A Pictorial Schema for a Comprehensive User-oriented Identification of Medical Apps

S. Bonacina; S. Marceglia; F. Pinciroli

eHealthLAB – Laboratorio di Informatica BioMedica e Sanità Digitale, DEIB – Dipartimento di Elettronica, Informazione e Bioingegneria, Politecnico di Milano, Milano, Italy

Keywords

Media tablet apps, computers, handheld/ trends, credentialing, quality control, software/utilization

Summary

Objectives: The huge amount of released medical apps prevents medical app users from believing that medical scientific societies and other accreditation bodies as well, have the resources and the power for assigning to any medical app a quality score. By the time being, any medical app user has to take the risks related to the frequently insufficient accreditation of that app. Providing clear user-oriented schemas, to be adopted both when putting a medical App on the market and when an App comes to be evaluated by a cohort or single users, becomes crucial. The aim of our research was to define a pictorial identification one-shot schema for a comprehensive user-oriented identification of medical apps.

Methods: Adopting a pictorial approach is common in software design modeling. To build up our identification schema we started from the limited number of Apps already available on a web site of app reviews (iMedicalApps.com), and we identified an appropriately large set of attributes for describing medical apps. We arranged the attributes in six main families. We organized them in a one-shot comprehensive pictorial schema. We adopted a traffic light color code for assessing each attribute, that was sufficient to provide simple elements of alerts and alarms regarding a single App. Then, we considered apps from iMedicalApps.com web site belonging to three medical specialties: cardiology, oncology, and pharma and analyzed them according to the proposed pictorial schema.

Results: A pictorial schema having the attributes grouped in the families related to "Responsible Promoters", "Offered Services", "Searching Methods", "Applications Domains", "Envisaged Users", and "Qualifiers and Quantifiers" has been identified. Furthermore, we produced a one-shot pictorial schema for each considered app, and for each medical specialty, we produced it also in an aggregated form.

Conclusions: The one-shot pictorial schema provides a useful perception of when and where to use a considered app. It fits positively the expectations of potential but different user's profiles. It can be a first step towards a systematic assessment of apps from the user viewpoint.

Correspondence to:
Stefano Bonacina
eHealthLAB – Laboratorio di Informatica BioMedica e Sanità Digitale DEIB
Dipartimento di Elettronica, Informazione e Bioingegneria
Politecnico di Milano
Piazza Leonardo da Vinci, 32
20133 Milano
Italy
E-mail: stefano.bonacina@polimi.it
Website: www.ehealth.polimi.it

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1. Introduction

In the expected, but still amazing, explosion of smartphones and tablets, Apps in the medical field are regarded as possible tools not only to improve patient-doctor interactions and communication, but also to provide "scalable and convenient" ways to support health care service delivery [1–5].

There is however a widely agreed perception that medical apps quality and safety is an underestimated problem that deserves careful consideration [1, 2, 6–10, 11]. It is recent news that Apple started rejecting medical Apps if metadata do not contain appropriate references and information sources [12]. In addition, App quality and associated risks for data protection and security is a trans-domain issue that goes beyond the medical domain, and it was addressed using computer science approaches grounded on the App's development paradigm [13] as well as on the assessment of malicious software included in the App [14]. The US Food and Drug Administration (FDA), following a guidance draft published in July 2011 [15], issued on September 2013 guidelines to regulate "Mobile Medical Applications" that can be considered as "medical devices" [16]. The last release of the guidance groups mobile medical Apps into three categories: 1) those that are considered as medical devices and fall within the regulation; 2) those that are not medical devices and fall outside the regulation; and 3) those that can be considered as medical devices and for which FDA will exercise enforcement discretion. Despite the specifications, it is clear that a large part of Apps available on markets for the main mobile operating systems (Apple iOS, Google Android, Windows Mobile, Blackberry RIM) remain

(or may remain) outside the regulation, and many of the most risky Apps, such as uncontrolled and not expert-reviewed reference books, fall outside the regulation [15, 16]. The idea of App regulation may also pose some problems related to additional costs and paperwork that may be not sustainable for developers [15] while the huge and still increasing number of released medical apps denies to believe that medical scientific societies, and other accreditation bodies as well, have the resources and the power enough to examine each medical App.

Apart from FDA regulation, others have proposed to approach the problem of App quality using standard reporting schemas to be compiled by the App manufacturers, applying the classical "quality auto-certification" strategy (Table 1) [17– 20].

One short "observation" paper proposes a list of potential criteria for a self-certification of medical apps [21]. The list is adapted from the criteria proposed by the HON code [20] to obtain credited medical and health web sites, more than 15 years ago. However, the list presented in [21] is still tuned on the original HON code philosophy devoted to health website certification, and does not consider that Apps are mainly developed anticipating and interpreting user's requirements, and not relying on commissioned specifications, stated in a contract between the customer and the developer. The App-Synopsis [17, 18] provides a comprehensive description of the App imprint, rationale, expected functionality, content reliability, and data protection policies that manufacturers can provide to ensure that their apps are reliable and safe. Similarly, an even more detailed App specification is provided by Happtique [19], ", a mHealth solution provider, that recently released its "Health App Certification program" that consists of a list of 32 "standards", describing App operability, privacy, security, and content.

