one know that the app does what it claims to do? If it does not, who is responsible? One could argue that for less the $1.00 US it really doesn't matter. Try it and see if it works. If it does - great! If it doesn't - so what, it only cost $1.00 US to find out.

This approach works for most instances. But in the instance of medical apps such an approach could cause harm. If the medical app makes a recommendation based on some form of automatic or manual input and if that recommendation is inaccurate or just plain wrong, a dangerous situation could result for the user.

2 The Problem

Here is the scope of the problem: A medical app is developed in Malaysia, purchased from the iTunes store located in the United States by a person located in Italy for use in Brazil. Who is the source of trust for the information or advice given by this medical app, the equivalent of the old book's cover? And who is responsible if there is a problem?

For medical devices in the past we have turned to national and international regulatory and standardization agencies like the US Food and Drug Administration (FDA), the US Federal Communications Commission (FCC), the European Committee for Standardization (CEN) or the International Standards Organization (ISO). But these agencies tend to take their time whereas the apps business is almost an overnight business. The development time of an app and the work flow of these agencies is a complete mismatch.

The problem of the medical app has arisen from the new phenomenon of m-Health (mobile health). M-Health can be seen as the practice of medicine and public health, supported by mobile devices, such as smart phones and wireless connectivity, for health services and information.

An alternative, perhaps a more popular definition, is the use of mobile devices to support health related monitoring and self-help activities.

In November 2012 the Pew Research Center, as part of its Internet Project, published a report entitled Mobil Health 2012 [1] that documented the prevalence of accessing health information through the use of a smart phone in the US. The report pointed out that 52% of smart phone owners gather health information using their phones. Latinos, African Americans, people between the ages of 18-49, or people who hold a college degree are more likely to gather health information through a smart phone. Women between the ages of 30 and 64 are more likely to have signed up for health text alerts. In 2012, 20% of smart phone owners already had at least one health app. Exercise, diet and weight related apps were the most popular.

3 Who is Responsible?

In the US wireless devices are regulated by the FCC, medical devices are regulated by the FDA. But who will regulate a wireless medical device?

In September 2012 the FCC m-Health Task Force made recommendations concerning who should be responsible for m-Health [2]. The general recommendation was that the FCC should continue to play a leadership role in advancing mobile health adoption. But the specific recommendations dealt with communication devices, communication links and access to communication links and devices. The question of m-Health software, medical apps, went unanswered.

4 An Uneasy Solution

One year later, in September 2013, the FDA published its advice Mobile Medical Applications: Guidance for Industry and Food and Drug Administrative Staff [3]. The FDA stated that it would regulate m-Health apps that provide diagnostic or clinical decision support, that convert a device into an accessory for an already regulated medical device or into a regulated medical device. Examples of accessory devices included remote display of ECG waveforms or medical images like pathology or radiology, or the control of a blood pressure cuff or an insulin pump. Examples of medical devices included sleep monitors, ECGs, tremor and balance monitors, and eye movement analyzers.

The FDA went on to describe a category of m-Health software that it does not expect to regulate but is reserving the right to do so - m-Health apps that manage health status. Included in this category are m-Health apps that: help users self-manage their wellness without providing suggestions or support to avoid disease such as managing weight or salt intake, or calculating the body-mass index (BMI); provide simple tools to organize and track health information such as data logs for allergies, obesity, heart disease or fitness; help document communications with a health provider; coach patients on how to cope with a disease such heart disease, high blood pressure, or diabetes but not how to treat it; provide access to health information such as medical dictionaries, textbooks, data bases, or web sites; and provide access and interaction with the patient's electronic health record (EHR) and personal health record (PHR).

If one were to summarize the FDA guidance one could conclude that the FDA will exercise its regulatory authority over a device or program which provides medical recommendations. Unfortunately this raises additional questions. When does the advice offered by an m-Health app fall into the regulated category of disease claims versus the unregulated category of wellness claims? When is an m-Health app an accessory to a medical device versus part of the communications network attached to that device? A tremendous number of m-Health apps are said to be designed to help us live healthier lives as opposed to managing a disease.

5 The Reality

The attempt to maintain the difference between disease and wellness can be seen on various software and device web sites. For example Owlet [4], a Bluetooth based sensor device that communicates with an m-Health smart phone app. The Owlet web site states that a Smart Sock (the device) is worn by a baby as he or she sleeps. The Smart Sock collects heart rate, oxygen, and sleep data and sends it via Bluetooth 4.0 to the parent's smart phone. The infant's data is then pushed to the cloud by the smart phone. The website clearly states This is not a medical device. This is for health and wellness purposes only. The statement may not be needed according the FDA advisory in that the sensor device is just collecting data and the m-Health app is just acting as a communicator between the sensor and the cloud. So the part of the system which needs oversight is the data interpretation system in the cloud and that system is not identified.

Newer m-Health apps and more advanced smart phones are making the distinctions made in the FDA guidance appear even less discernable. M-Health apps have been developed which use the smart phone's microphone to measure heart rate and the phone's accelerometers to measure tremor. Smart phones are now being developed that have built in EKG sensors. It would appear that the distinction boils down to a single criterion: Does the app make a medical recommendation?

As already noted, the majority of m-Health apps don't make medical recommendations, they loosely give wellness advice. In a paper published in the Journal of the American Medical Association, Powel, Landman and Bates [5] proposed a neutral third party as an internationally recognized testing and certification body following the Health on the Net (HON) Foundation [6] model which is often used by health related web sites. The problem may be

the business plan. At less the $1.00 US per download, will the developers support such an endeavor? If they will not, who will pay for the service?

The experiment was tried by a company named Happtique [7], a for-profit arm of the non-profit Greater New York Hospital Association. In late February 2013, Happtique published final standards for its m-Health Application Certification Program (HACP) designed to serve as a "good housekeeping seal of approval" for m-Health apps. HACP was designed to evaluate and certify m-Health apps for privacy, security and content. In June, Happtique announced a collaboration with the Association of American Medical Colleges (AAMC) and the Commission on Graduates of Foreign Nursing Schools to evaluate the m-Health apps.

Happtique's business plan included a $2,500 US to $3,000 US charge for each app evaluated. Apps would be evaluated within 30 days of submission. The certification program would determine if a given app: met stated data security standards; operated as intended; protected user privacy; and contained credible content. In November 2013 HACP certified its first cohort of m-Health apps.

It would have been nice if this was the end of the story and HACP became the solution to the m-Health app problem. But on December 13, 2013 Happtique had to suspend the program, less than two weeks after it approved the first cohort of m-Health apps. The problem, security issues were discovered in two of the apps it had just certified as secure. The result was a disappointing and embarrassing end to a program that was designed to boost physicians' confidence in m-Health apps to the point where they would feel comfortable prescribing them to patients.

6 Perspective

In the United States, m-Health and m-Health apps are likely to take a non-medical track. The FDA has clearly stated that they intend to regulate medical apps and will probably not look after health apps. Health insurance in the United States is through a private rather than government payer system. The system is resistant to pay for anything which is not considered required medical. Health products are paid for by the purchaser with no reimbursement. The entire food supplement and health food industry is based on this system and the advertising for and label of each of the products clearly states This product is not intended to diagnose, treat, cure, or prevent any disease. The public is willing to accept the implied risk and gladly pays for the products. The business model for non-medical m-Health apps will likely follow the already established non-medical health industry model.

Acknowledgements

This research was supported by the Intramural Research Program of the National Library of Medicine, NIH.

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Medical Apps – The Road To Trust

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Abstract

Objectives: With health apps and medical apps gaining popularity, assessing their quality still remains an open question. Users are often unaware of potential pitfalls and unsure whether an app can be trusted.
Methods: Following an overview over the current situation (including inherent risks and limits) that also covers existing measures and regulatory questions, additional methods for aiding those preforming app assessments are proposed.
Results: Two methods that may aid various stakeholders in their evaluations are outlined.
Conclusions: The presented tools are currently being evaluated and open for discussion; we believe them to be easy to use.

Keywords

Trust, Peer Review, Certification, Mobile Apps, Mobile Health

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EJBI 2015; 11(3):en7–en12
received: June 6, 2014
accepted: September 9, 2014
published: April 20, 2015

1 Introduction

Not least due to their easy usability and the numerous possibilities they offer, mobile smart devices (phones, tablet PCs) and the apps they are running have reached high penetration levels in the general population as well as for professionals. The health sector is no exception: users are confronted with an overwhelming number of apps to chose from.

Unfortunately, independent of where these technologies are used, users are often ignorant about potential risks that they pose. Such risks may for example include misleading or false information (sometimes due to unreliable information sources being used by the authors of the app), but also errors in included algorithms. Shortcomings of the employed hardware, e.g. inadequate sensors integrated in a specific mobile device or differences in the specifications of sensors between devices that appear similar at first glance may also cause problems. In highly sensitive areas such as medicine and health, this is simply unacceptable.

The situation is additionally aggravated by two points. Firstly, users are rarely provided with adequate information that would allow them to assess whether an app is adequate for the desired purpose and can be used without risks for the users themselves or – in the case of professional users – the health of the patients they treat. Problematic apps may also pose a danger to the privacy and integrity of the entrusted health related data. Secondly, existing laws and regulation only apply to a negligible number of apps; depending on the jurisdiction where they are used, such apps usually include those with an intended diagnostic or therapeutic purpose. Thus, currently, users cannot count on app safety being ensured via regulatory measures.

For apps where regulation does either not apply or is not observed (although it would very well be expected), various initiatives of the private sector try to step in and offer certification with the aim of providing a certain level of "security" for users.

Nevertheless, independent of whether regulation applies or not, one shortcoming of all certification processes is that they are often quite time consuming and rather expensive. Thus, these processes are often avoided by developers or providers. In the case of private certification initiatives, users may also often not be aware of their existence. Even if they are, it is often unclear which criteria are applied during the certification process.

As a consequence of the overall situation, users often tend to sift through ratings other users have given an app

in the app stores or they look at information publicized in other places, e.g. blogs and other web resources. Still, information gleaned from such sources is often rather unstructured and incomplete and may also be biased.

Resolving the aforementioned problems will necessitate a collaborative effort by all stakeholders involved, including lawmakers and policy makers (on national as well as international levels) as well as developers, store providers and last but not least, the users themselves.

Definition of Health Apps and Medical Apps

In a relatively recent evaluation performed by Research2guidance in 2013, around 97,000 apps with health related content were counted [1] on various full catalogue app stores and it is estimated that this number continues to grow by approximately 1,000 apps each month. Exact numbers for each of the two categories "health apps" and "medical apps" are hard to come by: the two terms are often used synonymously there is often no clear dividing line between both categories. On the part of the store providers, clear guidelines governing which apps should be assigned to which category are lacking as well. Nevertheless, the differentiation between both types of health related apps is important since both classes have different kinds of inherent risks and limitations [2]; these will be explained later on.

The WHO's definition of health may easily serve as a guide for differentiating between the terms "health" and "medical" and thus also for differentiating between apps for both areas:

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [3]. Following this definition, "health apps" include mobile applications that aim at influencing the physical, emotional and social well-being in a positive manner. While this definition certainly also encompasses apps with an intended diagnostic or therapeutic purpose, apps following this paradigm cover key areas of medicine and as such, should be assigned to the specific category of "medical apps" instead of the more general category of "health apps".

Limitations and Risks

Usage scenarios for both health apps and medical apps are manifold. Nevertheless, even though they open up many new and exciting possibilities, it should not be forgotten that smart devices and the apps running on them have the potential to cause significant harm to patients. Unfortunately, especially for casual users who are unfamiliar with such questions, possible limitations and risks may not be immediately obvious.

Limitations can for example be due to conceptual weaknesses and poor usability. They may also be caused by deficiencies of the included content, the implementation itself or problems of the devices used for running the apps, such as insufficient memory or computing power for the stated purpose of the app. Inadequacies or incompatibilities of the sensors integrated in a mobile device may also be a cause of problems [2].

Trustworthiness and reliability are other aspects that must be kept in mind: It is not only of interest whether a health app or medical app contains credible and valid content and functions as expected, but also how it handles the acquired (medical) data, which tends to be of a highly sensitive nature. Moreover, many apps tend to be more "talkative" than they should be in a medical context. For example, if an app starts to track its users and possibly combines this information with medical and health related data it has been entrusted with, this is highly disturbing and may easily lead to a breach in patient confidentiality. Altogether, the noted points may seriously impact patient care [4].

There is only a limited number of systematic high-quality studies that have taken a closer look at using apps and smart devices for different purposes in a medical setting (e.g. [5, 6]). Often, these studies have a special emphasis on quality, safety and performance of the investigated apps or the notable lack thereof.

A point noted as contributing to shortcomings in the aforementioned areas is the lack of evidence with respect to the presented content [4]. This can be an additional factor contributing to an app's poor quality, independent of whether it targets professional users or private users. Examples of problems that were noted for apps used in the professional domain include the calculation of medical scores or drug dosages; while the performance of most apps was satisfactory, a few of the evaluated apps made clinically relevant calculation errors [6] with potentially serious or even lethal effects on patients' health. On a side note, some of the problems that were identified in apps performing some sort of calculation were due to poor usability rather than erroneous calculations [7].

Apps intended for private use by patients or healthy persons interested in their health and well-being suffer from somewhat similar issues, although the situation may be additionally aggravated by the fact that laypersons are often even less aware of potential problems than professionals. A prime example for this are apps that promise to diagnose possibly malignant lesions on a patient's skin. In a recent study [8] dealing with four apps promising to evaluate pictures taken by a smart devices' camera with respect to potential malignancies, only a single app gave satisfactory results. This app simply sent the acquired images to a human expert for evaluation. For the other three apps – where the evaluation was performed based on automatic image segmentation algorithms – specificity and sensitivity were low and the results were unacceptable.

While the existence and use of such apps may possibly raise awareness and instigate beneficial skin-monitoring behaviour [9], it may be dangerous if users place too much trust in what such an app tells them: at best, the results may raise a false alarm and trouble a patient unnecessarily. On the other hand, if users rely on an app that tells

them that their lesion is nothing to be concerned about although it is malignant, valuable time may go by until professional medical advice is thought. This is an intolerable situation for diseases such as malignant melanoma where timely treatment is essential.

Although the studies mentioned above are far from giving a complete overview over the subject matter, it is apparent that even seemingly professional apps may have serious weaknesses that can lead to serious consequences for patients' health or the safety and integrity of their personal data. For professional users, namely health care professionals using an app as well as developers and distributors of an app, such problems may result in liability issues with all their consequences.

To alleviate the currently unsatisfying situation, some question whether current rules for regulation are sufficiently applied and whether there is professional involvement during the development of apps that are to be used in medical settings. In contrast to [5], we believe that, while certainly being necessary, current rules and regulations cannot be the sole solution. Available regulatory measures do not cover all apps that are intended for a health related field of application. Currently, many apps fall through the figurative cracks of regulation, necessitating additional tools and measures for protecting all stakeholders, from patients to medical professionals as well as developers and distributors.

The following sections will describe basic aspects of regulation as they pertain to health related apps. They will also list currently available options for such apps outside of regulation, and propose measures we would like to see implemented.

2 Apps and Regulation: A Risk Based Approach

As mentioned above, the differentiation between health apps and medical apps is important considering what happens if a product is labeled as a "medical device": If the intended use of a product (as assigned by the manufacturer) – be it hardware or a software application – is medical (e.g., in the context of diagnostics or therapy), conformity to regulation has to be shown. For the US and the European Union, the legal requirements for medical products are basically comparable, but neither here nor there have laws and regulations been adapted to the specifics of medical apps. Thus, existing laws for medical devices are applied. As for other medical products, there are different classes depending on the inherent risks of the product.

In the US, medical apps are subject to an official approval procedure and manufacturers have to compile and submit an extensive list of documents covering risk management, information about software requirements and architecture, quality management, testing and so on. In September 2013, the FDA published a guidance document with specific provisions on how to deal with medical apps [10]. This document is aimed at both manufacturers and FDA personnel and specifies that mobile medical apps that only pose a minimal risk for users are exempted from regulation ("enforcement discretion"). This is a pragmatic approach that befits the overwhelming number of available medical apps and also tries not to impede innovation. The guidance document is only meant as a guide for applying existing regulation to medical apps and is not legally binding [11].

The rules in the EU do not differ much and require similar documentation to be put together. It depends on the risk class assigned to the app whether this documentation simply has to be kept at hand in case of inquiries or whether it has to be submitted to a notified body. In contrast to the US, there are no exemptions for low-risk apps.

Liability

The differentiation between health apps and medical apps is also important in the context of liability. With a few exceptions, e.g. in the case of Android allowing installation of apps from third party sources, mobile apps are usually distributed via official app stores. These stores usually do not make provisions for the peculiarities of medical products. Nevertheless, both for distribution as well as use of apps in a medical setting, there are are legal pitfalls regarding competition law and liability [12]:

Regarding competition law, if an app's intended use (as assigned by the manufacturer) is medical and it is nevertheless distributed without following the appropriate regulatory procedures, this may be a breach of the law against unfair competition and may cause competitors to take legal measures and to claim damages.

Manufacturers can also be held liable if their product, in this case the app being used, is deficient. As already mentioned in the introduction, causes for such defects are manifold. They can range from errors within the software itself to insufficient documentation or inadequate or missing safety notes. All these sources of error may incur liability.

On the other hand, when medical personnel makes use of medical apps while diagnosing or treating patients, they may also be held liable. Any such procedures must follow common professional standards and liability ensues in case anything goes wrong; it is not sufficient to simply put the blame on the manufacturer of the app.

3 What Measures Are Available?

With development cycles of apps shortening dramatically and the rapid integration of innovative new technologies, it is has become quite difficult for users to keep up with developments and to determine whether a medical or health related app meets their needs and demands for quality. The most popular information sources users turn to, i.e. user comments on the app stores as well as various

web pages, blog posts etc. are often not reliable [13]: In most cases, there is little to no background information about these sources and anything posted on such media must be taken with a grain of salt.

There is still an ongoing discussion about quality standards, how they can be applied, appropriate testing be performed and how users can be informed about the results in a transparent manner.

Private Or Commercial Certification

For apps that are not subject to regulation, one possibility is to obtain certification from one of the many, often private, initiatives although this is not mandatory. Certificates these institutions offer are usually based on tests they carry out themselves, but, since many initiatives keep their evaluation criteria under cover, such certification is not necessarily reliable.

This became apparent at the end of 2013, when Happtique, a mobile health solutions company and subsidiary of the Greater New York Hospital Associations for-profit arm GNYHA Ventures, suspended its mobile health app certification program after serious security issues had been found in apps Happtique had previously certified as secure [14]. In addition to such issues, even for private or commercial initiatives, the overwhelming number of available medical apps prohibits an exhaustive evaluation of all available apps. For users, it is therefore a matter of chance whether evaluation results obtained in such a manner are available for an app they are interested in.