However, all these attempts are devoted to the manufacturer/developer side, and address content appropriateness mainly through the presence of appropriate references and, only marginally, on the appropriateness of the content for the target users. Conversely, users of medical Apps, either healthcare professionals or citizens/patients/students, seek also advice regarding the service offered and the interfaces adopted to provide such contents/services in the specific view of the app user type. The guidelines to select mobile medical applications published by the Healthcare Information and Management Systems Society (HIMSS) by the mHIMSS App Usability Working Group are in fact focused on App Usability as preferential selection criterion for users when facing a huge number of Apps possibly answering their needs [22]. To this regard, besides the usually simplistic and unreliable user's satisfaction rates and number of downloads, medical Apps users can only rely on medical professional-reviews [23, 24] and/or other opinions found on the web.

On the clinical side, as shown in Table 1, Apps are mainly evaluated by professional users focusing on their contents, in a specific medical domain, considering evidence-based medicine as main criterion: the compliance with guidelines, or the ability of an App to provide results comparable with those suggested by an experienced clinicians, together with the documented involvement of clinicians in the development process are being used to rate available medical Apps [2, 8 –10, 21, 22, 25 –30]. On the citizen/patient side, the "library of NHS reviewed phone apps to keep people healthy" is founded on evidence-based medicine [30].

However, the observations from the clinical side remain only either domain-only focused or user-only focused, analyzing and evaluating specific functionalities provided by the Apps to help patients/clinicians in managing the pathologies the App is designed for.

The present situation claims for more comprehensive views, like an ID card, able to show a set of essential and user-grounded attributes of any generic medical App, not necessarily bounded to a medical specialty domain, understandable and potentially filled in by each of the possible interested parties. This would contribute to enrich the present situation for defining App quality and safety.

To this end, we 1) tested whether a structured one-shot pictorial schema, to be filled as a user-oriented ID card to highlight the risky factors of any medical app can be built up, and 2) proposed a possible arrangement of such schema. We came to our schema by analyzing the reviews made by a team of medical professionals of more than 100 medical Apps in three wide clinical domains (cardiology, oncology, and pharma), and synthesizing the attributes evaluated by these reviews. Considering a traffic-light color code to provide the user's opinion on the specific attribute characterizing the App, we came to a pictorial schema open to be filled-in by any stakeholder of the medical process, including the final user, in a widely transparent process.

2. Methods

To build up our one-shot pictorial schema, we used the medical professional reviews of more than one hundred of medical apps, quoted into a widely recognized web site of medical app reviews (iMedicalApps.com) [23], from middle November 2012 to middle February 2013. After having defined the attribute families, from the review texts, we synthetized the attributes to be included in each family. We hence obtained the pictorial schema that was then used to represent not only the Apps already considered for the analysis, but also other Apps belonging to the same clinical domains.

More specifically, we adopted the following steps:

1. Choice of medical Apps reviewing sources;
2. Choice of medical Apps domains and App enrollment;
3. Single App analysis;
4. Definition of attribute families;
5. Valuable attributes;
6. Creation of the one-shot pictorial schema;
7. Application: examples of App evaluation through the one-shot pictorial schema.

2.1 Choice of Medical Apps Reviewing Sources

As we sought for an identification schema to represent medical Apps for users, we first looked for present sources of medical Apps reviews and evaluation. This approach to the usability evaluation is also

Table 1 Present attempts of medical Apps quality evaluation

N	Medical domain	Medical Apps Type	Evaluation		Reference
			Applied criteria	Professional involved as evaluator	
Evaluation of Apps from the clinical viewpoint					
1	Diabetes management	Apps to support patients in self-monitoring blood glucose, taking diabetes medications, and calculating insulin dose	Efficacy of the functions provided by the App (score 1–5)	Researchers with medical background	[10]
2	Medication adherence	Apps to support patients in taking their medications according to the prescription (time interval-dose)	List of desirable attributes including available functions, data storage, security issues, costs, guidelines compliance scored and weighted	Researchers with pharmaceutical background	[25]
3	Medical information	Apps to support clinicians in resource-limited settings in decision making	Comparison between Apps on smartphones and PubMed4Hh for drug-related, diagnosis-related, and treatment management-related decision making	Resident physicians at the University of Botswana	[26]
4	Asthma	Apps supporting patients in asthma self-management through specific tools and/or information provision	Compliance with available guidelines	Researchers with eHealth background	[2]
5	Microbiology	Reference microbiology Apps (guidelines, textbooks, test interpretations); antibiotic guidance (calculators, advices); other Apps for Microbiology	Medical professional involvement in App development process and evidence-based content	Researchers with medical background	[9]
6	Pain	Apps focusing on pain education and/or management targeted not only to healthcare professionals but also to patients	Application purpose, functions available, healthcare professionals involvement during development	Pain researchers	[8]
7	Dermatology	Apps for melanoma detection	Apps Specificity, sensitivity, Positive and Negative Predictive Values (PPV and NPV) tested against board-certified dermatopathologists	Dermatopathologists	[27]
8	Orthopaedic surgery	Apps to support orthopaedic surgeons	Number of reviews, popularity	Orthopaedic surgeon	[28]
9	Gross anatomy education	Apps for tertiary education in gross anatomy	Usability, specification, academic level, quality of images and of software	Researchers with anatomy background	[29]
Evaluation of Apps from the Manufacturer viewpoint					
10	Medicine	All Medical Apps	Criteria adapted from the HONCode for the development of websites with medical content	Researcher with eHealth background	[21]
11	Medicine	All Medical Apps	Usability, Efficiency, Effectiveness, and User Satisfaction	Developed by mHIMMS (mobile Healthacare Information and Management System Society) and usable by Final users	[22]
12	Medicine	Medical Apps that are considered as "Medical Devices"	Quality criteria of Medical Devices	US Food and Drug Administration	[16]
13	Medicine	All Medical Apps	Imprint, Rationale, Functionality, Validity and Reliability, Data Requisitioning & Management	Researchers with eHealth background	[17, 18]
14	Medicine	All Medical Apps	Operability standards, Privacy standards, Security standards, Content standards	Mobile health service and system provider	[19]

suggested by HIMSS [22]: among the hints provided by HIMSS to evaluate usability, the use of review sources alternative to market reviews is encouraged to obtain an unbiased and informing advice about the App. App markets, available for all the mobile operating systems, provide some information regarding App downloads and general user satisfaction, not specifying both the type of user and the kind of "satisfaction" measured. Moreover, on the Internet, it is possible to find anecdotal reviews and comments about single Apps, as well as comparisons between Apps providing similar services. Conversely, we decided to use reviews coming from the iMedicalApps.com website [23], in which medical professional users provide their textual and blog-style feedback on Apps in several medical domains. iMedical Apps reviewers are required to be medical professionals, and to have knowledge on mobile platforms (iOS, Android). In this way, we could base our work on the opinions that medical professionals provided regarding a medical App, after they have used and tested it. In order to complete the scenario, we added to these reviews some of the information on App markets that is normally taken into consideration by users to evaluate the App (mainly the number of downloads, and the metadata regarding the developer). Since iMedicalApps does not have a commercial approach in the App selection process, nor it allows monetary funding or advertisement in exchange of App reviews (see footnotes in the iMedicalApps.com homepage), we could exclude possible biases in the Apps repository we used for enrollment.

2.2 Choice of Medical Apps Domains and App Enrollment

Since our work pioneers the idea to create an identification schema for medical Apps mainly based on user-oriented and usability criteria, we decided to focus on medical Apps belonging to some specific medical domains. In this way, we could retrieve a large number of Apps reviewed by medical professional users, thus facilitating the identification of App evaluation attributes. More specifically, we focused our attention on three major medical domains: cardiology and oncology, that refer to the most frequent causes of death, and pharma, that refers to the big issue of drug prescription, administration, monitoring, compliance, adherence, and interactions. Cardiology is a medical specialty in which biosignal recording and analysis is frequently used, and Apps used to either record or interpret heart functions are available for healthcare professionals as well as for patients (also including the use of third-party devices). In addition, the time-to-care is often short in some acute phases, and the availability of references to best practices and guidelines might be useful (e.g, heart attack and the