Peer Review

Another potential solution that is often suggested is to implement peer review (by experts in the field) for apps, similar to common procedures used in the scientific domain [15]. Although at first glance, user ratings and evaluations published in the app stores may appear somewhat similar to peer review, one should be careful before relying on such ratings. There is usually little to no information about the background and qualification of those voicing their opinion on the stores [13]: are they really qualified and are the statements biased in any way?

Thus, even in such a sensitive field such as medicine, the final decision on whether to trust an app rests with the user. A well-founded decision is only possible based on adequate information and this information should be provided to users in a comprehensive and comprehensible manner, e.g. in the form of an app synopsis [16, 17], via a structured list covering important points (Table 1).

4 Providing Adequate Information

Regulation as well as peer review and certification by private initiatives usually more or less rely on third parties performing the evaluation or assigning a label. Users do play an active role in this context. In addition, the aforementioned processes do not necessarily include adequate information being made available to users upon which they can decide whether they deem a health related or medical app trustable and usable for their specific purpose or not. To be able to do so, users must be provided with comprehensive and easy to use tools they can use. They also need to be made aware of factors they should consider in order not to overlook any important points.

Table 1: Basic categories and criteria for app evaluation, adapted from [16], where a more detailed version is provided.

Criteria	Content
Imprint	Information about the manufacturer or distributor of an app and his associates Meta data of the app
Rationale	Description of the intended purpose(s), target audience, the setting(s) where the app is to be used, its categorization as a medical or non-medical app
Functionality	Description of the functionalities and features included in the app as well as its restrictions and limits Details about the measures used for ensuring good usability
Validity and reliability	Reliability of contained information Description of quality assurance methods used during development
Data requisitioning and management	Amount and types of data collected and processed by the app
Data protection and privacy	Does the manufacturer adhere to data protection and privacy laws; is regulation observed (depends on the intended purpose); jurisdictions involved
Data transmission and storage	Description of measures taken to protect data entrusted to the app (storage and transmission)

App Synopsis

Extensive and accurate information is essential for all evaluations and who is better suited to carry out the task of providing this information than the manufacturer? To simplify all further processes, both for users as well as others performing an evaluation and to improve the comparability between apps, the information should be provided in a structured and standardized manner, e.g. in the form of an app synopsis as it is described in [16] and [2]. Every additional piece of information, especially if it is presented in the structured manner defined by the app synopsis (Table 1, may significantly aid users in evaluating whether an app meets their needs and can be used in a safe manner, even if they are not really familiar with performing such evaluations.

Since users often tend to look for information directly on the app stores, the app synopsis should be provided there as well as on the manufacturer's homepage. Its aim is not to replace what (private or commercial) certifica-

tion initiatives or regulatory processes have to offer. It is rather meant as an additional measure and to provide all stakeholders with an easy to use source of information in cases where regulation and certification do either not apply or prove inadequate and thus, open questions remain.

Although many of the aspects covered by the synopsis have previously already been dealt with by other projects and initiatives, not all of these target apps. For example, the HONCode (Health On the Net Foundation) code of conduct for medical and health related web pages is a prime example of an initiative with somewhat similar criteria [18]. While its listed criteria can certainly be applied for medical apps and health apps, for apps, additional points need to be considered. In contrast to web pages, users often perceive an app as an integral part of their device and not as an extension that would warrant special caution. Due to this misconception, users may easily be tempted to enter information into an app that they would never willingly disclose on a web page that, when combined with other information (e.g., location based data, personal data) already available on the devices can significantly increase the risk.

Providing Additional Support to Users For Self-Performed Ratings

While providing adequate and comprehensive information, e.g. following the aforementioned app synopsis is already helpful, unfortunately, such information is not always being made available.In cases where third party evaluations or certificates are either unavailable or are not deemed sufficient, users are still left to their own devices for assessing whether they can rightfully place their trust in an app.

As outlined in [19], one possible solution in such cases is to provide users with a tool that can aid them in this assessment process, ideally before they download the app they are interested in. While the app synopsis that is to be used by manufacturers and aims at providing as much information as possible in a clearly structured manner, users want to take a swift decision. Therefore, they need a tool that allows them to sift through and rate the available information as befits their needs. If – by chance – a manufacturer has already provided information following the app synopsis, this is an easy to fulfill task, since the proposed user checklist is based on the app synopsis and thus, users can easily match the items of the synopsis and the checklist. In all other cases, the checklist can still guide users through distilling the necessary information from available information sources, e.g. as provided by the manufacturers themselves, but also from third party sources.

The list consists of 38 questions. These questions are divided into 7 categories and cover aspects that are important in the context of rating the safety and effectiveness of both medical as well as health related apps. While all 38 questions touch on points that are important for obtaining a comprehensive picture of an app, for each category, there are one or more key questions. Table 2 lists the 7 categories and corresponding key questions. Depending on the setting an app is to be used in, even a single unsatisfactory answer to a key questions may very well serve as a show stopper; the final decision rests with the user.

Table 2: Categories and corresponding key questions for the user checklist, adapted from [19]

	Category	Key Question(s)
1.	Status of the app	– Is the app a medical product (certification according to regulation) or is there other certification?
2.	Purpose	– Has the app's purpose been clearly stated?
3.	Included functionality	– Are the descriptions of the included functionality thorough and comprehensible, does the functionality match the actual needs?
4.	Risks and limitations	– Are the app's limitations and risks listed (related to medical aspects, data protection & privacy etc.)
5.	Reliability of the content	– Have the identities of the authors/developers and their qualifications been disclosed? – Are the information sources employed for providing the app's content reliable? – Are there potential conflicts of interest leading to a bias in the provided information/functionality?
6.	Data protection & privacy	– Do users remain in control of their data (what is recorded and when); are they informed about how they can influence the collection process? – Can the app be used without entering sensitive data and is data requested on a voluntary basis? – Have adequate precautions for ensuring data protection and privacy during storage and transmission of data been taken and are users informed about their rights in this context?
7.	Imprint	– Is there sufficient contact information specifying where users can turn if they have any questions?

5 Conclusion

Adequate information remains the cornerstone of all evaluations – independent of whether they are performed by notified bodies, by independent initiatives or the users themselves. In addition to the methods we outlined above, i.e. the app synopsis on the manufacturers' side as well as the checklist that is aimed at users, there are various approaches with similar aims, namely supporting all those dealing with app evaluation in a medical context with sufficient information in order to allow them to make informed decisions.

For example, the one-shot pictorial schema developed by Bonacina et al. [20] provides users with a "user oriented ID card" for apps that can draw their attention to the "risky factors of any medical app". Somewhat similar to both our proposed checklist as well as the synopsis, its elements are divided into 6 attribute categories, but instead of simply checking of each item contained in this checklist (with special attention towards the key questions), the pictorial schema uses a traffic light scheme to denote how well an app scores with respect to each element. Due to its visual nature, this pictorial schema is certainly easy to grasp once it has been compiled. As the authors state [20], the pictorial schema can be compiled by "generically interested citizen, a healthcare provider, a doctor, a nurse, the app manufacturer, a declared cohort of users, a scientific society, a governmental body". Nevertheless, we believe that for those who simply want to quickly determine whether an app they are considering meets their demands, and especially for casual users who are unfamiliar with the process of evaluating medical and health related apps, it may be somewhat tedious to compile. Still, due to its granular nature, it is certainly well suited for professional demands.

Aside from existing laws and regulations for medical and health related apps, there are currently many different initiatives wooing for the attention of all stakeholders, but independent of the approach being applied for evaluating and rating an app, the final decision about an app always rests with the users. They have to assess and decide on their own whether the benefits they anticipate from using an app in a medical context can outweigh its perceived risks [19] or whether they would rather get professional advice before making a decision.

In conclusion, there are currently many interesting developments and it remains to be seen where the "road to trust" will lead: It is important to provide users with apps that are trustworthy and well adapted for the settings they are to be applied in. This is essential in order not to gamble away the trust users place in these exciting technologies and thus hinder future innovations. To smoothly pave this "road to trust" will require a collaborative effort from all sides, including lawmakers as well as developers and last but not least the users themselves.

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Balancing Calories with Smartphone

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Abstract

Background: People gain weight when assume more calories than their body can consume. Instead, they lose weight when they consume more than what they eat. Comparing the body to a closed system, we can call calorie balance the difference between the input and output calories. However, keep a balanced diet regime is never a rewarding activity and often people give up.
Objectives: The goal is to help subjects with overweight problems: educate these people reduces the number of people that might migrate in the obese class. We propose an application to encourage healthier lifestyles, whose innovative feature is an automatic adaptive monitoring of the daily calorie balance. The system uses a familiar device and motivates the users to reach best result with the diet.
Methods: The energy consumption is related to the oxygen consumption, obviously also if combined with physical activity. The heart rate is directly related to the supply of oxygen. Using this simple relation, the heartbeats are bound to the calorie consumption.
Results: People achieve a greater awareness about food dosage and its calories weight. Moreover the application allows a more careful choice in food selection in order to not vanish the efforts made to change the lifestyles.
Conclusions: We have obtained good result with off-the-shelf hardware and user friendly software solutions. The users consider the system like a game where they have to keep higher the burned calories level. A motivational application has been found to be a winning card to promote healthier lifestyles, without intimidating the user.

Keywords

Mobile Applications, Overweight, Energy Metabolism, Oxygen Consumption, Sedentary Lifestyle

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EJBI 2015; 11(3):en13–en21
received: June 10, 2014
accepted: September 22, 2014
published: April 20, 2015

1 Introduction

With the increasing availability of food and with the decrease of physical activity, economically developed societies are experiencing a continuous increase in the percentage of overweight people. The obesity problem is often related to excessive calories contained in food as well as to a decrease in physical activity and a more sedentary lifestyle. Accordingly the population can be divided into three classes:

1. normal people: with adequate weight to body structure and age;
2. overweight people: with 5-25% of weight more than the optimal value for the structure and age;
3. obese people: over 25% of weight more than the optimal value for the structure and age.

This situation can be different in relation to the social contexts, but usually the cardinality of population in class (b) exceeds the population amount of the other two classes. Hence, more incisive actions must be implemented in the second group, also considering that people in class (c) come from class (b). The target people of our application is composed of overweight subjects within a range of 5-25% of the ideal weight for age and gender. For these subjects a change of diet jointly with an increased physical activity should be proposed. The goal is to balance caloric intake with energy consumption, but new problems arise when a new diet is started. Even if a great motivation pushes the subject to start the new regime and to make more physical activity, more and more people give up quickly. No appreciable weight-loss that comes in the short term and a sensation of excessive strictness cause (also) a sense of defeat that not help to reach the target results.

The contribution of this paper is to propose a complete and autonomous auto-adaptive system, able to monitor in a simple and effective way the calorie balance. The application presented does not consist in a medical device, but it is a motivational application based on a physical-

medical theory [9]. The calories consumption is linearly related to oxygen consumption, that is directly tied to blood capacity and increases linearly with heart rate in standard workout conditions. Hence knowing the user's heart rate, it is possible to establish his/her calories consumption. On the other hand, the calories intake are calculated based on dishes that the user marks as eaten through a simple and intuitive interfaces. With these two kinds of complementary information it is possible to calculate, display and continuously update the input/output calories balance in order to give a rapid feedback whenever the user wants. Thanks to the continuous detection of the cardiac parameter of the subject, the smartphone app can calculate with a good approximation the energy expenditure of the user. Then, knowing the quantity and the type of eaten food, it is possible to inform the user about his lifestyle caloric balance. The system presents an auto-adaptive methods able to increase accuracy and keep always updated the metabolic model.

Thanks to the growth of the mobile device market, smartphone applications for health care are going to be widely used. The other systems which aim to help the user in tracking his/her calorie balance, ground their calculations only on what the user insert. Typically neither verifications nor adjustments are carried out to verify if the user inserts correct values or if the user metabolism does not correspond to the standard adopted one. These approach can show inaccurate values to the user that can lead him/her to erroneous countermeasures while trying to lose weight. Our system improves this issue using an algorithm able to compensate any change in the user lifestyle.

The outline of the paper is as follows. Section 2 specifies better the objectives of our work with some hints about the human metabolism, compared with other experience. Section 3 shows how the system works and all its features. The paper ends with some results in Session 4, a brief discussion on issues about certificates for medical devices in Session 5 and conclusions in Section 6.

2 Objectives

The cardinality of the overweight people group is greater than the other sets, so the main goal is to help the people of that class. It is reasonable to think that if we educate overweight people we can reduce the number of people that might migrate in the obese class. We decided to design and develop an application for the automatic auto-adaptive monitoring of the daily calorie balance. It uses a familiar device for the user and helps them to reach best result with the diet. Moreover, the system supports the user in a continued way in order to avoid an early abandonment of the diet for example because the results are slow in coming.

How to measure continuously the heartbeat and how to bind it to the burned calories in a consistent way were the first problems. The target was to avoid too complex evaluation methods that could be not accessible on a large scale, for instance as the Benedict-Roth apparatus [26]. We have developed a method able to adapt day by day the metabolic rate estimation, in order to follow the changes in the user metabolism. Further important features make the application able to provide a tracking system on patient's eating habits, in order to provide feedback on "choosing a dish" or "dietary errors".

2.1 Metabolism and Physics Principles

The term Basal Metabolism indicates the set of all chemical reactions that occur in the body and we can distinguish two phases:

- Catabolism the set of reactions in which complex molecules are broken down into simple ones with the release of energy;
- Anabolism the set of reactions in which complex molecules are synthesized from simpler ones with the storage of energy.

These two phases of metabolism are closely linked one with the other. Catabolism reactions provide the energy and the materials needed for anabolic reactions, which the body uses to build molecules and cellular structures necessary for its survival. Three-quarters of the energy released by the nutrients oxidation is thermical energy, while the remaining quarter is mechanical energy. Any chemical reaction and underlying metabolic processes involve energy exchanges, similarly all activities carried out by the human body require energy. The concept of energy is related to the oxygen consumption, hence all human internal chemical processes use oxygen for their reactions. All human activities contribute to the total amount of burnt oxygen that a normal non agonistic body uses in everyday life.

The synthesis of new materials, anabolic processes, in overweight people are more active than catabolic ones. In summary the increase in body weight is the result of an unbalance between the energy assumed with food and the energy cost of the organic functions (internal metabolism and physical activity). To carry out the activities, the organic chemical energy is processed and made available through the metabolic processes. That phase uses oxygen as an essential reaction element: oxygen consumption is proportional to the amount of transformed energy that is taking place within the body. If energy intake is greater than the oxidation reactions can use, chemical conversion processes are activated to fix the amount of unused energy in reserve tissues (fat tissues) that increase the body weight.

To monitor the changes in body weight, without interacting with mechanisms of assimilation and transformation, there are only two alternatives:

1. limit the energy intake through food;
2. increase the energy consumption through physical and mental activity.

For our work it has been crucial to emphasize that the energy consumption is directly related to the oxygen consumption and it related to the heartbeats.

2.2 Related Works

Usually other similar projects focus only on calculating the energy consumption [1, 18] or just on the caloric intake [2]. They fail to help the user to read parameters indicating whether he/she is doing a good job with the diet or the physical activity. People who are aware of the meaning of kcal will appreciate an automatic calculation of daily calorie intake [3], but for others it will be just a number without any important meaning. As a result they might not realize that a wrong eating habit may undermine the sacrifices put in place.

The heart rate monitoring mechanism is often used to derive the calories consumption of a person [19]. In particular, thanks to the performance of the new mobile devices this technique quickly became familiar in the smartphone application universe, but rarely the available solutions are supported by a base medical-physical theory. In [20] they proposed a very interesting system but no adjustments are made to compensate the variations of the user's metabolism. In [6] they understood the desirable necessity of a continuous heart rate monitoring and the target to be not bound by the proximity to the radio base station. Hence their system communicates with the smartphone of the user, allowing him/her to move outside any predefined limited coverage areas. In [21] a bulky device is proposed to monitoring the calorie balance using a PDA, the resulting system is quite invasive and users can be unmotivated to adopt it. Several other solutions have been proposed to monitor the heart rate in a non-invasive way with a wearable ECG system [4] or a ring sensor [5]. Another interesting system is to use the camera to monitoring the heartbeat [22], but in this case the user should remember to measure it regularly and the system would not have a constant data stream. Other more precise systems [23, 24] require a periodical calibration phase to measure resting metabolic rate, using specific instrumentation. Resting metabolic rate changes over time and varies the resting energy expenditure.

As stated in [7], we should not underestimate the danger of providing incorrect details to the end users, with which they can mistakenly change their eating habits or their lifestyle. From [8] we can see that the population in Western Europe is at risk for obesity but being able to gain access to advanced technologies such as smartphones and biomedical sensors, they can easily benefit from the use of techniques of automatic control of the calories consumed. Moreover, solutions to encourage and motivate healthier lifestyles [25] can be very important, especially if they are easily available as the mobile phone applications.

3 Methods

The proposed application allows the user to continuously measure the number of heartbeats that he/she has during the day. It uses a chest belt to calculate the energy consumption thanks to the relationship that binds oxidation reaction with oxygen consumption and heart rate. In standard conditions the oxygen consumption is proportional to the heart rate. The system starts using a first approximation: a default energy value is associated to a heartbeat. Then a better estimation can be reached considering the operating conditions detected by the instruments and applying weight-functions to the single beat.

This calibration is achievable by asking the user to measure its own weight and counting the total number of heartbeats in a given period. Knowing what he/she ate, it is possible to correct the first estimated value. The application adopts this algorithm to calibrate the weight of each heartbeat for the specific user in term of energy consumption. The user just has to write down the foods that consumes and his/her weight and he has to wear the chest belt. Thanks to the cardiac measurements made by the sensor, the application will calculate all the rest using the standard tables of food energy [15, 16]. The user received the updated results on the smartphone display and is able to adjust his/her eating and physical habits. The concept behind this system is the possibility of being able to determine the energy expenditure of a subject knowing his/her heart activity [9].

It is really important to track in a continuous manner the users heart rate. We can achieve this purpose using a sensor with local memory or a sensor without local memory, that sends its readings to a device with storage and computational capabilities. Smartphones appear to be excellent candidates for this purpose: the user can always keep it close enough to receive the sensor signal. To preserve the battery power on both side a Bluetooth Low Energy protocol has been chosen to perform the communications. Currently the market offers many sensors with different shapes and features. A chest belt, with a Bluetooth 4.0 transmitter and an accuracy at least within three percent, is a kind of sensor that meets the need. The user can wear it as just wake up. It can feel the heartbeat thanks to two electrically conductive pads and with a simple formula it can update its internal heart rate measurement. Then it sends at regular intervals the read values to the application which resides on the user's smartphone. The smartphone application is able to show and manage every significant information in a very simple interface (Figure 1).

3.1 Auto-adaptive Behavior

How many calories does the user burn with a heartbeat? Is this value fixed or not? How does it change with respect to lifestyle change? Auto-adaptive behavior is the main innovative feature of the system.