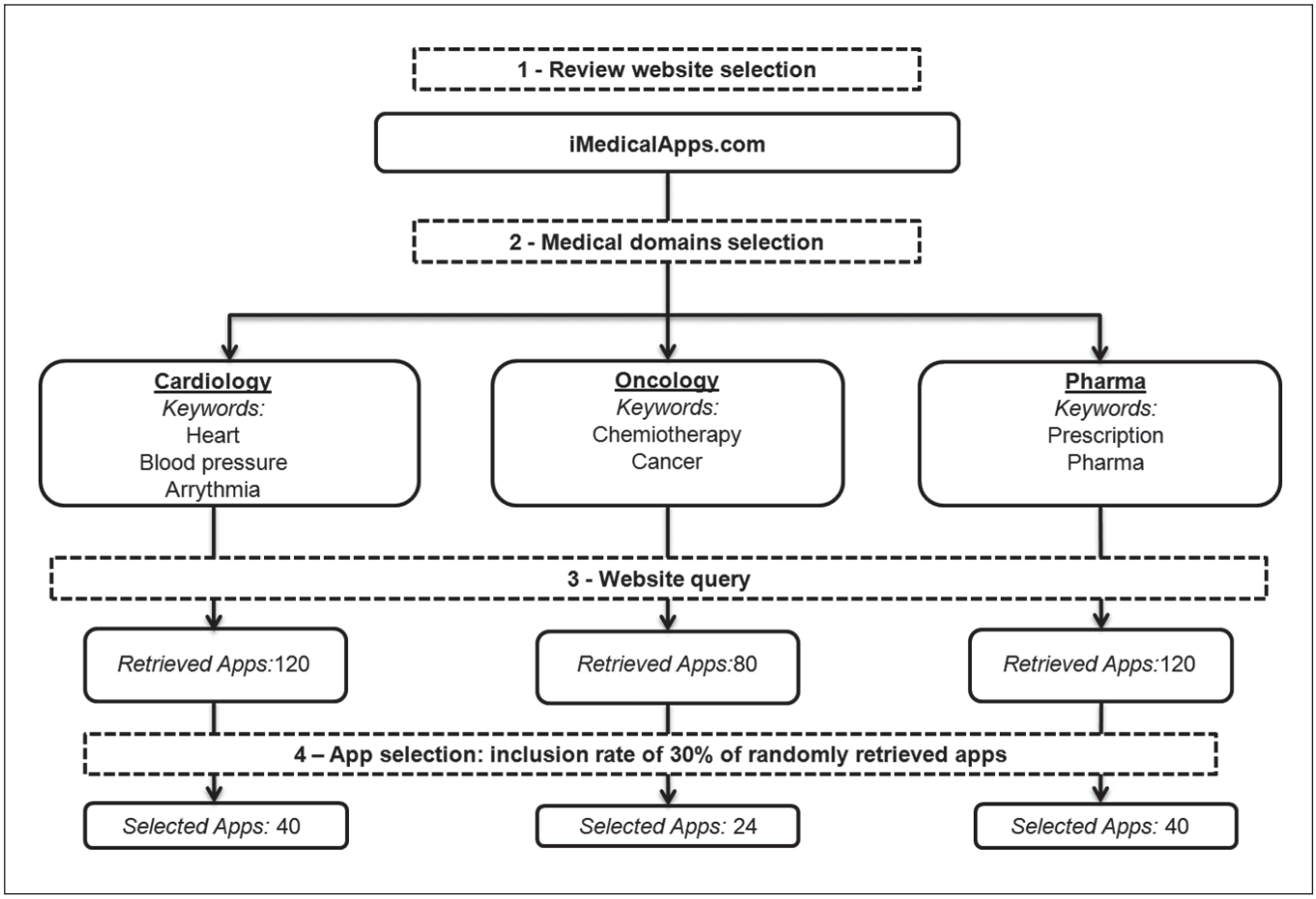

Figure 1 Flowchart of App review selection in the three clinical domains (Cardiology, Oncology, and Pharma)

survival chain). Oncology is a medical domain in which early detection strategies are gaining increasing attention and information campaigns can be easily offered through mobile technologies. Also, the response to treatments is seen in very long time windows (usually five years), and nobody denies that patients require support from both communities and healthcare providers. All together, these three areas cover a wide range of possible heterogeneous Apps in terms of type of users, data and information treated, aims, services, and functions, thus likely providing a good basis for the definition of a trans-domain identification schema.

Our analysis was not aimed to rank Apps to be used in the clinical care process – as these are usually delivered within a suitably pre-designed care or educational environment – , but we pursued an objective identification of attributes that are welcome by the potential users as soon as they perceive the existence and availability of an App suitable for their needs.

Reviews of Apps were enrolled from the iMedicalApps [23] website, that was searched using the three main keywords "cardiology", "oncology", and "pharma", that were followed by other domain-specific terms, like "arrhythmia", "electrocardiography", "chemotherapy", to extract any remaining relevant App (Figure 1).

The search was aimed to obtain a relevant number of Apps reviewed by a team of medical professionals in the iMedicalApps website, covering the three medical domains we selected. As shown in Figure 1, we searched Apps using the domain-specific keywords, and we randomly chose the 30% of the Apps retrieved by the domain-specific search. Considering that all the Apps retrieved by the search in iMedicalApps are reviewed, after the randomization, we only excluded Apps that:

- Did not exist more on their market. This ensured that we could find App metadata and other information in the market store.
- Were available only for old operating systems. This ensured that the App could be installed, if needed.
- Were available only in a language different from English or Italian. This ensured that we were able to understand App contents, independently from the review.

2.3 Single App Analysis

From the review of each App, and also from the information available on market stores, we completed, for each App, the general descriptors listed in Table 2. They were listed according both to the criteria used in the literature (Table 1) and the authors' large experience in the eHealth domain.

The majority of them are shared among the three medical domains, and included the App name, the reference/developer, the price, the operating system, the envisaged users, the phase of the medical process (education, prevention, diagnosis, therapy) or of the drug process (assign, transmit, deliver, administer, monitor, analysis [31]) the App is used for, a brief description (aims and main functions), release and revision dates, the evaluation methodology (if any), the presence of evidence-based content, and the positive and negative aspects as evidenced by the review/s. Others are specific for the domain, as, for example, the environment (Hospital ward, Emergency, Surgery, Patient's home) for cardiology, the inclusion of images and the customizations for oncology. We did not include the App cost in the analysis, since it does not impact on App-related risks.

If any information was missing, to complete the analysis, some Apps were downloaded on tablets or smartphones available at the authors' laboratory, and other ma-

Table 2 Characterization of the single app in its medical domain

Cardiology	Drug Management	Oncology
• App Name	• App Name	• App Name
• Reference/Developer	• Reference/Developer	• Reference/Developer
• Brief Description	• Brief Description	• Brief Description
• Target Tablet (/Operating System)	• Target Tablet (/Operating System)	• Target Tablet (/Operating System)
• Price	• Price	• Price
• Language/s	• Language/s	• Language/s
• Year of release	• Year of release	• Year of release
• Date of last revision	• Date of last revision	• Date of last revision
• Envisaged Users	• Envisaged Users	• Envisaged Users
• Medical process phase (Education, Prevention, Diagnosis, Therapy)	• Drug process phase (Prescribing, Administration, Management, Therapy, Delivery)	• Medical process phase (Education, Prevention, Diagnosis, Therapy)
• Validation methodology	• Validation methodology	• Validation methodology
• Evidence-based content	• Evidence-based content	• Evidence-based content
• Privacy Management	• Privacy Management	• Privacy Management
• Personal data acquisition	• Personal data acquisition	• Personal data acquisition
• Positive features (From iMedicalApps.com)	• Positive Features (From iMedicalApps.com)	• Positive Features (From iMedicalApps.com)
• Negative features (From iMedicalApps.com)	• Negative features (From iMedicalApps.com)	• Negative features (From iMedicalApps.com)
• Address on iMedicalApps.com Web Site	• Address on iMedicalApps.com Web Site	• Address on iMedicalApps.com Web Site
• Environment (Envisaged Hospital departments or Emergency Room)		• Images Acquisition
		• Customization 1 (query)
		• Customization 2 (reminders)
		• General domain
		• Specific domain

terial such as blogs or websites in which the App was commented were taken into account.