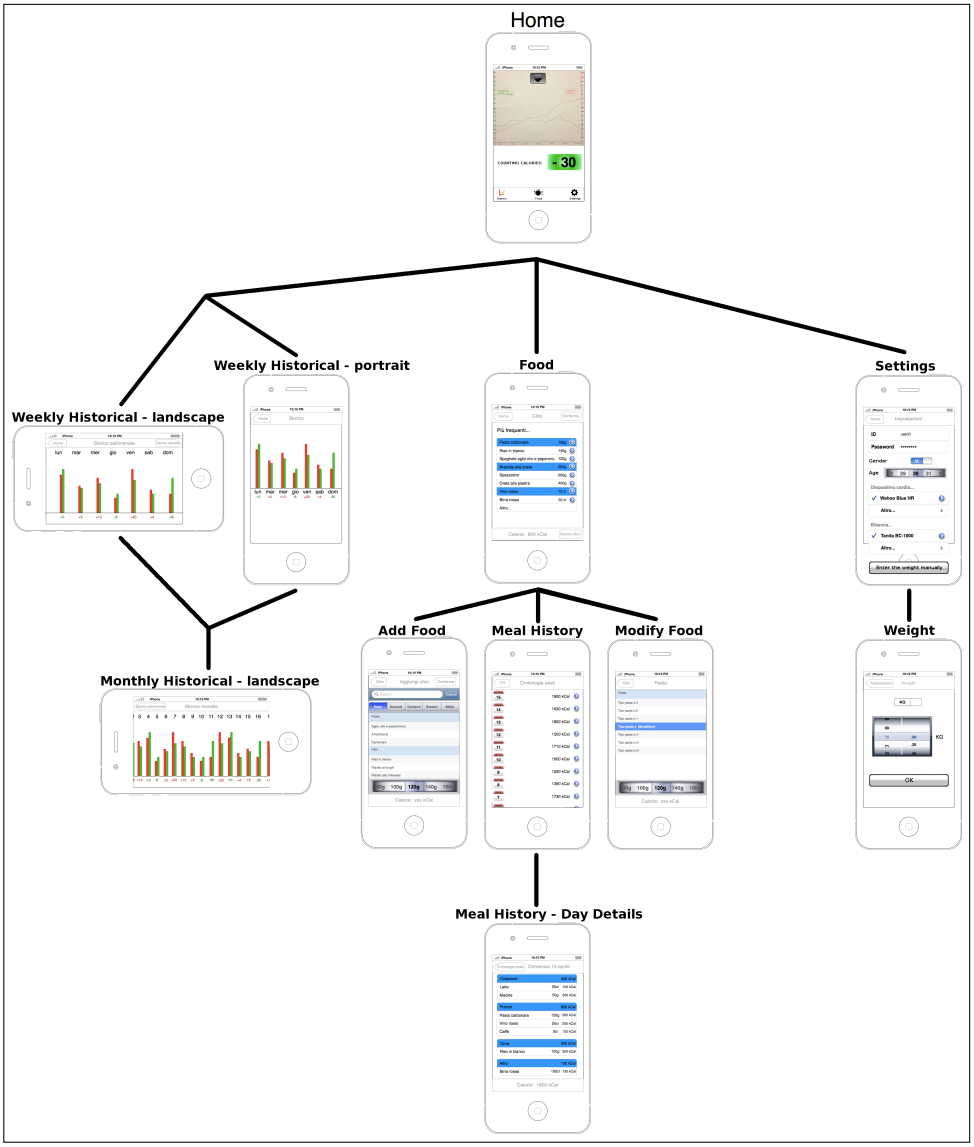

Figure 1: Application flowmap.

3.2 A Common Approach

The estimated "calorie weight" for each heartbeat can be calculated by a specialist, for instance with a Benedict-Roth spirometer. This measure, although very faithful to the real relationship between heart rate and calories burned, refers to a particular time of the year and to a particular physical state of the subject. These conditions can change, even considerably if the subject follows a diet. Hence any fixed value can invalidate the accuracy of a system like the proposed one, especially if the user metabolism evolves day by day. Moreover only few users can access to the spirometer at the same time.

Therefore it is not possible to rely on a single precise measurement. We developed another method, less precise, integrated into the application and able to follow the subject habits.

3.3 The Auto-adaptive Approach

No spirometers or special tools are needed, but the user inserts some data through the application interfaces. First of all it is necessary to estimate the relationship "Beats per Calorie" (BPC) and then keeping updated this value. BPC is the number of heartbeats required to burn one calorie. The initial estimate can be defined dividing the daily calorie needs of the subject [17] (estimated on gender, age and weight) with the number of heartbeats occurred in the first day of use. Then the BPC correction can be done when the user makes a further weighing. It is possible to derive it from the stored data, in relation to the time elapsed from the previous weighing using this formula:

$$\Delta K = K - HB/BPC \tag{1}$$

where ΔK is the delta-calorie, K is the calorie intake, HB is the heartbeats number occurred and the BPC is the

previous estimate of Beats per Calorie. Assuming that the subject weight changes due to an accumulation or a loss of body fat (except great developments of muscle mass) the energy produced can be estimated in 7.7kcal/gr. Hence if the ΔK between two weighings fits this equation:

$$\Delta W = \Delta K / 7.7 \text{ kcal/gr} \quad (2)$$

where the ΔW is the real difference of weight, it means that the initial BPC estimate is fine. Otherwise the BPC in (1) should be adjusted in order that ΔW complies with (2).

To limit damages caused by an incorrect reading or too much readings taken at a short distance, a restriction of the incisiveness of the correction formula is performed. Also because people at home usually have not accurate balance scales, the algorithm can be led to an erroneous correction if a wrong weighting result is inserted in the formula. To limit that this possibility occur, after a weighting the algorithm doesn't correct the previous BPC with 100% strength; instead throttle the correction based on how much time has passed since the previous weighing. Therefore, weighting far back in time make a strong correction on the BPC, while close weighing affect it very little.

The application initially uses a standard estimate value to calculate the calories burned, given a certain number of heartbeats. Then it starts to auto-adapt to the metabolic characteristics of the user. Using the application, the algorithm is able to correct its parameters, providing as reliable as possible the energy consumption of the user. This behavior allows the system to provide responses always accurate, despite the user's metabolism varies as a result of the new lifestyle undertaken. In addition to the benefit of "chase" the metabolic behavior of the user, the auto-adaptation capability allows the application to tolerate the possible inaccuracy of the heart rate detection system. It is useful if the user decides to use a cheaper and less precise chest belt.

In a human-computer interaction system the component more prone to errors is often the human one, our system improves this lack. The auto-adaptation function is able to tolerate the estimation errors that the user can commit when inserts the amounts of eaten food. The auto-adaptation retains its validity only in the case where this estimation error lies inside a tolerance range, otherwise the computation is repeated. The system is able to adapt to mutable variables listed above because starting from a default BPC, a consumption of calories between two user weightings is estimated according to the number of heartbeats recorded. If the amount of intaken calories is equivalent to those consumed at the time of the second weighing, the user must weigh as much as the first time. Otherwise if he/she has increased/decreased weight and the system does not detect this variation, it means that the estimation of calories applied to each beat is too low/high. In this case the application automatically corrects the previous value to bring it closer to the real value.

3.4 Incentive Functions

Among the peculiarities of the system there are some incentive functions. They ensure a better user experience and they help the user to keep the right food habit. These functions are designed in order to simplify the whole system.

3.4.1 Immediate Feedback

There are several difficulties that characterize the diet. The two causes that mostly affect the failure rate are the non-continuity and the early abandonment of the controlled diet.

This is mainly due to the fact that the human organism is slow to react to the diet and physical activity change: the first significant results are postponed for several weeks after starting the diet. This expectation can be too long for those who were not sufficiently determined. This situation leads them to a temporary or permanent abandonment of the diet regime.

One of the main features of our application is to encourage the user to continue and possibly to correct his/her diet regime. The system provides rapid feedback, calibrated on the number of calories burned or stored day by day, transmitting a simple message like "Keep it this way! You are going right!.

3.4.2 Choosing a Dish

For each dish the application shows the caloric weight expressed in kcal per 100 units of measurement (kcal/100gr for solids and kcal/100ml for liquids). If the user is undecided on the menu to be prepared, he/she can use this function to choose the food that better benefits to his/her diet regime. He/she can verify what he/she has already eaten in the previous meals and the calorie assumed. The application drives towards the better choice than otherwise the user probably would not perform.

3.4.3 Understanding of Dietary Errors

The history functions automatically annotate the eaten and burned calories. These features are very important, especially in the "Annual History" mode. The user can see if in the past he/she has fulfilled more or less the diet regime that had been proposed and which of his/her eating habits are more counterproductive. These functions allows the user to act with more accurate cuts on the foods more frequently assumed and that contributing negatively to a healthy and balanced diet regime (Figure 2).

Figure 2: Details for foods eaten in the past.

3.5 Tracking Functions

In addition to the incentive functions a further important functionality is offered to the user. He/she can see which diet and physical workout he/she has held in the past. The Historical calories functions allows to check in the past days, weeks or months how much the user has been diligent. The Historical meals allows to understand what eating habits have impacted the most on the diet performance (Figure 3).

Figure 3: Details for calories balancing in past weeks, month and years.

The user is constantly informed about the danger of certain lifestyles: for instance he/she can notices an increase in weight corresponding to a time of stress or to frequent fast-food meals. If these situations will occur again in the future, the user will be able to recognize them and he will be able to react more quickly.

These storage functionality are extended also to heartbeats data. Hypothetically the doctor can be able to detect any abnormalities of the heartbeat during normal daily life, while doing sports or even during the sleeping phases.

4 Results

Smartphones represent the principal platforms for this kind of applications. They are the most common device currently used and they are considered by the people a familiar and multifunctional gadget. For these reasons the first experimentation of our system has been started on a iOS smartphone.

Among the results of the application it is interesting to highlight that the users have developed a greater awareness on the food's dosage and on the calorie weight of the nutrients. Moreover, the users have developed a better ability to choose dishes at time of food selection in order to not frustrate the efforts made to change their lifestyle.

Proving the system with a sample of users for a medium-long period of time, a good ease of use hes been detected by the subjects. In addition they expressed a positive opinion with respect to the type of help offered by the application with simple and intuitive graphs like the one shown in Figure 4.

We were initially doubtful about the choice of the chest belt, but the majority of the users do not feel it too intrusive. They find very useful the integration with their smartphone to which they are accustomed.

A small number of user were available to use the chest belt also during the night. Hence we could test how the system reacts if receives more information. Despite the application received the heartbeats also during the night, the error on the final computation was similar to the users that used the chest belt only during the day.

4.1 Case Study

In this section we propose a case study to better understand how the system works in a real situation. Let's consider a woman, as an example, Juliet: aged 30, 1.60m tall, 60kg of weight, working as a teacher, so with low/medium activity index.

The first day, until the first weighing, the application counts 2100 kcal/day and assuming 100,000 heartbeats per day, the estimated BPC is 47.62. Juliet wears the chest belt daily and annotates how much she eats. After few days, the application reminds Juliet to insert a new weight. Until now the application knows neither about Juliet's metabolic consumption nor her accuracy in determine how much she eats. The new weight makes the auto-adaptive algorithm able to start its work. The application knows how many heartbeats Juliet's heart did, how many calories she ate, and now also a weight difference from two

different weighing. If the expected weight and the real weight are the same, each parameters is correctly tuned. Otherwise, if the real weight is different from the calculated one, some parameters are not correct. It can be the consequence of a poor accuracy chest belt, some mistakes made by Juliet or the BPC value used. The proposed solution implies that the auto-adaptive algorithm computes multiple parameters (also considering hour of the day, how many days passed from last weighing, connection-loss rate with the chest belt and others) and proposes a new BPC correct value. This value will be used until next weighing, when will be adjusted again. This happen for every weighing. The estimated BPC value becoming each time more faithful to the real one. Julia should just remember to enter the eaten foods and any mistakes that can be made in this phase will be offset by the correction of the BPC.

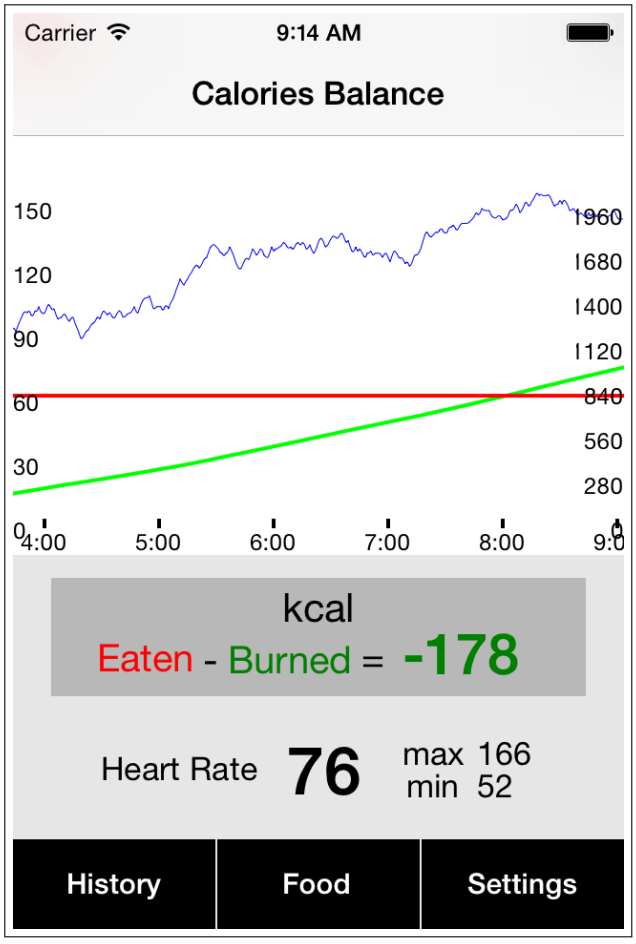

Figure 4: Details for foods eaten in the past.

Juliet can decide to wear the chest belt also during the night. However, in few days (e.g., 5 day later in this example) the application learns the Juliet lifestyle and two different situations may occur:

(a) Juliet has eaten more (or less) than she needed and has kept constant (or varied) the physical activity. As a result, she has put on weight (or lose weight). After the weighing she annotates the new value and check s the situation, for instance:

(i) For 5 days she introduces 3.000Kcal/day, keeping 100.000 heartbeats. Her weight is grown of 585gr.

(ii) For 5 days she introduces 1.800Kcal/day, but double the heartbeats with more physical activity. Her weight is decreased of 1.558gr.

In both cases the BPC used was correct and Juliet detects the same weight variation on the balance.

(b) Juliet detects a different weight variation on the balance compared to the value indicated by the application. It means that the initial estimate BPC was not correct. In that case the application detects the error and adjusts the value for the next computation.

5 Discussion

Mobile applications to monitor vital signs and subject health status are definitely an interest area, so as to draw the interest of the FDA. The agency has recently published a set of guidelines [10] to improve the functionality and the interfaces of these applications. mHealth is an emerging and rapidly developing field and it is appropriate to devote a paragraph to assess the nature of the proposed system.

As defined by the European union regulations [11], mobile health covers medical and public health practice supported by mobile devices. The legislation still includes applications such as lifestyle and well being applications that may connect to medical devices or sensors. While the Italian legislation [12] transposing EU directive [13] considers a medical device an instrument used in medicine for diagnostic and/or therapeutic purposes: "any instrument, apparatus, appliance, material or other product, whether used alone or in combination, including the software necessary for its proper functioning, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease".

Up to now cardio chest belts are not completely considered medical devices and we do not consider the proposed application a clinical-medical device. For this reason it has not been submitted to a large-scale clinical trial, but we use a sample of users to verify the system.

The verification performed could still be useful if in a near future a certification process will be required in order to mark the system as a medical device. For us the test shown in the previous section highlights the real potential of the system. Considering the potential of these new technologies and the forecasts made by PwC and GSMA [14], which indicate that in 2017 mHealth could potentially save a total of € 99 billion in healthcare costs in the EU, we believe that the certification path will soon be mandatory.

6 Conclusions

The application presented is a motivational application that helps the user to keep a healthier lifestyle. The system has been developed using commercial software and simple hardware solutions. It makes the user able to monitor his/her cardiac performance and food habit, in order to estimate the calories balance during all day. The user inserts the amount of food that he/she ate using the various available functions and the system calculates the calories intake that these foods have led to the subject. Knowing the heart activity and the food eaten it is possible to calculate the calorie balance. In practice, it determines the difference between the calories that the person has acquired through intaken food and those who he/she consumed conducting normal activities or workout (in addition to the basal metabolism).

Then it presents the possibility for the user to access the cardiac and metabolic data and the related historical values. The user can use these information to establish the effectiveness of the diet and the lifestyle adopted. Indeed with these values the conditions with which the user can obtain most benefits are immediately identifiable and the corrections on the diet and/or on the physical activities may be taken.

The main feature of the system is the ability to auto-adapt the computation, following the user lifestyle change. This characteristic protects the application from any errors that can be occur. An Incentive Function gives to the user immediate feedback on energy balance and it represents the main motivational features.

The whole system continues pushing the user to do his/her best to maintain negative the daily amount of calories stored. An exhausting commitment as a diet is tackled in a better way if it's seen as a daily game, as this application aims to do.

Acknowledgements

We would like to thank Prof. Romani Zannoli of the Department of Experimental, Diagnostic and Specialty Medicine of University of Bologna, for the idea to use the heart rate to compute the oxygen consumption and its relative burned calories.

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Mobile Apps as Medical Devices

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Abstract

Background: In 2007, the European Parliament and Council amended the previous version of its directive on medical devices, allowing software to be by its own a medical device.
Objectives: Aim of the present paper is to discuss the above mentioned issue when applied to mobile apps, and to tentatively apply medical devices classification rules to a sample of apps.
Methods: Medical devices can be assigned to four different classes (I, IIa, IIb, III) depending on their invasivity, clinical risk, duration of the contact with the body, and active or passive devices. Guidelines have been released regarding classification of software. We identified a sample of apps in Android Store (categories: Medical and Health&Fitness) suitable for such classification, and attempted to apply the above mentioned rules.
Results: Among the 80 selected apps, 32 resulted not being classifiable as medical devices (40%), 20 as class I (25%), 26 as class IIa (32.5%), and 2 as class IIb (2.5%). If we look at ratings and number of downloads as a measure of apps usefulness, it seems like class II apps are slightly more useful than class I apps.
Conclusions: It seems that a fair amount of present apps could be subject to medical device classification, and these of higher category (and thus higher risk) are those possibly more interesting for users. This pushes for some attention towards them, not necessarily in terms of ruling, but at least of clear identification of functions and limitations.

Keywords

Mobile Applications, Medical Device Legislation

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EJBI 2015; 11(3):en22–en27
received: November 14, 2014
accepted: Januarz 13, 2015
published: April 20, 2015

1 Introduction

A device is defined as medical if it is an instrument, an apparatus, an implant, an in-vitro reagent, or similar or a related article that is used to diagnose, prevent, or treat disease or other conditions, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means (the latter action being the basis for medicinal products). Almost every country has some classification scheme to describe medical devices in classes related to the potential risks that could derive from their use. Here we will deal with the European Directive on Medical Devices ([1]) as an example, since main points are similar among regulations.

In 2007, the European Parliament and Council amended [1] the previous version of its directive on medical devices [2] to take into account some novel needs in the field. Among the various amendments, at least one is crucial for computer science researchers and software systems developers: while in the previous directive software appeared only considered as a possible part of a more complex device, in the latter version software may be by its own a medical device, as reported in the premises:

"It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device." However, *"Software for general purposes when used in a healthcare setting is not a medical device."*

One consequence of this is that stand alone software is defined as active device: *"Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. (...) Stand alone software is considered to be an active medical device."*

Furthermore, software is intended to be subject to state-of-the art development and maintenance practices: *"For devices which incorporate software or which are med-*

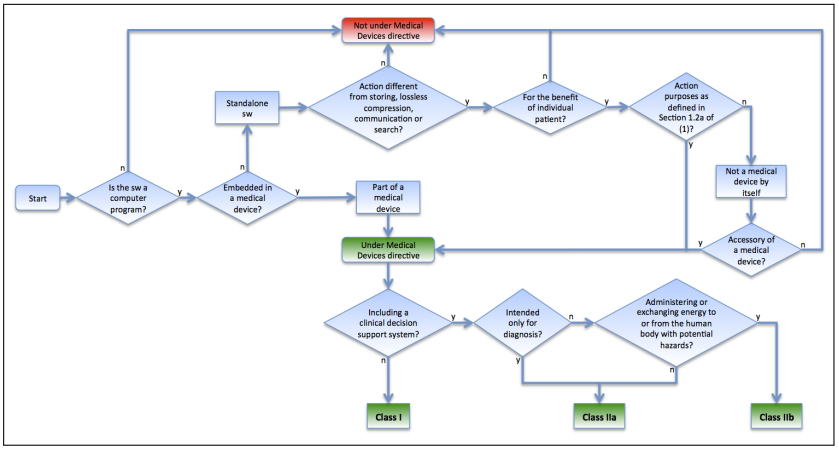

Figure 1: A decision diagram to assist qualification of software as medical device[7].

ical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification." The decision diagram in Figure 1 better clarifies whether a software may be classified as medical device.

The most recent amendment proposal ([3]) include some further detail regarding software. First of all, there is a generic reference to the fact that it *"shall be designed and manufactured to remove or reduce as far as possible and appropriate the risk associated with the possible negative interaction between software and the environment within which it operates and interacts."*

More important for the aim of present paper are the next two points. A first note is related to the technical aspects of software running on mobile systems: *"Software intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise)."*

Finally, lay persons are recognised as possible users of medical devices, and there is an article (*"18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons"*) describing the practices to be followed for medical devices aimed at them. Among the provisions:

- the device should be easy to use by the intended user,
- it should reduce as far as possible the risk of error,
- it shall, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the device will perform as intended by the manufacturer, and if applicable, is warned if the device has failed to provide a valid result.

In the recent years, the availability of smartphones and tablets is driving to so-called "m-Health" (Mobile Health) applications, based on phones, short text messaging, mobile web access, up to the most recent smartphone and tablet applications [4].There are growing research efforts [5] but also growing concerns about their safety and effectiveness [6].

Aim of the present paper is to discuss the above mentioned classification of software as medical device when applied to health-related mobile apps, and to tentatively apply classification rules to a sample of apps.

2 Software as Medical Device

Medical devices include a large array of health-related entities ranging from bandages to highly complex systems like Magnetic Resonance Imaging. They can be assigned to four different classes (I, IIa, IIb, III) depending on their clinical risk, invasivity, duration of the contact with the body, and active or passive devices. Classes range from low (I) to potentially high risk (III). Rules for classification, described in Annex IX of the directive [1], define the boundaries of the categories. Classification is based only on the intended purpose as described by the manufacturer.

A device is invasive if it penetrates inside the body, either through a body orifice or through the surface of the body. By definition, software is not invasive, although it could be part of an invasive device. Duration of contact, when relevant, can be transient (less than 60 minutes), short term (less than 30 days) or long term (more than 30 days of continous use). An active medical device depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. By definition, standalone software qualifying as medical device is also active.

Depending on class, different rules apply regarding notification, declaration of conformity, surveillance, etc. Since stand alone software is not invasive but is an active device, this drives its classification. On the other side, software that is accessory to other medical devices functioning automatically falls into the category of the host

device. In fact, guidelines have been released regarding classification of software [7], including a flowchart that helps in deciding how to classify. Let's now look at the main classification rules for software.

One decisional rule to establish whether software is or not a medical device is: *"Step 3: if the software does not perform an action on data, or performs an action limited to storage, archival, communication, simple search? or lossless compression it is not a medical device."*

Thus, apps aimed only at collecting data and possibly presenting them may easily be excluded from the definition. Instead, *"Software which is intended to create or modify medical information might be qualified as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals when reviewing medical information, the software could be a medical device."*

Another rule (Decision Step 4) is about software for the benefit of individual patients. This software is intended to be used for the evaluation of patient data for supporting or influencing the medical care (thus software that aggregates data is excluded - e.g. software for statistics of epidemiology).

Finally, if the software is specifically intended to provide one or more of the features stated in the definition of medical device (diagnosis, monitoring, treatment, etc), it is a medical device.

Further rules help in identifying whether stand-alone software can be considered an In Vitro Diagnostic medical device (IVD), when used in support to in vitro diagnosis systems. Stand alone software that meets the definition of a medical device shall be considered as an active medical device, so that rules 9, 10, 11 and 12 of Annex IX [2] may apply:

- software as therapeutical device fall into class IIa or IIb. One reported example is insulin dosage planning stand alone software, which can be easily recognised as a possible feature of a mobile app.
- Software intended for diagnosis or therapy falls again oin IIa or IIb. Again, an interesting example is software for the presentation of the heart rate or other physiological parameters.
- Other usages fall into class I.

In practice, if a software encloses a medical decision support component, it is classified as IIa or IIb. Class III is for long term invasive medical devices and thus it does not seem applicable, as now, to software.

Since we are interested in medical apps running on regular mobile devices like smartphones and tablets, even when connected to other medical devices like sensors, from now on we will focus attention on stand alone software.

app	free	rating	d/l	class
ACLS sim 2012	no	4.2	7500	-
Acupressure	no	4.3	30000	-
ATLS Trauma Guidelines Manual	no	5	300	-
Blood Pressure Diary Pro	no	4.3	7500	I
Blood Pressure Pro	no	4.4	750	IIa
Esame di stato	no	4.7	750	-
Fast Infusion Dosage	no	4.6	750	IIb
First Aid Kit	no	4.7	300	-
In Case of Emergency (ICE)	no	4.2	75000	-
MedCalc 3000 complete	no	3.4	75000	IIa
Medical Encyclopedia	no	3.7	3000	-
Medical mobile	no	4.1	750	-
Menstrual Calendar Premium	no	4.4	75000	IIa
MiCuroDaMe	no	3	300	-
Muscle trigger	no	4.4	30000	-
Pediatri	no	4.1	300	-
Pill Organizer Pro	no	4.5	300	-
Pocket Lab Values	no	4.3	7500	-
Prontuario farmaceutico	no	3.6	750	-
Sleep Diary Pro	no	4.3	3000	I
3D Anatomy Learning	yes	4.3	300000	-
Adv. Real Blood Press Calc	yes	3.8	300000	I
Blood Pressure (My Heart)	yes	4.1	3000000	IIa
Doctissimo Ma Grossesse	yes	4.3	300000	I
Electrocardiogram ECO Types	yes	3.9	750000	-
Emogas PRO	yes	4.3	30000	IIa
Farmaci in Pronto Soccorso	yes	4.7	30000	IIb
Farmacia di turno	yes	3.9	750000	-
Gravidanza Mia Free	yes	4	75000	-
Improve EyeSight	yes	4.1	300000	IIa
Medscape	yes	4.4	3000000	-
My Menstrual Diary	yes	3.9	300000	IIa
My Ovulation Calculator	yes	3.8	750000	IIa
Myopia Exercise	yes	3.6	3000	IIa
myPill BC Reminder	yes	4.3	300000	I
Organs 3D (Anatomy)	yes	4.1	30000	-
Prontuario Farmaceutico SSN	yes	3.8	75000	-
SmartPharma Lite	yes	4.4	300000	-
URIGHT Temperature Manager	yes	2.7	30000	I
Weight Calories Watch	yes	3.8	30000	I

Table 1: Medical apps.

Table 2: Health and Fitness apps.

app	free	rating	d/l	class
Abs Workout PRO	no	4.6	30000	-
BikeComputer Pro	no	4.7	30000	I
Conta Calorie Italiano	no	3.8	3000	IIa
Daily Workouts	no	4.4	30000	-
Diet Points Diary	no	4.3	300	IIa
Dukan Diet	no	3.9	30000	IIa
Endomondo Sports Tracker Pro	no	4.5	750000	I
Freeletics	no	4.1	30000	-
Garmin Fit	no	3.5	30000	I
HIT Interval Workout Pro	no	4.4	30000	-
iDukan Dukan Diet Tracker	no	4.1	7500	I
Instant Heart Rate Pro	no	4.4	300000	I
Just 6 Weekds	no	4.7	300000	-
My Diet Coach Pro	no	4.6	75000	IIa
QuitNow! PRO: Stop Smoking	no	4.5	30000	I
Runtastic PRO	no	4.6	750000	IIa
Smart Alarm Clock	no	4	7500	IIa
Stop Smoking	no	4.3	30000	-
WomanLog Pro	no	4.7	300000	IIa
Yoga.com Studio	no	4.4	3000	-
Accupedo Pedometer	yes	3.9	3000000	I
Aquafresh Nurdle Time	yes	3.7	75000	-
BMI Calculator Weight Loss	yes	4	7500000	IIa
Bunnys Period Calendar/Tracker	yes	4.4	750000	IIa
Calorie Counter - MyFitnessPal	yes	4.7	30000000	IIa
Cardiograph	yes	3.9	30000000	IIa
Daily Butt Workout FREE	yes	4.4	3000000	-
Hydro Drink Water	yes	4.5	750000	I
La tua dieta personalizzata	yes	4.3	750000	IIa
LifeSum Calories Counter	yes	4.1	3000000	IIa
Monitor Your Weight	yes	4.4	750000	IIa
My Tracks	yes	4.3	30000000	I
Noom Weight Loss Coach	yes	4.3	30000000	I
Period Calendar / Tracker	yes	4.7	30000000	IIa
Real Blood Pressure (BP) Calc.	yes	3.6	300000	I
RunKeeper GPS Track Run Walk	yes	4.4	30000000	IIa
Runtastic Heartrate	yes	4.4	3000000	IIa
Take Temperature Fever?	yes	3.1	30000	I
Water Your Body	yes	4.4	3000000	I
Workout Trainer	yes	4.3	7500000	-

3 An Experiment: Matching of Currently Available Apps with the EU Classification of Medical Devices

We wanted to verify whether the issue of classifying apps as medical devices it is actually valid in the present reality, made of few platforms with their own apps and app stores. For this, we identified a sample of apps in principle suitable for such classification, and attempted to apply the above mentioned rules.

3.1 Material and Methods

We focused on the Google Play store for Android devices. While apps are sold also on iTunes Store for IOs devices, and, on smaller numbers, on Windows Store for Windows devices, often apps are available for all platforms. Thus, analyzing just one store is not a limitation.

To obtain a sample of apps candidates for a possible classification as medical devices, we identified two suitable categories available on the store: *Medical* and *Health & fitness*.

Inside the above mentioned categories, we analysed in detail the 20 most popular free apps and the 20 best selling paid apps, for a total of 80 apps. Table 1 shows the selected apps in the medical category, Table 2 those pertaining to Health & Fitness.

For each app, we collected from the store the average user rating (a user expressed judgment ranging from 1 to 5 stars and often accompanied by a review) and the number of downloads (the range categories published in the store: 500-1000, 1000-5000, 5000-10000, etc). To estimate the average number of downloads, we assigned each category the middle number of downloads for its class (e.g., 500-1000 becomes 750). We then examined the app and applied the above mentioned classification rules, assigning each app to no, I, IIa or IIb. When in doubt, we attempted to be uniform in our classification decision.

3.2 Results

Among the 80 apps, 32 resulted not being classifiable as medical devices (40%), 20 as class I (25%), 26 as class IIa (32.5%), and 2 as class IIb (2.5%) (Table 3).

Table 3: Apps per free/for sale and per class.

Free?	no	I	IIa	IIb	Total
For sale	21	8	10	1	40
Free	11	12	16	1	40
Total	32	20	26	2	80

If examining separately the two store categories, it can be noted that in the medical category there are less medical devices than in the Health & fitness category (Table 4). Some examples of apps per class are:

- not a medical device: health information apps, drug databases (without decision support);
- I: calculator apps, e.g., how much water to drink, with alerts, pill reminders, etc.;
- IIa: diet supporting apps that personalize diet basing on weight, age, gender, lifestyle and adapt it according to modifications; ovulation/menstruation calculators;
- IIb: only two apps have been classified this way, and both help to calculate infusion rate in critical care, emergency and urgent therapies.

While some aims seem typically classified as medical (e.g., blood pressure tracking, drugs related apps, pill reminders, etc) and some as health &fitness (e.g., diet and physical activity apps), some other apparently equivalent apps can be found in both categories, thus suggesting that the distinction between the two categories is most likely arbitrary.

Table 4: Apps per category and per class.

Category	no	I	IIa	IIb	Total
Health & Fitness	10	13	17	0	40
Medical	22	7	9	2	40
Total	32	20	26	2	80

While our classification attempt shall not be taken as a definitive evaluation of those apps, it suggests that in fact medical and fitness apps indeed pose an issue in terms of their effect on the human body, and thus there is some need for, at least, their evaluation from this point of view.

If we look at ratings as a measure of apps usefulness, it seems like class II apps (including both IIa and IIb due to the low numerosity of the latter) are slightly more useful than class I apps. This is reflected also in the estimated average number of downloads, that seem higher for class II apps (Figure 2).

4 Discussion

Although our analysis is limited in terms of sample size, it seems that a fair amount of present apps could be subject to medical device classification. Furthermore apps of category II (and thus higher risk than I, since classes are related to potential hazard) are those possibly more interesting for users. This asks for some attention towards them, not necessarily in terms of ruling, but at least of clear identification of functions and limitations.

A seminal effort in the ruling direction has been done by the Commissione Regionale Dispositivi Medici of the Emilia Romagna Region in Italy [9], which also identified a number of apps that have been already certified by either FDA or EC under the above mentioned rules. A lighter approach towards the development of a sort of "identity card" for medical apps has been instead proposed by Bonacina et al [10], where the focus is on a clear identification of features aimed at users (but possibly also at rulers in need of understanding what an app really does).

Since it is likely that medical devices are even more frequent in apps aimed at specific users, e.g., chronic diseases patients, we plan to expand our analysis on a previously collected sample of apps for diabetic patients [8], which may provide further insights on this issue.

The classification as medical device could identify a way for ruling apps safety at least from a technical point of view, although it may easily become too restrictive for small developers. In fact, FDA started efforts towards regulation of medical apps [11] and a survey of stakeholders evidentiated the following suggestions [12]:

- Clarify the difference between a medical app and a wellness app;
- Clarify the difference between diagnosing and monitoring;
- Establish the risk-level threshold for FDA enforcement;
- Define the limits of the FDA's rule on apps that serve as device accessories;
- Make a plan for how to handle "modular" apps.

These suggestion act in the direction of recognising what is really medical and what is more related to well-being in the heterogenous world of health-related apps, and can be certainly applied to the European situation too. In fact, EU recently started a consultation on this very specific topic, aimed at collecting opinions on safety, privacy, interoperability and legislation related to mobile apps [13].

5 Conclusion

The presented approach has been applied to medical apps, intended as software that runs on mobile platforms, but this is not the only way of realizing the same behaviour. In particular, Web 2.0 sites are nowadays fully fledged applications, able to do everything it can be done with a programming language. Nevertheless,they are yet commonly considered as web pages, for which no rules are apparently available except volunteer codes of conduct that in principle provide an ethical standard for web publishers, like HONcode [14]. It should however be noted that, among the examples in [7], software modules on servers might be qualified in their own right as medical devices depending on their intended purpose. This will open regulation to web-based apps too.

Since the classification as medical device is based on the intended purpose, that is in our case, how the app function is marketed, any too rigid regulation attempt might drive to mislabeling the software. This may be done for example by presenting it as educational even if the true purpose is diagnostic or therapeutic.

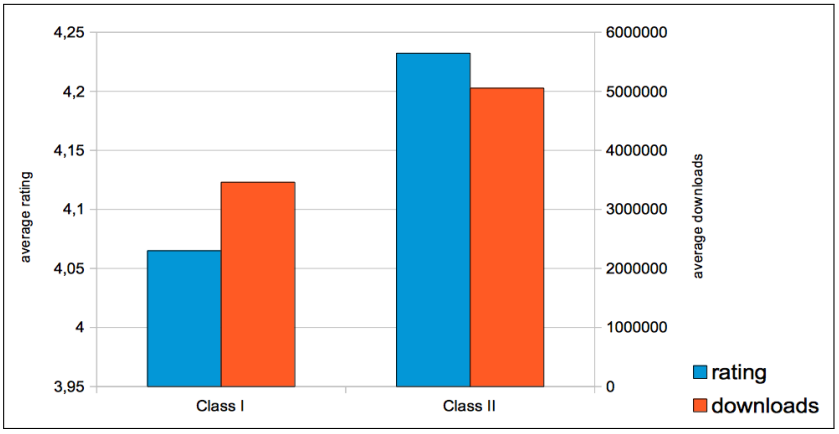

Figure 2: Average ratings and downloads for Class I and Class II apps.

This kind of issue might have driven FDA in his decision of relaxing attention on some app categories that by definition are medical devices but presumably pose low risks [15]. For these apps, FDA will in fact exercise enforcement discretion, that is, no real regulation. Examples include apps that help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions; Provide patients with simple tools to organize and track their health information; diet and physical activity trackers/helpers, etc. On the other side, FDA will regulate apps that transform a mobile device into something equivalent to traditional medical devices, like drug dosage calculators and planners.

While the above mentioned relaxed approach sounds appropriate, the absumption of low risk is however a crucial point. To transform it to some more operational criterium for identifying whether an app can be hazardous or not, maybe a framework for applications risk assessment like the one suggested by Lewis and Wyatt [15] can be useful to formally characterize the possible risks connected to app categories. This might in turn provide a more evidence-based approach to medical app safety, similarly to what occurs for medicines.