2.4 Defining Attribute Families

We defined, according to the literature [18] and relying on the elements included in the "user interface design cycle" [32] six attribute categories (that we called "families") that will be used to include the attributes of our identification schema.

1. Responsible promoters – this is the family that recalls the "imprint" criterion in the App-Synopsis. However, in our attempt, we wanted to focus on the institution/company/healthcare provider that holds the major perceived responsibility and it does not necessarily coincide with the App developer. A trusted promoter provides a positive quality element for the App. The promoter could be different from the app developer. For example, when the customer of the developer is a publisher or a drugstore, these two hold the responsibility to promote the App, even tough they did not develop the App by themselves.
2. Offered services – this family is used to identify the functions and services offered by the App, as indicated in the section 5.4 of the IEC 62366:2007 standard [32]. From the point of view of user's evaluation, the functionalities that will be listed as attributes in this family should be those usually effective in answering the question "why does the user feel to be potentially interested into this App?".
3. Searching Methods – the attributes in this family are those describing the interfaces provided by the App to access and "consume" its contents (as in the section 5.7 of the IEC 62366:2007 standard [32]). User-friendly and clear interactive practicalities are effective in taking the user really using an app. For user's evaluation, searching methods are part of this user-App interaction, and represent "how the user wishes to use an App".
4. Application Domains – This attribute family represents the context in which the user wishes to use an app, so that the future user can understand whether or not App contents are tuned for the specific context (see for example Standard C10.01 of the Happtique certification program or section 5.1 of the IEC 62366:2007 standard [32]). This implies that each domain-tailored app is not granted to be useful in another, even still, medical domain. Hence, Apps in which the application domain is not well defined could become risky if used in a different application domain.
5. Envisaged users – Envisaged users are those user profiles for which an App can be of potential interest. The value of this attribute resides on the effectiveness of an App for the declared user types.
6. Qualifiers & Quantifiers – In this family, we decided to include all the objective quantifiers (i.e, number of downloads) and the subjective qualifiers (for example, user satisfaction index) that the average user welcomes to know when selecting an App. Even though these Qualifiers & Quantifiers can be influenced by marketing issues, their relevance on user's decision making is not negligible, and they should be included in the schema.

Table 3 The rules to give each traffic light color to each family of attributes

Family of attributes	GREEN	YELLOW	RED
Responsible Promoters	Trusted promoters well known as active in the field	Something in between (e.g.: promoters active out of the field of Medicine, etc.)	Untrusted promoters
Offered Services	The offered services are useful and appropriate for the field	Something in between (e.g.: the offered services are partially useful or appropriate for the field)	The offered services are neither useful nor appropriate for the field
Searching Methods	The searching methods are not trivial and the result-set presentation is effective	Something in between (e.g.: the searching Methods are not so trivial and the result-set presentation may make sense, etc.)	Both searching methods are trivial and result-set presentation is weak
Application Domains	The borders of the application domains are fully described	Something in between (e.g.: the operating domain is only broadly described, etc.)	The borders of the application domains are weak and may induce risks
Envisaged Users	The envisaged users are clearly mentioned and user needs are profiled	Something in between (e.g.: envisaged users' needs are identified just broadly)	The envisaged users are neither mentioned nor their needs are profiled
Qualifiers & Quantifiers	Availability of trusted positive evaluations	Something in between (e.g.: evaluations are available but it is difficult to say they are significant)	Availability of trusted negative evaluations

2.5 Valuable Attributes

We used App reviews to identify the type of 1) responsible promoters, 2) offered services, 3) searching methods, 4) application domains, 5) envisaged users, and 6) qualifiers and quantifiers that characterized all the Apps analyzed. The values obtained for each App were categorized to identify the attributes belonging to each family. For example, if we found Apps for which the responsible promoters were hospitals, "Hospital" could become one of the attributes of the "Responsible Promoter" family. The labels to the attributes were defined by generalization: if the value of the attribute that we found in an App review fitted with any of the previous identified

Table 4 The list of the apps considered into the assessment grouped by medical specialty