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Application Resilience and Antifragility from the Internet of Medical Devices to Healthcare Governance Systems

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Abstract

For Healthcare, the potential benefits of applying "Internet of Medical Devices" (IoMD) to solve both the cost problem and to improve patient safety and outcomes are tremendous. The medical industry is quickly adopting mobile technology (mHealth) as a means of connecting lay users with medical professionals. Unfortunately, current apps can be quite fragile to unespected event, and unpredictable changes can be very disorienting at enterprise level. These major changes, usually discontinuities referred to as fractures in the environment rather than trends, will largely determine the long-term future of organization. They need to be handled, as opportunities, as positively as possible. We need more robust, resilient and antifragile application to be ready for next generation systems. They are mandatory to develop antifragile self-organizing and self-regulating system further. Health Information community can take advantage of a new HICT Natural Framework proposal, to get a more reliable conceptualized synthetic and powerful systemic vision, to be used in advanced modeling for healthcare application and organization (HO) and high reliability organization (HRO) in general. Two application examples are presented. HICT Natural Framework can be used to develop competitive applications, from telemedicine apps, antifragile anticipatory learning system (ALS), health information management system, to health governances policies for advanced HO, new competitive HRO "environmental friendly" information management strategies conveniently, and beyond. The present paper can give a relevant contribute to that perspective and to let you achieve pactical, operative results quite quickly.

Keywords

Medical Apps, Health Information Systems, Health Care Quality, Antifragile Systems, Anticipatory Learning Systems, Health Governance

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EJBI 2015; 11(3):en28–en36
received: June 10, 2014
accepted: December 22, 2014
published: April 20, 2015

1 Introduction

Digital medical devices, wellness and wellbeing apps are rapidly improving, but connected care via health services in the cloud will be the next really important milestone.[1] All network-connected devices that record health data from humans make up the "Internet of Medical Devices" (IoMD). The advent of mobile technology has redefined how modern consumers read the news, communicate with others and entertain themselves on the go. The medical industry is quickly adopting mobile technology (mHealth) as a means of connecting lay users with medical professionals. In 2013, the global mHealth marketplace already represented a staggering $1.3 billion annual economic impact, and analysts are confident that this trend will continue upwards. Consumers have increasingly shown a willingness to adopt mHealth applications as a part of managing their health. Whereas years ago patients needed to make a doctors appointment for a proper diagnosis, the Internet has placed a world of information at patients fingertips. Furthermore, many medical organizations have begun to recognize the value in providing high-quality care, even if it means serving a smaller group of people. Using mHealth platforms to deliver such services is a natural transition. In most ways the invasion of technology in Healthcare is no different than how mobile digital capability is changing that way we all live.[2] For Healthcare though, the potential benefits of apply-

ing these technologies to solve both the cost problem and to improve patient safety and outcomes are tremendous. Personal health devices will change how we deal with our health in just as significant of ways. We are just at the start of this health device movement. Over time more and more important information regarding our health issues will be instantly communicated as needed to the concerned consumers, to the health care professionals, and will automate important health care in many ways (early detection, medication, etc.). Most current applications are designed to function in an ideal network environment, but that's never the case in the real world. Quite often, applications have to face unexpected perturbation, from network behavior and configuration to user problematic interface, etc., and to address the errors that inevitably surface, if they are programmed for. Unfortunately, current human made application and system can be quite fragile to unexpected perturbation because statistics can fool you, unfortunately.[3] We need resilient and antifragile application to be ready for next generation system. Can we achieve application resilience and antifragility at system level conveniently? They are mandatory to develop antifragile self-organizing and self-regulating system further. While the amount of data doubles every 1.2 years, the processing power doubles every 1.8 years. Unfortunately, the complexity of networked systems is growing even faster. In other words, attempts to optimize systems with the usual top-down approach will be less and less effective, and cannot be done in real time. Paradoxically, as economic diversification and cultural evolution progress, a big government approach would increasingly fail to lead to good decisions.[4] The logical answer is to use distributed (self-)control, i.e. bottom-up self-regulating systems. Cybernetics (i.e. advanced control theory) and complexity theory tell us that it is actually feasible to create resilient social and economic order by means of self-organization, self-regulation, and self-governance.[5, 6] If we want to to achieve self-organization, self-regulation in a competitive arbitrary-scalable system reference framework, we need application resilience and antifragility at system level first. The present paper can give a relevant contribute to that perspective and to achieve practical operative results quite quickly.

2 Objectives

This paper offers theoretical and operative answers to previous question. We revised scientific literature extensively, to look for already available effective solutions. Unfortunately there was none able to fulfill our system requirements, so we have to propose a new reliable approach (see section 4 Results, and section 5 HICT Natural Framework proposal). First of all, we need to have a good understanding about the root of the problem: ontological uncertainty. Second, we need to learn why contemporary applications can be quite fragile to unexpected perturbation, if managed by classic probability risk management technique and tool only.

3 Methods

First, we document how, even across so many different scientific disciplines, "Scientists 1.0" have not yet worked out a definitive solution to the fundamental problem of the logical relationship between human experience and knowledge extraction. Then, we analyze uncertainty sources according to two main reference knowledge areas: a) natural uncertainty and b) epistemic uncertainty, to arrive to a systemic solution: ontological uncertainty management at system level. Third, based on previous knowledge, we formulate a simple four-level reliability hierarchy scale for system properties (from most to less vulnerable) to grade system ability to face uncertainty and unexpected perturbation. Fourth, recently discovered (Computational Information Conservation Theory) CICT rational number system **Q** numeric properties are applied to previous system property hierarchy scale to build resilience and antifragility at system level, to arrive to a convenient arbitrary-scale HICT Natural Framework proposal. Two examples are presented.

3.1 The Root of the Problem

At system level, the classical instrumentation noise discrimination problem is still faced by the single domain channel transfer function concept (Shannons noisy channel, 1941), starting from classic Shannons information theory concept,[8] and then applying traditional perturbation computational model under either additive or multiplicative perturbation hypothesis.[9] In general, H(x), called "Shannon entropy," is the average unpredictability in a random variable, which is equivalent to its information content. The interested reader in digging deeper details into mathematical theory of entropy and information theory, inference, and learning algorithms, is referred to [10] and [11] respectively. As a matter of fact, biologists measure information in different ways. Neurobiologists and researchers in bioinformatics often measure information using information-theoretic measures such as Shannons entropy or algorithmic compression on mutual information. Behavioral biologists and evolutionary ecologists more commonly use decision-theoretic measures, such the value of information, which assess the worth of information to a decision maker. It can be shown that these two kinds of measures are intimately related in the context of biological evolution research areas.[12] In communication theory, the transmission of information is the reduction of uncertainty about what signals will come through a channel. In thermodynamics, a decrease in entropy refers to the fold reduction in the number of states that a system can be in. In evolutionary biology, the fitness value of a cue about an uncertain environment refers to the fold increase in the number of surviving lineages made

possible by responding to the cue.[13] In 2004, University of Michigan physicist Mark Newman, along with biologist Michael Lachmann and computer scientist Cristopher Moore, has extended the pioneering 1940s research of Claude Shannon to electromagnetic transmission. Specifically, they show that if electromagnetic radiation is used as a transmission medium, the most information-efficient format for a given message is indistinguishable from blackbody radiation.[14] In other words, since many natural processes maximize the Gibbs-Boltzmann entropy, they should give rise to spectra indistinguishable from optimally efficient transmission. Furthermore, in 2008, Calude and Svozil proved that "Quantum Randomness" (QR) is not Turing computable.[15] In 2013, at Politecnico di Milano, academic scientist Fiorini confirmed Newman, Lachmann and Moore's result, creating analogous example in pattern recognition and image analysis, by CICT [17], putting even more into evidence the fundamental information double-bind (IDB) problem at the core of contemporary classic information theory and current instrumentation systems. Unfortunately, even across so many different disciplines, scientists have not yet worked out a definitive solution to the fundamental problem of the logical relationship between human experience and knowledge extraction.

3.2 Ontological Uncertainty Modeling and Management

In the past five decades, trend in Systems Theory has slowly shifted from "General System Theory," introduced by Ludwig von Bertalanffy and classic single domain information Shannon's channel transfer function approach to the more structured ODR Functional Subdomain Transfer Function Approach (by Observation, Description and Representation Functional Block; see Figure 1).[18] Shortly, the ODR approach allows for fitting theoretical system modeling and design consideration to practical implementation needs much better (according to information "Input, Processing, Output" paradigm, respectively), than classic single block domain channel approach. Nevertheless, if careful information conservation countermeasure is not provided at each step, from source to destination, ODR transmission channel could suffer from the same problem, discussed earlier.

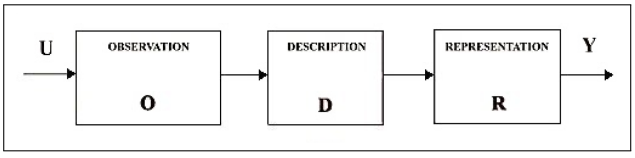


Figure 1: Decomposition of classic Single Domain Channel Transfer Function into more structured ODR Functional Subdomain Transfer Function Approach (Observation, Description and Representation Functional Blocks)[18].

Two basic areas of uncertainty that are fundamentally different from each other were recognized as traditional reference knowledge: natural and epistemic uncertainty. Intrinsic randomness of a phenomenon (e.g. throwing a dice) or natural uncertainty cannot be reduced by the collection of additional data and it stems from variability of the underlying stochastic process. On the other hand, epistemic uncertainty results from incomplete knowledge (or lack of information) about the process under study. Unlike natural uncertainty, epistemic uncertainty can be reduced by the collection of additional data. Statistical and applied probabilistic theory is the core of traditional scientific knowledge; it is the logic of "Science 1.0"; it is the traditional instrument of risk-taking.

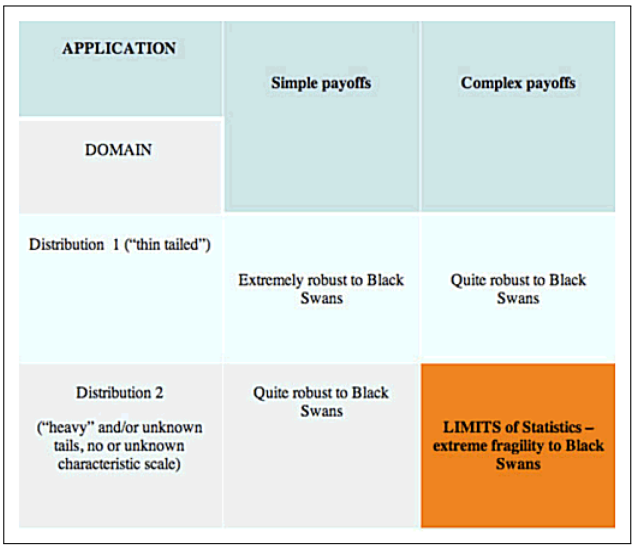


Figure 2: The fourth quadrant. The South-East area (in orange) is where Statistics and models fail us [19].

In turn, epistemic uncertainty sources can be reconducted to three main core conceptual areas: a) Entropy Generation (Clausius-Boltzmann), b) Heisenberg Uncertainty Principle and c) Gdel Incompleteness Theorems. A further detailed description of epistemic uncertainty core conceptual areas far exceeds the size of present paper and the interested reader is referred to the extensive bibliography available elsewhere. Usually, epistemic uncertainty sources are treated with the traditional approach of risk analysis, but deep epistemic limitations reside in some parts of the areas covered in decision making. These limitations are twofold: philosophical (mathematical) and empirical (human known epistemic biases). We can talk about system knowledge uncertainty by referring to "Application" and to "Domain", according to the four-quadrant scheme of Figure 2.[19] Decision theory, based on a "fixed universe" or a model of possible outcomes, ignores and minimizes the effect of events that are "outside model" or unexpected perturbations. A fixed model considers the "known unknowns" (North-East-quadrant), but ignores the "unknown unknowns" (South-East-quadrant).[20, 21, 22] The idea of known and unknown unknowns recognizes that the information those in positions of responsibility in government, as well as in other human endeavors, have at their disposal is almost always incomplete. The best strategists try to imagine and consider the possible, even if it seems unlikely. They

are then more likely to be prepared and agile enough to adjust course if and when new and surprising information requires it, when things that were previously unknown become known.[22] So, we have even to think about uncertainty in the characterisation of uncertainty by counterfactual thinking.[23]

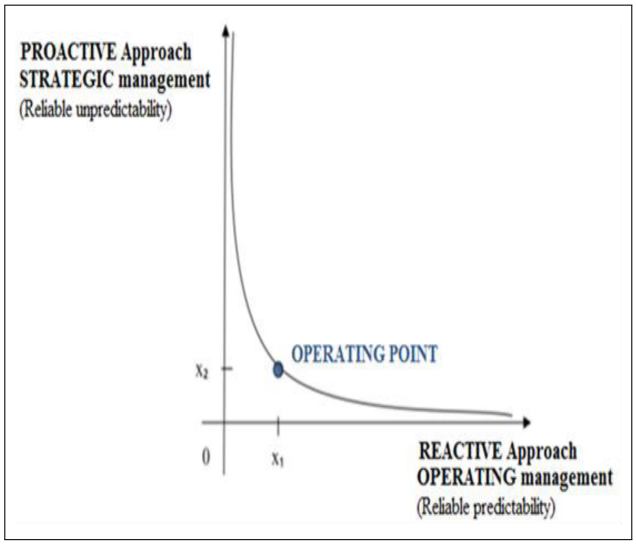


Figure 3: Operating Point can emerge as a new Transdisciplinary Reality Level, based on Two Complementary Irreducible Management Subsystems [26].

In the fourth quadrant of Figure 2, knowledge is both uncertain and consequences are large, requiring more system robustness and resilience.[19] In fact, can we understand health without considering wild diseases and epidemics? Indeed the normal is often irrelevant. Almost everything in social life is produced by rare but consequential shocks and jumps. The traditional bell curve ignores large deviations, cannot handle them, yet makes us confident that we have tamed uncertainty. Uncertainties are characterized as epistemic, if the model developer sees a possibility to reduce them by gathering more data or by refining models. Uncertainties are categorized as aleatory if the modeler does not foresee the possibility of reducing them. From a pragmatic standpoint, it is useful to categorize the uncertainties within a model, since it then becomes clear as to which uncertainties have the potential of being reduced. But, more generally, decision theory, based on a "fixed universe" or a model of possible outcomes, ignores and minimizes the effect of events that are "outside model". While the advantage of differentiating between natural (aleatoric) and epistemic uncertainty in analysis is clear, the necessity of distinguishing between them is not, by an operative point of view. As a matter of fact, epistemic and aleatory uncertainties are fixed neither in space nor in time. What is aleatory uncertainty in one model can be epistemic uncertainty in another model, at least in part. And what appears to be aleatory uncertainty at the present time may be cast, at least in part, into epistemic uncertainty at a later date.[24] It is much better to consider ontological uncertainty [25] as an emergent phenomenon out of a complex system.[26] Then, our ontological perspective can be thought only as an emergent, natural operating point out of, at least, a dichotomy of two coupled irreducible complementary ideal asymptotic concepts: a) reliable predictability and b) reliable unpredictability (Figure 3).

4 Results

Based on previous knowledge, we formulate a simple four-level reliability hierarchy scale for system properties (from most to less vulnerable) to grade system ability to face uncertainty and unexpected perturbation (4.1 A Four-Level Reliability Hierarchy Scale). Then, recently discovered CICT rational number system **Q** numeric properties are applied to previous system property hierarchy scale to provide examples of resilient and antifragile system at different systemic operative levels (4.2 Two Application Examples, and section 5 HICT Natural Framework proposal).

4.1 A Four-Level Reliability Hierarchy Scale

In agreement to Taleb [7], our main idea is not to attempt to predict black swan events, but to build robustness against negative ones that occur and be able to exploit positive ones. We can conceive a simple four-level reliability hierarchy scale for system properties (from most to less vulnerable), to describe system capability to face uncertainty and unexpected perturbation: a) Robustness, b) Resilience, c) Antifragility and d) Hippocraticity.

a) Robusteness: statistical and applied probabilistic theory is the core of traditional scientific knowledge; it is the logic of "Science 1.0"; it is the traditional instrument of risk-taking. It provides an acceptable cost/benefit ratio to manufacturer, but in some cases it may not represent an optimal solution to end user/customer/consumer.

b) Resilience: For living matter, in 1888, hormesis was first described (though still not given a name) by a German toxicologist, Hugo Paul Friedrich Schulz (1853-1932), who observed that small doses of poison stimulate the growth of yeast while larger doses cause harm.[27] A human body can benefit from stressors (to get stronger), but only to a point (Wolff's Law, 1892).[28] Newly engineered composite material of carbon nanotubes arranged in a certain manner can produces a self-strengthening response previously unseen in synthetic materials, "similar to the localized self-strengthening that occurs in biological structures."[29]

c) Antifragility: even better. The notion of antifragility, an attribute of systems that makes them thrive under variable conditions, has been proposed by Nassim Taleb in a business context first.[7] Antifragility is a decelerating sensitivity to a harmful stressor, producing a convex system response that leads to more benefit than arm. We do not need to know the history and statistics of the system to measure its antifragility, or to be able to predict black swan events.[7]

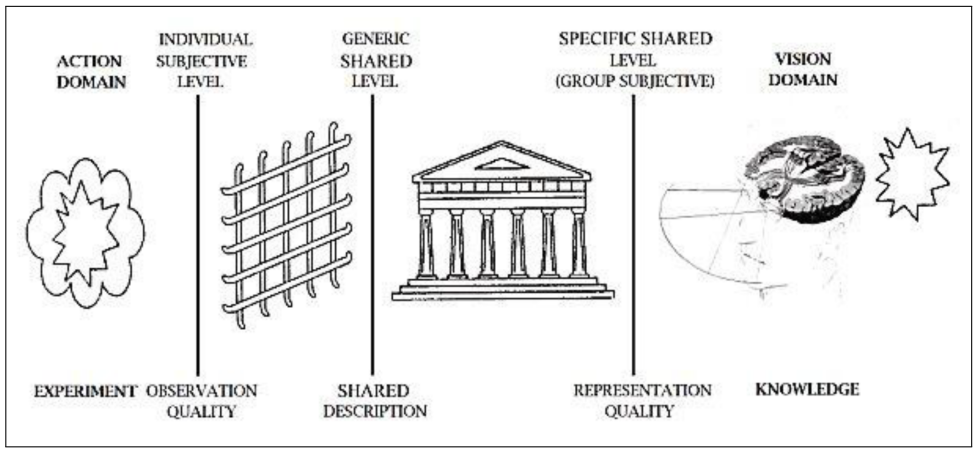


Figure 4: ODR Co-domain Diagram for HO and HRO [17].