#	Cardiology	Drug Management	Oncology
1	• 12-Lead ECG challenge	• AHRQ ePSS—The Agency for Healthcare Research and Quality's electronic Preventive Services Selector	• BRCAmanager App
2	• AF Guide: the Atrial Fibrillation Reference	• American Medical Association My Medications	• Breast Cancer
3	• AFib Educator 2.0	• Analgesic	• Breast Cancer Glossary
4	• Anatomy heart instant	• Antibiotics I-Pocketcards	• Cancer Coach
5	• Arrhythmias	• Antibiotics Manual Flash Cards	• Cancer Management HandBook
6	• Auscultation Primer	• Are My Meds Safe for my Baby?	• Cancer Signs and Symptoms
7	• Blood Pressure Diary	• CAP guideline	• Cancer.net
8	• Blood Pressure Report	• Clinical Pharmacology Mobile	• CancerTrialsApp
9	• Calorie Counter & Diet Tracker	• ClotRX	• Colorectal Cancer Miniatlas
10	• Cardiac Images	• Davis Mobile Pharm Phlash!	• DoctorMole
11	• Cardiograph	• Dragon Medical Search	• eCancer
12	• CathSource	• Drug Doses	• i Doc 24
13	• ClotRx App	• Drug Guide for Consumers	• Keep A Breast
14	• CPR game	• Drugs and Bugs	• Lange's Histology Flashcards
15	• ECG guide	• EMRA Antibiotic Guide	• Melapp
16	• ECG Interpreter, Calipers, Treatment Advisor	• eOpioid™: Opioids & Opiates Calculator	• My Self Checker
17	• ECG Notes	• Epocrates	• NCCN Guidelines
18	• ECG Rhythm tutor	• FIRSTlight HD	• Oncorx-mi
19	• Echocardiography Atlas	• Food and Drug Administration Drug Safety Podcast	• PFT a-Pocketcards
20	• Heart Failure Trials	• Harriet Lane Handbook	• Pocket guide to hematologic cancer
21	• Heart Illustrated Pro	• HAS-BLED Bleeding Risk Calculator	• Radiation Passoport
22	• Heart Murmur Pro	• I.V. Drug Handbook	• Re-mission
23	• HeartWise Blood Pressure Tracker	• Infantrisck center	• Tumorpedia
24	• History & Physical Exam i-pocketcards	• inPractice® HIV	• UMSkin Check
25	• iBP Blood Pressure	• iPrescribe	
26	• iBP Blood Pressure	• Johns Hopkins Guides	
27	• iCath	• Johns Hopkins Guides (ABX, HIV, Diabetes)	
28	• iHeart Touch	• Johns Hopkins Guides (ABX, HIV, Diabetes)	
29	• Instant ECG	• Lange's Top Pharmacy 300 Drug	
30	• iResus	• Lexi-Complete	
31	• iStethoscope	• Managing Dabigatran	
32	• iVCL (Virtual Cath-Lab)	• Medescape	
33	• Managing Dabigatran	• Medicine Central	
34	• Master Diagnostician Series: Approach to Anemia in the Adult Patient	• NICE BNF	
35	• Nice Guidance	• OncoRX-MI	
36	• OAPN Coronary stenting	• Oral Contraceptive Pill Reference	
37	• Pocket Heart App	• palmEM: Emergency Medicine Essentials Quick Reference Guide	
38	• Quit Forever	• pedi quickcal	
39	• Resuscitation!	• Pediatric Emergency Drugs	
40	• SimMon	• PediDoser	

labels, the App was labeled accordingly. Otherwise, a new label was created.

Then, we sought for information, available in the App review, regarding the evaluation of each attribute. For example, if the responsible promoter is a publisher, the trustworthiness of the publisher resides in its activity and reputation in the field. And this information is usually evidenced in the App review, or it is easily retrievable on the Internet.

2.6 Creation of the One-shot Pictorial Schema

The adoption of a pictorial approach is frequently effective in software design modeling. We hence created a pictorial schema that could graphically and instantaneously synthetize ("one-shot") the values of the attributes characterizing the single App.

In our pictorial schema, each of the attributes has a name and has a circular shape lollipop, or stick, to be filled in with a qualitative score, that we decided to express by the green, yellow and red traffic light colors. The rules for defining and regulating the use of each color for each family of attributes are reported in Table 3. Whereas the red color and the green color are well defined, the yellow is "something in between". Even though this evaluation scale does not precisely rank the "score" of an App, the three-scale code is enough to evi-

Table 5 Family and attribute description, and the number of occurrences of each attribute in the selected App reviews. Note that, in some cases, the number of occurrences of attributes in a family is higher than the total number of Apps selected. This is due to the possibility that an App satisfies more than one attribute (for example: an App can offer both guidelines and newsletters).

Family description	Attribute Description		Number of occurrences in App reviews			
	Name	Rationale	Cardio-logy	Onco-logy	Pharma	Total
Responsible Promoters: institution/company/healthcare provider that holds the major perceived responsibility. The promoter could be different from the app developer	Medical System Companies	Possible responsible promoters as an app can help patients to manage personalized devices.	27	1	0	28
	Drug companies	Possible responsible promoters as an app can help prescribers to manage personalized drugs.	1	0	0	1
	National Services	Possible responsible promoters because they are in charge of the responsibility to help in protecting the population: apps can be new tools for prevention and instruction.	1	0	6	7
	Hospitals	Public and private hospitals can appreciate the app modality for delivering-on-demand indications, without excluding a certain degree of their interest in patient loyalty, too.	1	0	11	12
	Drugstores	Possible responsible promoters in order to serve better its customers, for example by providing them with an app to care more about the correct assumption of the drugs on sale.	0	0	1	1
	Medical Association	Possible responsible promoters as an app can make the access to guidelines/recommendations issued available everywhere.	2	10	2	14
	Publisher	Possible responsible promoters as an App can facilitate the access to knowledge.	3	13	24	40
	Total Responsible Promoters		**35**	**24**	**44**	**112**
Offered services: functionalities are effective in answering the question "why the user comes to this App?".	Handbooks	Apps that make content of medical education available anywhere, even at student's home	10	9	20	39
	Guidelines	Tools that provide the available recommendations to guarantee the correct management of the patient, mainly in emergency situation in the medical practice.	15	2	27	44
	Newsletters	Information coming from communities and provided to the users.	0	1	8	9
	Calculators	Services that provide indicators calculated from anatomical parameters (for example, Body Max Index calculator, drug dose calculator).	5	5	17	27
	Forecasters	Result of simple calculus/algorithms that can be used to forecast a patient's state, or a condition (for example, survival expectations).	5	5	1	11
	Geo-Health	Services that help in finding rapid – and even graphically mapped – answers to questions like "where is the nearest pharmacy/ emergency room / etc.?"	0	1	2	3
	Simulators	Virtual spaces where to test alternative procedures, of various type, for keeping the impact on the patient as safe as possible.	14	0	1	15
	Others	Services for monitoring, measuring, bio-signal classifying, alert management.	0	5	2	7
	Total Offered Services		**49**	**28**	**78**	**155**

Table 5 Continued.

Family description	Attribute Description		Number of occurrences in App reviews			
	Name	Rationale	Cardiology	Oncology	Pharma	Total
Searching methods: They are part of this user-App interaction, and represent "how the user wishes to use an App".	Alphabetical Order	Searching method where items are listed in alphabetical order.	6	9	28	43
	Images	Searching methods managing "images" and videos including also semantic querying.	9	2	8	19
	Predefined Comparisons	This method lets the user compare in a single view more images or information.	7	2	14	23
	Multisources	Apps allowing "multisource" bioimage availability and comparisons to provide different views and insights on the same tissue (for example: CT scan and MRI).	11	2	10	33
	Chemical Structures	Searching method that allows users to navigate inside the chemical structures of drugs or human tissues.	0	0	2	2
	Scrolling of Lists	List of items that the user can select: it is a useful tool, but, for long lists, its effectiveness decreases.	19	14	27	60
	Others	Searching methods based on keywords, videos, interactive menus.	1	6	1	8
	Total Searching Methods		**53**	**35**	**90**	**178**
Application domain: the context in which the user wishes to use an app	Complex Prescription	App mainly thought to support the prescription process, especially when it requires multifactorial evaluations or the combination of more than one drug/treatment.	4	0	25	29
	Education	App thought for the education of medical students or of other health professionals.	18	16	12	46
	Mobility	App mainly thought for localization, navigation, and availability of contents in mobility.	2	7	17	26
	Emergency	App mainly thought to support the instant delivery of the best ever acquired aggregated and multidisciplinary knowledge.	3	0	3	6
	Drug Shortage	App mainly thought to support the immediate supply of drugs in order to guarantee the continuity in medical assistance for example inside a hospital or rest home where a high number of patients are treated with drugs stored in an unique pharmacy.	2	0	1	3
	Specific Sub-Specialty	Specific domain dedicated to the diagnosis and treatment of specific diseases in a medical sub-domain (for example: breast cancer)	25	13	0	38
	Video Manual	Training domain based on video manuals, also for patients/citizens (for example: video instructions on the use of a drug)	6	3	0	9
	Total Application Domain		**60**	**39**	**58**	**157**
Envisaged users: those user profiles for which an App is of potential interest	Students	Students of medicine.	23	4	7	34
	Citizens	Including patients.	14	18	8	40
	Professionals	Health professionals.	34	9	42	85
	Others	Caregivers, family of patient, National Services employees.	0	1	0	1
	Total Envisaged Users		**71**	**32**	**57**	**160**
Qualifiers and Quantifiers: all the information that the average user welcomes to know when selecting an App.	Significant Testimonial	Like National Services, Medical associations, or recognized specialists.	0	5	24	29
	Timing	Release date: timing attribute aggregates sub-attributes like "beginning date" and "trend" (continuous in time, periodic, concentrated in a short time window)	2	0	1	3
	User Satisfaction Index	Subjective perceptions like: a positive/negative judgment on a credited blog, the number of finger up/down in social networks, an insight published on a (scientific) journal, the personal opinion, the star rating available on App markets.	40	3	40	83
	Download Number	It represents how many times the App was downloaded (Usually available in the App market)	0	1	9	10
	Total Qualifiers and Quantifiers		**42**	**9**	**74**	**125**

dence its risks and the advantages. Hence, if an attribute could not be clearly set to green or red, it was set to yellow. Each family of attributes belongs to a rectangle, upon which attributes' lollipops are connected to.

2.7 Application: Examples of App Evaluation through the One-shot Pictorial Schema

To verify whether this pictorial approach can lead to an easily perceivable and effective identification schema for medical apps, we applied it to all the Apps we have enrolled in our study, and produced more than one hundred pictorial schemas.

Furthermore, we tried to see whether the one-shot pictorial schema was able to synthetize the information regarding more Apps belonging to the same domain. To do so, we built another version of the one-shot pictorial schema in which we substituted the lollipops with bars representing the number of Apps having a green/yellow/red score in their single pictorial schema.

Finally, to verify the consistency of the attributes we have obtained, we applied the schema to other Apps retrieved from the NHS App Library [30], and saw whether they fit in the schema. An independent user (biomedical engineer, PhD candidate) was provided by the empty schema, the family and attribute description as in Table 5, and the color coding (Table 3) and was requested to randomly select three Apps in the NHS App Library, one for cardiology, one for oncology, and one for pharma and to fill in the pictorial schema for them, by either using available medical professional-reviews or by using the App on the personal mobile device.

3. Results

3.1 Apps Enrollment and Analysis

As reported in ▶ Figure 1, the search started in iMedicalApps.com resulted in about 120 Apps in the cardiology domain, 120 Apps in the pharma domain, and 80 in the oncology domain. We randomly selected the 30% of the Apps retrieved in each group, so that we enrolled 40 Apps for the cardiology domain, 24 Apps for the oncology domain, and 40 Apps for the pharma domain. Table 4 reports the names of the Apps enrolled in the study for each medical domain.