d) Hippocraticity: it is even a stronger concept for a natural resilient and antifragile system, which can emerge from a self-balancing complex system to its environment, when human being health conservation is mandatory (intrinsic safety and security system). Canadian ecologist Crawford Stanley (Buzz) Holling (1930-) focused on natural living organism antifragility, including resilience, adaptive management, the adaptive cycle, and panarchy. Panarchy is a conceptual term first coined by Paul Emile de Puydt (18101891) in 1860.[30] Here, "Panarchy" refers to the framework for conceptualizing the type of coupled human-environment systems described in Gunderson & Holling [31] and more briefly, with some changes, in Walker et al.,[32] and Gotts.[33]

4.2 Two Application Examples

Classical experimental observation process, even in highly ideal operative controlled condition, like the one achieved in contemporary most sophisticated and advanced experimental laboratories like CERN,[34] can capture just a small fraction only of overall ideally available information, from unique experiment. The remaining part is lost and inevitably dispersed through environment into something we call "background noise" or "random noise" usually. That is even more true at clinical level, specifically. Our first example, to get more resilient system, can use CICT rational number system **Q** numerical properties, to get closer to real computational information conservation by a top-down point-of-view. So, ODR Functional Sub-domain Transfer Function block diagram (Figure 1) must be coupled to a corresponding irreducible complementary "ODR Information Channel Co-domain Diagram" to get reliable strategic overall information functional closure (Figure 4).[17]

We use an arbitrary-scalable system top-down approach, i.e. from overall system to system components, an so on, arriving to single block, single digit computational information conservation. In this case, we start with Natural numbers as generators, and their geometric powers, to compute their coherent functional closures, by using decimal system operative representation ($r = 10$), with no loss of generality. To get a coherent functional closure our rule is simple. One digit word number to the second power gives two digit number word, to the third power gives a three digit number word, to the fourth power gives four digit number word, and so on. Leading zeroes do count, so you have to fill in all word digits. We start with Natural number $D = 3$ as a generator, and $W = 1$, where W is the word representation precision length of number D and k its power exponent. We have:

$$
\begin{array}{ll}
3^1 = 3 & 10^1 - 3^1 = \bar{D}.(1)_1 = 7 \\
3^2 = 09 & 10^2 - 3^2 = \bar{D}.(13)_2 = 91 \\
3^3 = 027 & 10^3 - 3^3 = \bar{D}.(139)_3 = 973 \\
\cdots & \cdots \\
3^k & 10^k - 3^k = \bar{D}.(3^0.10^{k-1} + 3^1.10^{k-2} + \\
 & \cdots + 3^{k-2}.10^1 + 3^{k-1}.10^0)_k \equiv PC
\end{array}
$$

where $\bar{D}$ is the additive 10^W complement of D, i.e. $\bar{D} = (10^W - D)$. On the left column we have the powers of 3 and on the right side their corresponding coherent functional closures. It is simple to see that for k going to infinity even the asymptotic expression in round bracket $(\cdots)_k \equiv PC$ from eqs.(1) becomes an infinite polynomial and therefore an incomputable expression. Nevertheless it has quite a definite and unique evolutive polynomial structure, easily to be computed exactly to any arbitrary precision by CICT.[17] As a matter of fact, CICT rational number system **Q** numeric properties allow to generate an irreducible co-domain for every computational operative domain used. Then, all computational information usually lost by using classic information approach, based on the traditional noise-affected data stochastic model only, can be captured and fully recovered to arbitrary precision by a corresponding complementary co-domain, step-by-step, to obtain a Resilient ODR system (RODR, for short), according to CICT Infocentric Worldview.[17] Applying this line of thought, you can develop more reliable, resilient med apps. A further detailed description of the diagram of Figure 4 far exceeds the size of present paper and the interested reader is referred elsewhere.[17, 18]

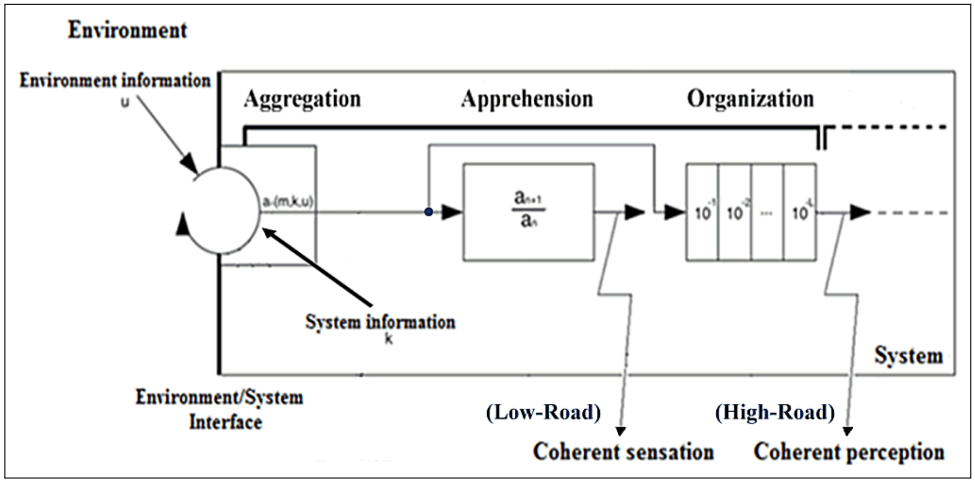


Figure 5: System internal control status(k) and system external input (u) are aggregated coherently by recursive sequence of order (m) to generate self-organizing attractor point information (Apprehension, coherent sensation) and self-structuring polynomial weighted information (Organization, coherent perception) [26].

This computational approach can be quite mandatory and convenient specifically for advanced Health Organization (HO) applications and High Reliability Organization (HRO) in general. Our second example is an antifragile, self-organizing and self-regulating anticipatory learning system (ALS) model from neuroscience, developed from a bottom-up point-of-view. Recent Neuroscience and neuropsychology achievements support both Emotional Intelligence (EI) and Emotional Creativity (EC) as multiscalable properties of living organism, from proteins to cell, from cell to organ, from organ to organism.[35] In human Eulogic Thought (ET), EI and EC coexist at the same time with Rational Thinking (RT), sharing the same input environment information. At brain level, it is possible to refer to "LeDoux circuit" (Logical Aperture) for emotional behavior (i.e. fight-fly) and to "Papez circuit" (Logical Closure) for structured behavior (i.e knowledge extraction and organization).[36] ET uses both Logical Aperture (to get EI and EC, to survive and grow) and Logical Closure (to get RT, to learn and prosper), both fed by environmental "noise" at the same time. We get an intelligently articulated operative asymptotic dichotomy, which we can use to model human learning behavior at systemic level efficiently and realistically. EI and EC have to coexist at the same time with RT, and at the same time, to share the same environmental input, even if they show an apparently uncorrelated behaviour.[37] We can use this operative asymptotic dichotomy to model efficiently and realistically system behavior, to get different consistent reality levels and worldviews (operating point in Figure 3).[38] Our main idea is binding unknown information to the known one recursively. Then, unknown "environmental noise" or/and "external signal input" information (u) can be aggregated to known "system internal control status" information (k), by the recurrence relation of order m, to provide structured synthetic attractor points. In this way system can search automatically for a minimum environmental perturbation level (system internal status) useful to insure sequence asymptotically convergence to get vital information from system environment (self-regulation and learning as quest for the difference that makes the difference, probing by probing...). Irrational numeric limit attractor points, identified by converging recursive numeric sequences allow the self-organizing and self-structuring of a mathematical Baires Space as attractor point families landscape, to manage numeric information usefully, to synthetise quick and raw system primary response "to survive and grow" (Apprehension, Open Logic Section, see Figure 5).[26] Homeostatic operating equilibria can emerge out of a self-organizing landscape of self-structuring attractor points with their own "World Cloud." Recursive sequence represents a mathematical method that holds anticipatory properties because it is possible to implement the anticipatory computation of any recursive sequences term.

To synthetise more organized and articulated, but slower, system response "to learn and prosper", it is necessary to structure recursive information into an "ordered polynomial reference framework", by "polynomial weighing" mapping, to obtain a "coherent perception" (Organization, Closed Logic Section, see Figure 5).[26] So, we get a sequence of different structuring operations to get external information more and more coherent to system internal status to arrive to a system "coherent perception" representation of external information. In this way, a natural balanced "Operating Point" can emerge, as a new Transdisciplinary Reality Level, from an irreducible complementary ideal asymptotic dichotomy: Two Coupled Complementary Irreducible Information Management Subsystems. Due to its intrinsic self-scaling properties, this system approach can be applied at any system scale: from single medical application development to full healthcare system governance strategic simulation and assessment application.[26] This approach allows you to develop more antifragile anticipatory learning system (ALS), for more reliable, safe and secure med app and system.

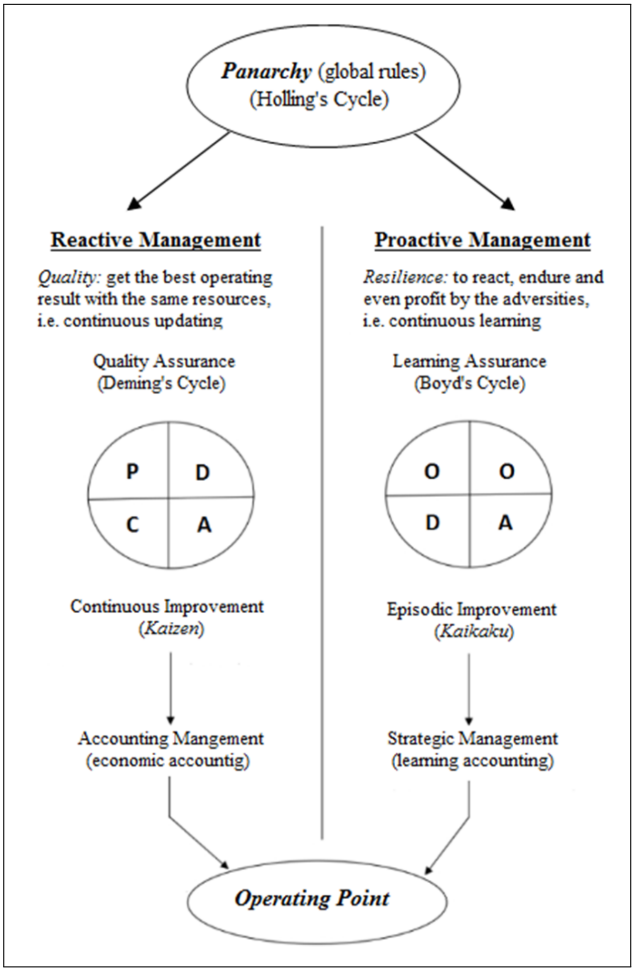


Figure 6: Our Final Architecture for HICT Natural Framework for Safety and Effectiveness Health Systemic Governance.

5 HICT Natural Framework proposal

Following this line of thought, at a higher level of abstraction, it is possible to conceive a general Health Information Conservation Theory (HICT) Natural Framework to develop advanced antifragile and hippocratic systems (see Figure 6). Again, environmental noise and input information are aggregated to system internal status information to provide a structured homeostatic synthetic operating point. Then, System Interaction by internal and external information aggregation can allow both quick and raw response (Proactive Management, to grow and survive) and slow and accurate information for future response strategic organization (Reactive Management, to learn and prosper) by coherently formatted operating point information. So, we can envisage again two coupled irreducible management subsystems, based on the ideal coupled asymptotic dichotomy presented in Figure 3: Reliable Predictability and Reliable Unpredictability Management Sub-System. In this way, to behave realistically, overall system must guarantee both Logical Closure (Reactive Management, to learn and prosper) and Logical Aperture (Proactive Management, to grow and survive), both fed by environmental "noise" (better from what human beings call "noise"), according to Holling's framework.[31]

Again, an operating point can emerge as a new Transdisciplinary Reality Level, based on Two Complementary Irreducible Management Subsystems (Figure 3). As an operative example, for Reactive Management system, we can choose from different documented operational alternatives offered by literature, like Deming's PDCA Cycle,[39] Discovery-Driven Planning,[40] etc., while for Proactive Management system, we can choose from Boyd OODA Cycle (1987),[41] Theory-Focused Planning,[42] etc. For present paper, as simple example, PDCAs cycle (Reactive Management) and OODAs cycle (Proactive Management) can be selected to represent two corresponding complementary irreducible sub-systems for advanced integrated strategic management. Then, our final operative reference architecture, for HICT Natural Framework for Safety and Effectiveness Health Systemic Governance, is given as from Figure 6. Cybernetics (i.e. advanced control theory) and complexity theory tell us that it is actually feasible to create resilient and antifragile social and economic order by means of self-organization, self-regulation, and self-governance. The work of Nobel prize winner Elinor Ostrom and others has demonstrated this.[5, 6] By "guided self-organization" we can let things happen in a way that produces desirable outcomes in a flexible and efficient way. One should imagine this approach embedded in the framework of today's institutions and stakeholders which, however, will learn to interfere in minimally invasive ways.

6 Conclusions

First, we documented how, even across so many different scientific disciplines, "Scientists 1.0" have not yet worked out a definitive solution to the fundamental problem of the logical relationship between human experience and knowledge extraction. Then, we analyzed uncertainty sources according to two main reference knowledge areas to arrive to a convenient problem solution: ontological uncertainty management at system level. Based on previous knowledge, we formulated a simple four-level reliability hierarchy scale for system properties (from most to less vulnerable) to grade system ability to face uncertainty and unexpected perturbation. Recently discovered (Computational Information Conservation Theory) CICT rational number system $\mathbf{Q}$ numeric properties were applied to previous system property hierarchy scale to to arrive to our new HICT Natural Framework proposal. The major added value of our approach is provided by our new idea of low-level system interaction, defined as internal and external information aggregation by system recursive sequencing. It can allow both quick and raw system response (Proactive Management, to grow and survive) and slow and accurate information unfolding for future response strategic organization (Reactive Management,

to learn and prosper) by coherently formatted operating point.[26] Now, it is possible, at systemic level, even to envisage a post-Bertalanffy Systemics Framework able to deal with problems of different complexity, in a generalised way when inter-disciplinarity consists, for instance, of a disciplinary reformulation of problems, like from biological to chemical, from clinical research to healthcare, etc., and trans-disciplinarity is related to the study of such reformulations and their properties. For the first time, Biomedical Engineering ideal system categorization levels can be matched exactly to practical system modeling interaction styles, with no paradigmatic operational ambiguity and information loss, as shown in Figure 7 (specifically, our innovative system interaction modality, called "Recursive Interactor", corresponds to the fourth order of biomedical cybernetics). Now, new health information application can successfully and reliably manage a higher system complexity than current ones, with a minimum of design constraints specification and of system final operative environment knowledge at design level, at any system scale. Health Information community can take advantage of a new HICT Natural Framework proposal, to get a more reliable conceptualized synthetic and powerful systemic vision, to be used in advanced modeling for healthcare application and organization (HO) and high reliability organization (HRO) in general. The present paper gives a relevant contribute to that perspective and to let you achieve pactical, operative results quite quickly. So far, according to our HICT Natural Framework, no country in the world seems to be well prepared for the "digital health" era yet. Therefore, we urgently need an U.S. Apollo-like program, and the equivalent of a Space Agency for HICT: an Health Innovation Alliance with the mission to develop the institution and information infrastructures for the emerging digital health society. This is crucial to master the challenges of the 21st century in a smart way and to unleash the full potential of health information for our euro-society.

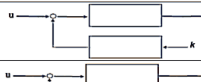
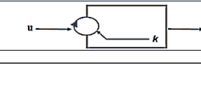
BIOMEDICAL CYBERNETIC ORDER	INTERACTION STYLE	GRAPHIC SYMBOL
Zero	Pure Spectator	
First	Ergodic Observer	
Second	Pulsed Egocentric Interactor	
Third	Iterated Egocentric Interactor	
Fourth	Recursive Interactor	

Figure 7: Our final post-Bertalanffy Systemics Healthcare Framework Proposal.

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eHealth for Hearing – New Views and Apps Practicalities

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Abstract

Background: We are observing a silent and disrupting revolution in the hearing health care practice due to the pervasive use of eHealth methods and technologies, in particular mobile apps. This situation is very new, e.g., in the novel interactions and relationship between actors, in the implicit knowledge relevant to actors, and in the acquisition and comprehension of health messages and fragmented, e.g., in knowledge, standardization, regulation, and in methods for quality evaluation, so here we propose a new paradigm.
Objectives: We want to contribute to the definition of the boundaries and rules of the new 'eHealth4Hearing' paradigm.
Methods: Starting from the needs perceived by people with hearing disabilities, we formulated a new 'eHealth4Hearing' paradigm and gave practical examples on its application.
Results: The 'eHealth4Hearing' paradigm is delivering a new patient-centered model where people have (1) tools for at-home checking of hearing status to monitor or to detect early hearing disabilities; (2) tools to acquire meaningful, accurate and personalized information on how their hearing condition may affect their lives and to simulate how different rehabilitation solutions will work for them; (3) tools for self fitting/control of hearing systems; (4) personalized solutions for sound enhancement through smartphones for people that do not require traditional hearing aids; (5) at-home interactive rehabilitation programs adapting to their speech and communication skills.
Conclusions: Researches have to be devoted to further boost the potential of 'eHealth4Hearing' and must address issues concerning safety, privacy, legal regulations, reliability and quality of the apps.

Keywords

eHealth, hearing health care service, paradigm shift, mHealth, patient-centered delivery model

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EJBI 2015; 11(3):en37–en49
received: October 31, 2014
accepted: March 4, 2015
published: April 20, 2015

1 Introduction

The word "e-Health" portrays various meanings to its readers from the general public, to the professionals, probably up to every of its stakeholders; among them are a high speed of communication, joined with a potentially high selectivity of the specifically delivered message, and the release of the former and rigid separation of some sensory channels (typically the visual and the auditory ones).

"Hearing" is a clinical domain where the interactions between the patient and their caregivers frequently are unsatisfactory on both sides, often just because of the people's ignorance of hearing basics. Additional elements of unsatisfaction are the subject's usually late understanding of their hearing status, the absence of easily accessible, reliable, and self-administrable hearing tests, and the ignorance of the growing time and efforts and difficulties requested by any rehabilitating hearing action even if it includes the adoption of costly hearing aids (HAs) when undertaken late in respect to the hearing loss process. Unsatisfaction occurs even if such hearing loss is perceived to be limited to specific and avoidable environments, such as listening to superimposed discussions at a meeting, watching television, answering the phone, etc. The patient must not simply decide to avoid these specific situations, as this decision may well be the beginning of a serious increases of their hearing loss.

Can we describe the practical differences between the historically intended hearing care environment and the envisaged 'eHealth4Hearing' one? Could the 'eHealth4Hearing' environment help improve some of the several keywords-for-hope that emerged, such as patient-

centeredness, patient empowerment, patient-caregiver relations, and others?

This paper is meant to give an answer to:

1. what could be the envisaged new 'eHealth4Hearing' paradigm;
2. how the 'eHealth4Hearing' paradigm may help patient-centredness, patient empowerment, and patient-caregiver relationships; and
3. what the main differences are between the traditional health care practice and services for the hard of hearing and those delivered through the new 'eHealth4Hearing' paradigm.

We will give practical examples of the implementation of the 'eHealth4Hearing' paradigm by reviewing the best-practices in the services provided by the apps in the field of hearing care.

The paper is organized as follows: we will first describe in Section 2 the main causes of hearing disability, the target groups we focus on, their perceived needs and the traditional healthcare and rehabilitation paths. At the beginning of Section 3, we will describe the new 'eHealth4Hearing' paradigm and its structure, starting with some envisaged scenarios (the 'whishing cases'). In Section 3 we will also give some highlights on the current opinions of the target groups and hearing care professionals on the new perspectives brought forward by the ICT for health and on the new paradigm in particular. In Section 3.1 we will review some of the new 'eHealth4Hearing' care services in practice. We will focus on the apps as examples of the possible strategies that can be adopted to implement the new services that will address the needs of the target groups we considered. In that section, in particular, we will review what the current best practices in the apps of the hearing care field are and will comment on how they address the needs of the specific target group and how they help patient-centredness, patient empowerment, and patient-caregiver relations. Finally, in Section 4 we will draw the conclusions and illustrate the future directions.

For sake of clarity, Appendix 1 shows the main components, i.e., the target groups, perceived needs, health care and rehabilitation paths, and the new 'eHealth4Hearing'services, that have been considered in our study, summarizing a brief description of their main characteristics. The detailed descriptions are given in the following Sections.

2 What We Inherited about the Current Needs

Hearing impairment (HI) is one of the most frequent sensory impairments, which affects newborns, children, adults, and the elderly. As of 2012, about 10% of adults under 65 years and 36% of those older than 65 years in Europe had a disabling hearing loss (HL) [1]. HL can be due to different etiologies, ranging from congenital causes, ear infections, assumption of ototoxic drugs (such as in the case of people treated with chemotherapy drugs), to noise exposure (affecting 16% of the adult population worldwide [2]) and the aging of the auditory system. Depending on age, etiology and severity of the impairment, people require different clinical paths and different care solutions. For example, solutions for people with severe-to-profound HL include HAs, cochlear implants, assistive tools, and sign language: in this last case, it has been estimated that around 500,000 people across the EU use sign language as the first-choice communication mean [1].

The psychosocial effects of HI can come slowly, but they can undoubtedly come to be evident and dangerous, with a detrimental impact upon an individual's quality of life. Effects include loneliness, social isolation, exclusion, stigma and low self-esteem, denial, difficulties in particular environments, memory loss, prejudice and abuse, and employment difficulties. Family relationships, education, cognitive skills and intimate relationships may also be affected [3]. Most of the effects are direct consequences of the problems experienced in interacting with other people and the individual's environment and can reduce a person's physical, functional, emotional and social well-being [4]. There is also a significant comorbidity in older adults with HL, for example, balance disorders and tinnitus [5], higher probability for depression [6] and higher risk of dementia [7]. Unmanaged hearing problems are also associated with poorer self-management of longterm conditions [8].

2.1 The target groups

As illustrated in Appendix 1, we considered four "functional" target groups of people, consisting of subjects with a HL, as described above, and including also subjects with tinnitus and speech, language and communication diseases. The target groups were defined according to the types of services that are required to manage their disability and not to the type (or etiology) of their impairment. As a matter of fact, it may happen that the same service helps people with different types of impairment. The four "functional" target groups are:

1. people needing/wishing to perform self-hearing assessment/monitoring hearing functionality;
2. people needing amplification;
3. people needing hearing and communication rehabilitation;
4. people needing assistive tools, including those hard of hearing using sign language.

2.2 The perceived needs

Figure 1 summarizes the five groups of the most frequently observed needs perceived by the target groups

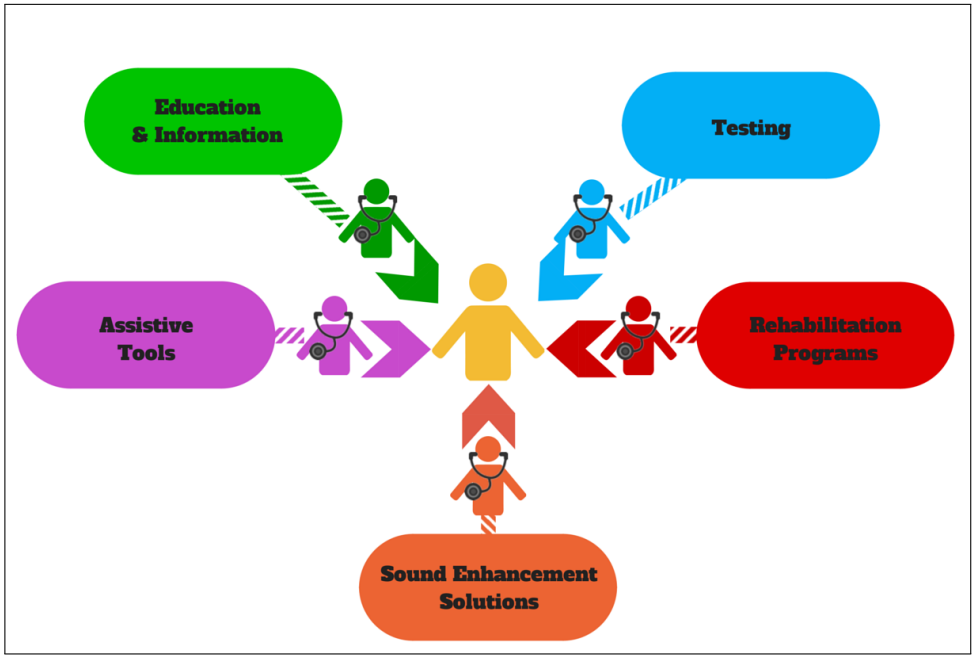

Figure 1: Traditional doctor-centric model. The needs perceived by people with hearing disabilities and the role of hearing care professionals: solutions to people's needs are conventionally delivered mostly through hearing care professionals.

considered so far (see also Appendix 1). Below is their description.

Education and Information Towards Empowered User Profiles

These are the needs perceived by all the four target groups described above (see also Appendix 1), since a better knowledge and education about their own or their relatives' hearing impairment could help the patients and their caregivers to be an active part of the process for the management of their health issues [9]. The most important needs are:

- Timely, accessible, meaningful, reliable and properly tuned information on hearing disorders and their impact on health, quality of life, communication skills and social inclusion (see, e.g. [9]).
- Accessible information on what options are available to treat hearing disability and which benefits each of these options can give to the specific hearing problem of the subject. For example, parents of hearing impaired children are required to make choices about the management of their child's hearing and therefore they need accessible information on outcomes, available technology for hearing amplification, communication options, education, and rehabilitation (see, e.g. [10]).

Sensitive Testing Towards Life-Long

These needs are important for the 1st target group and can be summarized as follows:

- Tools for measuring and monitoring hearing function and for detecting early hearing impairment to be used at home (see, e.g., [11]).

Sound Enhancement Solutions Towards Flexibility and Multi-sensorial Integrations

These are the needs perceived by 2nd target group:

- Straightforward and flexible tools to adjust and tailor in real time the listening settings of hearing systems, with limited intervention of a hearing care professional or technician or of cumbersome hardware (see, e.g., [12]). Availability of technological solutions for HA self-fitting or self-adjustment is one of the top five key factors that would increase the likelihood that an unaided patient will seek a HA [13].
- Quick, easy and cheap solutions for personal sound amplification other than traditional amplification solutions (e.g., HAs) (see, e.g. [14]).

Rehabilitation Programs Towards Best Fitting and Flexibility

These are the needs perceived by the 3rd target group:

- Easy and meaningful tools to perform home-based hearing rehabilitation that interactively adapt to the listening and communication skills of the subject [15]. The flexibility of scheduling, possibility to perform rehabilitation at home, and ease of rehabilitation procedure are factors that most influenced hearing rehabilitation outcomes in adults [16].

Assistive Tools

These are the needs important for the 4th target group:

- Easy, cheap, flexible and reliable solutions to assist hard of hearing and deaf people to live more independently by using telecommunication devices [17], reacting to sound in the environment [18], and learning and using sign language.

Patients and healthcare professionals believe that traditional care models are somewhat inadequate to satisfy their expectations and that digital technologies are the key-factors for creating new care models [19]. About 50% of healthcare professionals participating in the survey in [19] said that digital visits could substitute more than 10% of in-office patient visits; about 42% of them said that they are 'at least somewhat comfortable' relying on self-test results to prescribe medication; and nearly 30% were in favor to promote self-management of chronic disease and would be willing to prescribe health apps. Patients also expressed their willingness to communicate with their caregivers online [19]. Similar trends/opinions were collected in other surveys, regarding things such as people beliefs and preferences on digital health care [20], the biggest qualities and needs perceived by consumers of health apps [21], and surveys conducted among healthcare providers [22].

2.3 The traditional healthcare and rehabilitation paths

We are witnessing a radical change in the way hearing healthcare can be delivered, the most evident being the trend towards the so-called patient-centered care model [15, 23]. Individuals are now provided with novel services and tools that show great promise to enhance the benefit of their healthcare and rehabilitation paths. Conventionally, before the advent of mobile solutions, these paths relied heavily upon frequent face-to-face appointments, large use of clinical equipment (for assessment and rehabilitation), and ample utilization of paper-based material. Appendix 1 summarizes the main traditional healthcare and rehabilitation paths for each of the four target groups.

1. People who need hearing screening, assessment and monitoring typically need to search for the nearest or most reliable clinical center or HA provider and ask for a hearing test. Moreover, people who need to monitor their hearing functionality frequently (e.g., because they are exposed to ototoxic agents or noise) should go through regular, time-consuming checks. This sometimes creates barriers that prevent people from checking their hearing as frequently and as accurately as they should.

2. People requiring hearing systems typically need to go through periodic and time-consuming fitting sessions with their audiologist or HA provider to adjust their amplification settings. The time and effort needed to reach a satisfying amplification may lead many people to neglect these appointments and greatly limits the benefit of the hearing system they wear.

3. People requiring hearing and communication rehabilitation, or speech and language training, typically need very frequent rehabilitation appointments with their therapist or speech and language pathologist and not all people can stand such a long and difficult process. Moreover, when the patient is a young child, the required time and commitment of parents or relatives can be huge and sometimes families are not able to afford such an effort potentially hindering the communication and learning development of children.

4. Deaf and hard of hearing people, who might benefit from assistive tools, typically find it difficult to communicate over the phone, or to live independently. Conventionally, they are used to relying on speakers or headphones to watch TV or listen to the radio or talk on the telephone, and sometimes they have no solutions to deal with everyday sounds that they cannot hear. It is clear that the use of smartphone-based, integrated solutions can be a simple, and ubiquitous, way to provide these people with tools to assist their communication and daily living.

3 'eHealth4Hearing': the New paradigm in the Hearing Health Care Field

"New Paradigm" is an infrequent and engaging expression. However, we decided to use this term because it comes from our perception that the hearing scenario allowed by ICT for health is quite new and better. To identify the reasons of such a perception of relevant novelty, let us think about a few practical cases and how easily they might be implemented by ongoing technologies. Even if the final solutions might still require some years of development, and reasonably they will be implemented one at a time, it is clear how their implementation was obviously impossible before these technologies had become available.

Wishing Case 1 – Could a self-administrable hearing test with the purpose of alert generation to be delivered/taken at home frequently, be considered useful to oncologic patients enrolled in at-risk-of-hearing-losses therapies? We also realize that "self-administrable" is the gateway making "frequently" affordable, as needed by "alert generation" in the attempt to better protect the already suffering patient. A tailored design of the already-available eHealth infrastructure let us believe that this scenario can be real. The practical absence of additional working time for the hearing therapist is a key factor for

making the process accepted also by national healthcare systems which are notoriously sensitive to money saving. The 'Wishing Case 1' is an envisaged scenario related to the first target group, the one of people needing/wishing to perform self-hearing assessment/monitoring (see Appendix 1).

Wishing Case 2 – Could a wider variety of standardized hearing sources, to be added to the historically settled tonal and vocal procedures for taking audiograms, be embedded in the hearing tests, in such a way to refine and add sensitivity and specificity to what is generally intended as audiograms, up to the point of profiling tests useful to specific working environments? Also in this case the positive answer can be trivial. Body auscultation for medical diagnosis, musicians activities, logopedists treatments and other working profiles would obviously appreciate the availability of hearing tests using ad-hoc hearing source collections, that can be taken at a distance, on demand, autonomously, at an only-minimally ICT-infrastructured environment. This 'Wishing Case' illustrates another scenario associated to the target group 1 (see Appendix 1).

Wishing Case 3 – Could a suitably designed but merging of both the hearing and visual human senses deliver services so as to facilitate the complex and uncertain counseling of people who begin to use HAs? Exercises where a same text comes from both a loudspeaker and a video display and these two sensory-sensitive sources are integrated in a training strategy that is easily monitored quantitatively, and seem to be ready for implementation, again by entry-level ICT infrastructures, even by not-so-complex apps. This 'Wishing Case' exemplifies two scenarios: the one of people needing amplification (target group 2, Appendix 1, for issues related to HA counseling) and the other of people needing hearing and communication rehabilitation (target group 3, Appendix 1, for issues related to auditory training).

We might not need to add more cases for beginning to welcome a common framework we name it "paradigm" - where each case is just one of its instantiations. In doing so, we explicitly recognize the truth that, also in the field of hearing loss, a "previous" paradigm already exists, as already effectively visualized in Figure 1. It should be easy to agree on, as it grounds on the generic and implicit hearing knowledge of our times. But the fitting into Figure 1 of each of the wishing-but-at-hand cases described above remains unclear, and relies too much on hopes and imagination.

While putting into practice our attempt towards a better framework, we came to Figure 2, where the "e-Health bus" and what it allows is the grounding element of the "new" paradigm. "Bus" is to be intended as in the computer domain. Its behavior lets each of the connected actors and services to ask to use it, - temporarily, almost entirely and on demand, - for its own communication purposes, such as the message contents and the message addressees [24]. Something like "what to say to whom". Moreover the "bus" allows each communication action to occur in real time in respect to the reaction times of humans - and is permitted at a distance. Also the autonomous self-search of an actor at any data source is a communication action. As the "e-Health bus" is a default ICT infrastructure, the Figure 2 as a whole is true. Nevertheless its truth carries also some difficulties. Research groups who historically settled on only the "previous" paradigm might take time to re-tune themselves so as to dominate all the possible instantiations allowed by the "new" paradigm. For the purposes of this article, we believe we have given sufficient observations supporting the idea that we are in front of a "new paradigm", to which Figure 2 provides a useful visualization.

Through the eHealth Bus, each of the actors can share resources, data, information and services with all the other relevant actors and can have direct access to the available resources and services. This new path potentially leads to a dramatic change both in the roles within the actors and in the way in which patient needs are addressed and solved. Differently from the traditional doctor-centric model (see Figure 1) in which the access to health care services, resources and solutions occurs mostly through the hearing care professional, now in the new 'eHealth4Hearing' care paradigm, patients can have direct access to a wealth of solutions, health services and resources. The new 'eHealth4Hearing' paradigm is centered around the patient, who is encouraged (and sometimes even pushed by the available technology and the input from the society) to take control of her/his own health.

There are several examples that illustrate the positive attitude of hearing care professionals and patients towards eHealth in the hearing care field. For instance, some of the novel ways with which hearing care services are starting to be delivered include: remote auditory examinations [25], self-assessment of hearing sensitivity [26], self-fitting of HAs [27], remote mapping of cochlear implants [28], remote delivery of cognitive-behavioral therapy [29], and remote counselling [30]. A positive attitude towards the 'eHealth4Hearing' concept is seen also in HA manufacturers: some of them are developing systems that, through a web-based platform and an ad hoc interface plug, will help people to self-adjust the HA gain and settings to optimize the comprehension of speech in noise and give an help to HA troubleshooting [31]. All these examples give a clear picture that, although at its beginning, the hearing care model is changing from its traditional configuration, and that hearing care professionals, patients and manufacturers are becoming more and more aware of this change (and are somewhat leading the change).

3.1 The 'eHealth4Hearing' Paradigm in Practice

As a practical exemplification of the 'eHealth4Hearing' paradigm, we will focus on mobile health apps. The number of health apps has more than doubled in the past 2.5

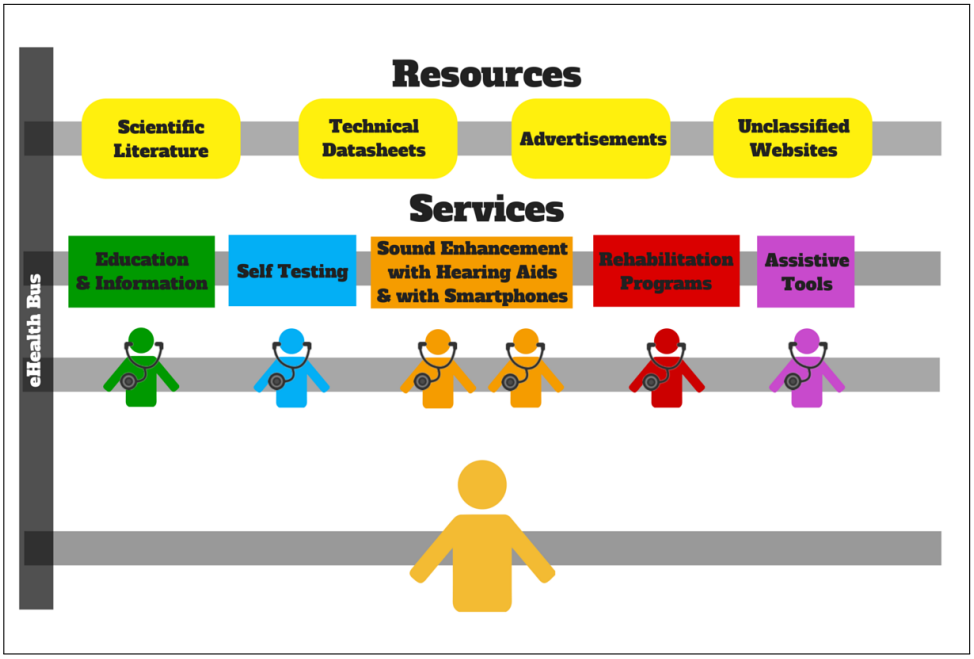

Figure 2: The new 'eHealth4Hearing' paradigm of health care practice: the application of ICT methods and technologies creates a new connecting path the 'eHealth Bus' among the different actors (hearing care professionals, providers, and patients), services, and the available resources. The eHealth Bus changes both the roles within the actors and the way in which patient needs are addressed and solved. The new 'eHealth4Hearing' paradigm is centered to the patient, who is encouraged (and sometimes even pushed by the available technology and the input from the society) to take control of her/his own health.

years, with more than 100,000 apps in Q1 2014 [32]. Current estimates [33] predict that by 2017, half of the 3.4 billion smartphone or tablet users worldwide will use mobile health apps. It is to be reminded, however, that the application of ICT in the hearing health care has been implemented also with web-information platforms on hearing matters, web services for the delivery of hearing tests, and tele-audiology services (see, e.g., [34])).

Apps in the field of hearing healthcare were searched for using the following keywords: hearing, audiology, audio, auditory, speech, language, tinnitus, hearing loss, HA, hearing system, cochlear implant, auditory training, hearing rehabilitation, assistive technology/tool/device.

Apps were pooled into five group of services, as illustrated in Figure 3, following the same classification schema used for describing the needs perceived by the target groups (Figure 2 and Appendix 1). Figure 3 also gives a short description of the main features of each group of services. Below is the description of each service, of its best practice implementation and the target groups that it addresses. Appendix 2 shows the number of apps we downloaded for each service and summarizes the relevant/innovative features of a number of apps that were selected as the representative ones.

Education and Information Services

These services address the needs perceived by all four target groups to easily retrieve specific educational material on hearing conditions (see, Appendix 2). Several apps in this group of services are a kind of 3D interactive and animated atlases describing the anatomical structures of the ear and use short educational videos; others explain main ear diseases, perform simulations allowing the users to playback pre-recorded common sounds or their own voice through different HL configurations; others explain in plain words the meaning of audiometric test results, and help in preventing hearing impairment by monitoring in real time the level of potentially harmful sounds. These apps contribute to enhance effective communication of health related information regardless of the level of health literacy and are likely to improve the engagement of people with their health concerns.

Self Testing

These services address the needs of the 2nd target group. They might assume particular relevance for older people and those with early signs of HL who may be reluctant to ask for an assessment by hearing care professionals. Self-testing (see Appendix 2) can be performed at home through smartphones or tablets with no requirement of particular settings (i.e., there is no need to perform the test in sound-proof booths). In most cases, tests require the use of general purpose headphones or earphones; otherwise, they require ad hoc headphones which can be purchased from the app developer. The test procedure is quick (usually it takes less than five minutes) and totally automated for what concerns both the delivery of the audio test signals and the storage and interpretation of test

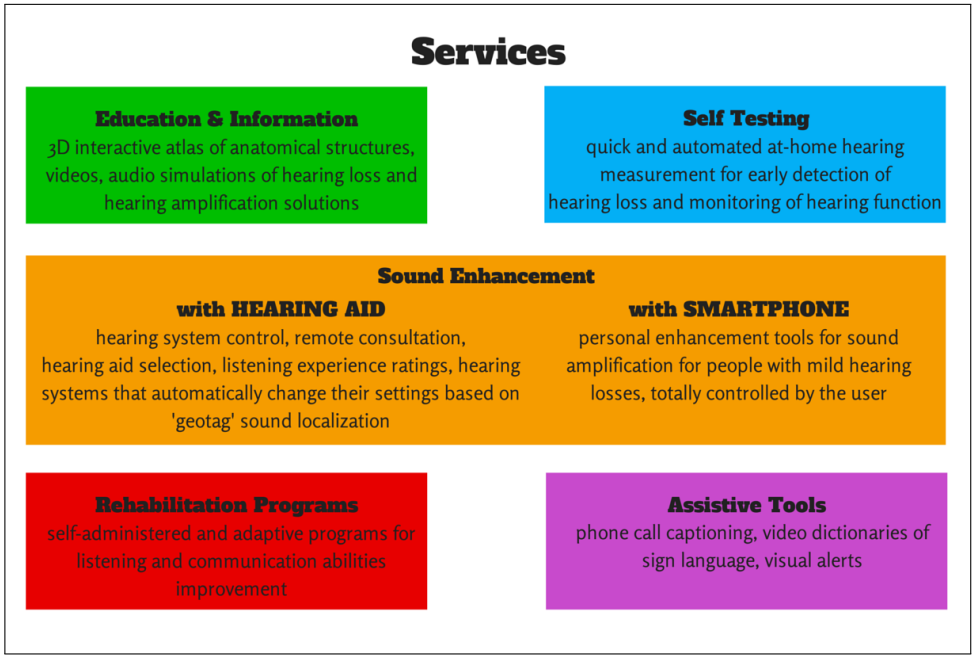

Figure 3: The new groups of services delivered in the 'eHealth4Hearing' paradigm through mobile apps.

outcomes. The tests score hearing functionality by measuring the audibility of pure tones or other audio signals, such as syllables or words embedded in noise. Some apps include also a way to measure the level of the background noise. Although there are still a lot of critical aspects that must be addressed, such as the reliability of the measures (due to, for example, the use of earphones of bad acoustic quality or that are not calibrated, or the administration of the test in rooms that are too noisy, etc.), these apps could promote early identification of hearing diseases (by making periodical hearing tests easy) and could also improve patient empowerment (by giving a clear and straightforward measure of HL).

Sound Enhancement Solutions

These services include sound enhancement solutions implemented with (i) smartphones and with (ii) HAs (see Appendix 2). Both solutions address the needs of the 2nd target group.

- Smartphone solutions. Apps in this group perform real time personalized amplification of voice and sounds by using the smartphone amplification and by delivering the amplified sound through the smartphone earphones. These apps are for subjects with mild HL that do not require classical HA amplification and are intended for occasional use, typically to enhance speech in noisy situations (such as in crowded spaces). Differently from standard HAs, which can be costly and are dispensed only by a hearing care professional after a hearing evaluation, these apps are available on the shelf. The most basic version of these apps applies a mere amplification of the volume of the incoming sounds; others allow the users either to choose one among a number of pre-set amplification programs or to customize the amplification profile to best fit their HL. Even in the basic configuration, these apps immediately provide some kind of amplification even to those subjects for whom traditional HAs would not be a feasible solution (being their HL of mild degree), thus potentially improving their quality of life.

- HA solutions.

A Hearing system control and maintenance: most HA manufacturers are producing hearing systems that can be remotely controlled (e.g., control of volume, listening program, sound settings, and direct streaming of phone calls) through dedicated mobile apps. In some more advanced apps it is also possible to tag a location and associate to that location a personalized sound setting that has been saved in the memory of the HA. These advanced apps can also record, play back and email audio streams received through the smart phone audio input channel and allow, finally, to use the smart phone as a microphone to stream conversation directly to the HA. All these apps allow people to suit their hearing systems on their sound preferences in real time, precisely, easily and with no extra hardware required.

B Remote consultation and individual engagement services: these apps are intended for counselling patients on their hearing status. They engage patients to become an active participant in the HA selection process. A number of apps allow capturing and rating patient personal listening experiences throughout the day and transmit these data to the hearing

care professional to be used at the next HA fitting session; finally other apps allow the simulation of the hearing sensation the user will feel after using different types of HAs.

Hearing Rehabilitation Programs

Apps in this group address the needs of the 3rd target group. They are usually in the form of interactive games and use audio, video, graphics and written materials. This group includes (see Appendix 2):

1. programs that help to improve listening ability in difficult conditions (e.g. in noisy environments) featuring games that challenge both cognitive and auditory sharpness and help to train the auditory system in different soundscapes;

2. programs that improve articulatory and phonological abilities (available also for multi-lingual speakers);

3. applications designed to change in real-time the tempo of the speech captured by the smartphone for training people with brain lateralization dysfunction;

4. applications that improve speech articulation skills using animations to view tongue placement and positioning during pronunciation and virtually 'see inside the mouth' as the sounds are being made.

Finally, there are apps that serve as a board and activity creator for speech therapists, teachers, and parents of children who need symbols to communicate and learn. These new apps make at home rehabilitation feasible with procedures that are self-administered, that interact with the patient, and adapt to the specific disabilities and to the new skills achieved by the patient during the treatment.

Assistive Tools

These apps assist users belonging to the 4th target group, including those hard of hearing using sign language (see Appendix 2). Here we found: apps that add captions to phone calls in a way similar to TV captioning to aid people with hearing impairment to communicate over the phone; video dictionaries for those who need to communicate by sign language that show the signs corresponding to a given word, explaining how to perform the sign and giving useful memory tips to improve the association of a word to its corresponding sign; apps that help people with hearing difficulties to react to the audio environment by producing an alert (such as vibrations or flashes) when the phone or the bell door is ringing, or when someone is knocking or opening the door.

4 Conclusions and instant directions

In this paper we defined the new 'eHealth4Hearing' paradigm of health care. This new path potentially leads to a dramatic change both in the roles within the actors and in the way in which people's needs are addressed and solved. Differently from the traditional doctor-centric model (see Figure 1) in which the access to health care services, resources and solutions occurs mostly through the hearing care professional, now in the new 'eHealth4Hearing' care paradigm, people can have direct access to a wealth of solutions, health services and resources. We gave a number of examples of the practical implementation of such a new paradigm through the use of health apps. The use of health apps is leading to a potentially new scenario regarding how hearing health care will be delivered in the future, since it is now feasible to perform do-it-yourself tests, and can provide access to better health knowledge and technological solutions best suited to their hearing and communication skills. The mobile app technology here reviewed makes use of a mix of sensory channels (audio, video, graphics, and text) to deliver the health message to the subject. The integration of different sensory channels enhances patient interactivity and patient engagement with their health concerns and, thanks to the use of meaningful language, graphics, video and audio clips, it increases the degree of understanding of the messages, regardless of their level of health literacy.

Despite the many positive opinions in favor of the new 'eHealth4Hearing' paradigm, there are, of course, barriers and concerns for its full implementation. Just as an example, the availability of the "e-Health bus", the grounding element of the new 'eHealth4Hearing' paradigm, implicitly asks the actor of any autonomous search - patients included - to become responsible of the accreditation of the data source they decide to navigate, not only in respect true versus false contents, but also in understanding if the lexicons used on that source are sounding to their background. Also, the 'eHealth4Hearing' paradigm raises issues ranging from traceability to data privacy and security, from process modeling to business sustainability. A recent survey conducted by [35] documented that data security, citizen privacy (and their legal and policy regulation), assessment of effectiveness and cost-effectiveness are currently the most important key barriers for mHealth implementation. Similarly, the key messages summarized in [36] are: the need for high-quality health apps; the need for standards for quality assessment; the need for a common legislation/regulation in the EU. Generally speaking, the critical issues that should be addressed in the immediate future include:

1. the need to develop methods to assess app quality and effectiveness [37] including the reliability and repeatability of the self-administered tests, the reliability of the information delivered to the subjects, the safety ([38, 39]);

2. the lack of a legal framework concerning health apps;

3. the lack of interoperability among different healthcare system nationwide, and at a European level;

4. the lack of regulation for protection of data acquired by health apps ([40, 41]), responsibility risk [42], safety and/or misuse risk [43], informed use and trust ([44, 45]);

5. concerns about security, privacy, data ownership, protection, and use [46].

Last but not least, it is worthwhile to mention here other concerns that come directly from the use of unregulated apps by healthcare professionals and, more important, by patients [47]. If the use of apps by professionals potentially raises less concern, due to their background and their ability to detect incorrect or harmful information and to correctly interpret the indications given by the apps, patients might be much more vulnerable to misuse and wrong interpretation of the directions provided by the apps (for example, this can lead to unjustified anxiety or concern about the user health condition). In a way, while technology allows improving patient empowerment by giving, for example, more efficient methods of information retrieval, dissemination (regardless of its reliability) and services for self-management of health condition, on the other hand, the lack of regulation raises many concerns.

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Appendix 1 – The major target groups and how they face the new eHealth services. For each target group (see Section 2.1), the table shows the perceived needs (Section 2.2), the traditional healthcare and rehabilitation paths followed to address the perceived needs (Section 2.3), and, the new services that can be implemented with the eHealth4Hearing paradigm (Section 3.1). Some envisaged scenarios are also given that correspond to the 'wishing cases' illustrated in section 3: (*) Wishing Case 1 and 2; (**) Wishing Case 3.

Target groups	Perceived needs	Traditional healthcare and rehabilitation paths	The new 'eHealth4Hearing' services
#1: People needing/wishing to perform self-hearing assessment and monitoring	Sensitive testing towards life-long monitoring	Hearing tests are delivered by hearing care professionals/HA providers in clinical centres; monitoring is done through time-consuming checks.	*Self-testing:* home-based and self-administered hearing testing with cheap, fast and automated procedures delivered through smartphones or tablets(*)
#2: People needing amplification	Sound enhancement solutions towards flexibility and multi-sensorial integrations	Adjustment of the amplification settings of the HA is done through periodic and time-consuming fitting sessions with the audiologist or HA provider	*Sound Enhancement Solutions:* immediate and personalized sound enhancement implemented with smartphones; remote control and maintenance of hearing systems; remote consultation and individual engagement services (**)
#3: People needing hearing and communication rehabilitation	Rehabilitation programs towards best fitting and flexibility	Rehabilitation is done during face-to-face sessions with the therapist. When the patient is a young child, the required time and commitment of parents or relatives can be huge and hard to afford.	*Hearing rehabilitation programs:* feasible, at-home rehabilitation with procedures that are self-administered, that interact with the subject, and adapt to the specific disabilities and skills of the subject(**)
#4: People needing assistive tools (other than amplification)	Assistive tools to live more independently	Speakers or headphones to watch TV, listen to the radio or talk on the telephone are the conventional solutions. Sometimes there is no solution to deal with everyday sounds that cannot be heard	*Assistive tools:* smartphone-based, integrated solutions for a simple and ubiquitous way to assist communication and daily living
All groups	Education and information towards empowered user profiles	Education and information is accessible mostly through hearing care professionals	*Education and information services:* effective communication of health-related information regardless of level of health literacy through simulations, educational games, 3D animated atlases, exploiting the mixing of sensory channels (audio, video, graphics, and text) to deliver the health message to the subject

Appendix 2: The table shows for each of the five service groups considered in this paper, the number of downloaded apps, the name of the apps selected as the representative examples of the application of the mobile health to the new 'eHealth4Hearing' paradigm, the relevant features and the links to the sources. The selection was not exhaustive: it was mainly for showing the way the apps are tuned to the new paradigm.

Service Group	N	Selected apps	Relevant target group & Interesting features	Reference
Education & Information	46	3D Human Ear HD; Advent MD; Audiosense; EarAlmanac; Ear Match; LUMA Audiology; Otolaryngology-Dictionary; Tinnitus Awareness.	Target group: all users 3D interactive and animated atlases of anatomical structures; performance of simulations of impaired perception due to HI; monitoring in real time the level of sounds and produce alerts when they become potentially damaging.	https://itunes.apple.com/us/app/3d-human-ear-hd/id509787528 http://www.advent.md/ http://www.audiosense.dk/en.html https://itunes.apple.com/us/app/earalmanac/id383598535 http://www.bluetreepublishing.com/Details.cfm?ProdID=412&category=10 https://itunes.apple.com/us/app/luma-audiology/id428563241 https://play.google.com/store/apps/details?id=com.focusmedica.md.otolaryngology http://www.canterbury.ac.uk/news/newsRelease.asp?newsPk=2222
Self Testing	34	Hearing-Check; Hearing Kit; HearingTest4All; Siemens Hearing Test; Sound; Test Your Hearing; uHear.	Target group: people needing/desiring self-hearing assessment/monitoring Check and measure hearing functionality using tones, syllables or words embedded in noise; check hearing and measure the level of the environmental noise.	http://www.actiononhearingloss.org.uk/your-hearing/look-after-your-hearing/check-your-hearing/take-the-check.aspx https://itunes.apple.com/us/app/kit-ascolto/id471740125 https://itunes.apple.com/us/app/test-delludito/id414035034 https://itunes.apple.com/us/app/est-delludito-siemens/id394674665 https://itunes.apple.com/us/app/sound/id427587943 https://play.google.com/store/apps/details?id=net.epsilonzero.hearingtest https://itunes.apple.com/us/app/uhear/id309811822
Sound Enhancement Solutions	43	Solutions with Smartphones: Hear; EarMachine; HearYouNow; Better Hearing; Sound Focus.	Target group: people needing sound amplification but not wearing HAs Solutions with Smartphones: provide basic amplification; provide ad hoc amplification through pre-set programs; provide amplification shaped on the specific user hearing profile.	http://www.loyalty-foundation.com/products.html http://www.earmachine.com/ https://itunes.apple.com/us/app/hearyounow-your-personal-sound/id569522474 http://www.thegoodear.com/betterhearing http://soundfocus.com/

		Solutions with HAs: TrueLink; ConnectLine; ReSound Smart; Beltone SmartRemote; miniTek Remote; Hearing Diary; Phonak Lyric; Lifestyle Solutions.	Target group: HA wearers Solutions with HAs: allow remote control of volume and listening HA programs to suit the current audio environment; allows geotag localization to automatically adjust the listening program to that tagged location; perform counselling of the patients on their hearing status; capture and rate user personal listening experiences with the HA throughout the day to optimize HA fitting.	http://www.trulinkhearing.com/ http://www.oticon.com/products/wireless-accessories/connectline/app.aspx http://www.gnresound.com/Services/Smartapp http://www.beltone-hearing.com/Products/Beltone%20Apps/Beltone%20Smart%20Remote%20App https://global.hearing.siemens.com/products/wireless/minitek-app/ http://www.oticonusa.com/hearing/resources/educational-library/hearing-diary.aspx https://itunes.apple.com/us/app/phonak-lyric/id565850562 https://itunes.apple.com/us/app/lifestyle-solutions/id410700882
Hearing Rehabilitation Programs	42	Hear Coach; Bilingual Articulation Phonology Assessment; Speech Corrector; Speech Tutor; Auditory Processing Studio; Custom Boards Premium	Target group: people needing hearing and communication rehabilitation Features interactive games that challenge cognitive and auditory sharpness; personalized training of articulatory and phonological abilities; change in real-time of the tempo of the speech for the rehabilitation of people with brain lateralization disorders; use of animations and virtually 'seeing inside the mouth' during pronunciation to train people with articulation disorders; challenge listening and language skills by interacting with the user with images and animations; board and activity creator for speech therapists.	https://itunes.apple.com/us/app/hear-coach/id489515928 https://itunes.apple.com/us/app/bilingual-articulation-phonology/id460830225 http://sound.eti.pg.gda.pl/~kosiq/typo/speech_corrector_en.php http://pocketslp.com/#speechtutor http://www.virtualspeechcenter.com/Resources/auditory_processing_studio_app.aspx http://smartyearsapps.com/service/custom-boards/
Assistive Tools	13	TapTap; UNI; My Smart Hands Baby Sign Language Dictionary	Target group: people needing assistive tools Add captions to phone calls; video dictionaries for sign language; produce alerts to react to the audio environment.	http://www.taptap.biz/index.php http://www.motionsavvy.com/ http://mysmarthands.com/baby-sign-language-apps/
Total number	178	37		