Considering the six families defined above, we extracted from the descriptions and reviews the categories of attributes belonging to the families, according to the results in Table 5. The final attribute set was:

1. Responsible Promoters (Publisher, Medical Association, Drugstores, Hospitals, National Services, Drug Company, Medical Systems Company)
2. Offered Services (Handbooks, Guidelines, Newsletters, Calculators, Forecasters, GeoHealth, Simulators, Others)
3. Searching Methods (Alphabetical Order, Images, Predefined comparisons, Multi-sources, Chemical structures, Scrolling of lists, Others)
4. Applications Domains (Complex prescriptions, Education, Mobility, Emergency, Drug shortage, Specific domain specialty, Video manual)
5. Envisaged Users (Students, Citizens, Professionals, others)
6. Qualifiers & Quantifiers (Download number, User satisfaction index, Timing, Significant testimonial).

The attribute sets we obtained are in line with the following considerations:

Responsible promoters. Publishers, aiming to diffuse knowledge, are possible responsible promoters, as an app can facilitate the access to knowledge. Also for "medical association", an app can make the access to guidelines/recommendations issued available everywhere. Even if less usual, a "drugstore" may try to serve better its customers, for example by providing them with an app to care more about the correct assumption of the drugs on sale. The "National Services", that are in charge of the responsibility to help in protecting the population, are included, too. For such services, an app can fasten the time to reach citizens with short and precise indications. Also public and private "hospitals" can appreciate the app modality for delivering-on-demand indications, without excluding a certain degree of their interest in patient loyalty, too. A "drug company", as well as "medical systems companies", can help both prescribers and patients to manage personalized and risky drugs/devices. For a "responsible promoter", its mission in promoting an App should be easily and clearly perceived by any citizens, and associated to the promoter responsibility profile.

Even though **Offered Services** and functionalities usually depend on the specialty/pathology is intended for, broad categories can still be defined. For example, a "Calculator" is a useful service. An entry-level example for the medical domain is the Body Mass Index (BMI) calculator. The usual BMI formula is widely agreed. But, if a calculus is only on the back and its results are presented as a "Forecaster" – the case can be that of survival expectations -, the scientific credentials of such forecasting actions should be declared with evidence and referenced in detail. "Newsletters" also are a useful service, as they tell what is going to be different in respect to the even recent past. "Guidelines" and "Handbooks" are well-known domains of both medical practice and medical education, and an app can make their content really available anywhere, even at student's home. "Simulators" aim to offer a virtual environment where to test alternative procedures, of various type, for keeping the impact on the patient as safe as possible, even if postponed. "Geohealth" apps help in finding rapid – and even graphically mapped – answers to questions like "where is the nearest pharmacy/ emergency room / etc.?".

Searching Methods. The value of the user-App interaction depends on its effectiveness: there is no doubt that "Scrolling a list" is a useful tool, but for long lists on small-sized displays, its effectiveness decreases. The availability of the usual word-processor-like searching modalities within a text is a frequently expected step forward. Moreover, given the relevance that bio-images have in the domain of medical diagnosis and therapy, searching methods managing "Images" and videos are highly appreciated in medicine, also for especially tablet PCs with their larger screen size better suited for visualization. Tools for "Pre-defined comparisons" let the user compare in a single view more images. Moreover, since different bio-images may provide different views and insights on the

same tissue, apps allowing "Multisource" bioimage views can be very effective.

Application Domains. A broad definition of the application domains is based on the categorization on the contexts in which the App can be used: "Education" asks for knowledge insights progressively developed from a general and gross towards a specific and complex granularity, delivered also according to the envisaged learning speed and skills of the learners. Conversely, "Emergency" conditions ask for the instant delivery of the best ever acquired aggregated and multidisciplinary knowledge. Other similarly envisaged domains are "Complex prescription", "Mobility", "Drug shortage", "Specific sub-specialties".

Envisaged Users. The definition of attributes in the "Envisaged Users" family highlights a subgroup of major stakeholders only, as singled out by "Students", "Citizens" (including patients), and "Professionals".

Qualifiers & Quantifiers. The "Number of downloads", even though not fully informative about quality, should not be ignored. This means that an about-never downloaded app (zombie App) will likely be poor in quality and effectiveness. The release date is also to be considered through the attribute "Timing", that aggregates sub-attributes like "Beginning date" and "Trend". We additionally diversified the latter among "Sharp", "Waved" and "Smooth", while we left "Pseudo-constant" with greater evidence. An example of "Sharp" is when everybody downloaded the app just the day after it was released, but nobody did so later on. An example of "Waved" is for seasonal allergies and related action, as well as for the major deadlines of any academic year. We also added the attribute "User satisfaction index", intended as a qualifier. A positive/negative judgment on a credited blog, the number of finger up/down in social networks, an insight published on a (scientific) journal, the personal opinion of users/clinicians: all these are examples of subjective perceptions to evaluate this attribute.

3.2 The One-shot Pictorial Schema

Figure 2 shows the pictorial one-shot identification schema created using the attribute families described above. The central empty area of the schema is used to include the app official name and its official description, together with the icon of the declared app operating system/s and device (iPad, iPhone, Android smartphone, Android Tablet, Blackberry, and Windows Mobile). A general evaluation of the attribute family, independent from the value of the single attributes, can be provided by using the circle within the rectangles.

3.3 Application of the One-shot Pictorial Schema to the Enrolled Apps

For each of the Apps considered in our study, we produced a one-shot pictorial schema following the rules and the coding described above. We produced 40 one-shot pictorial schemas for the cardiology do-

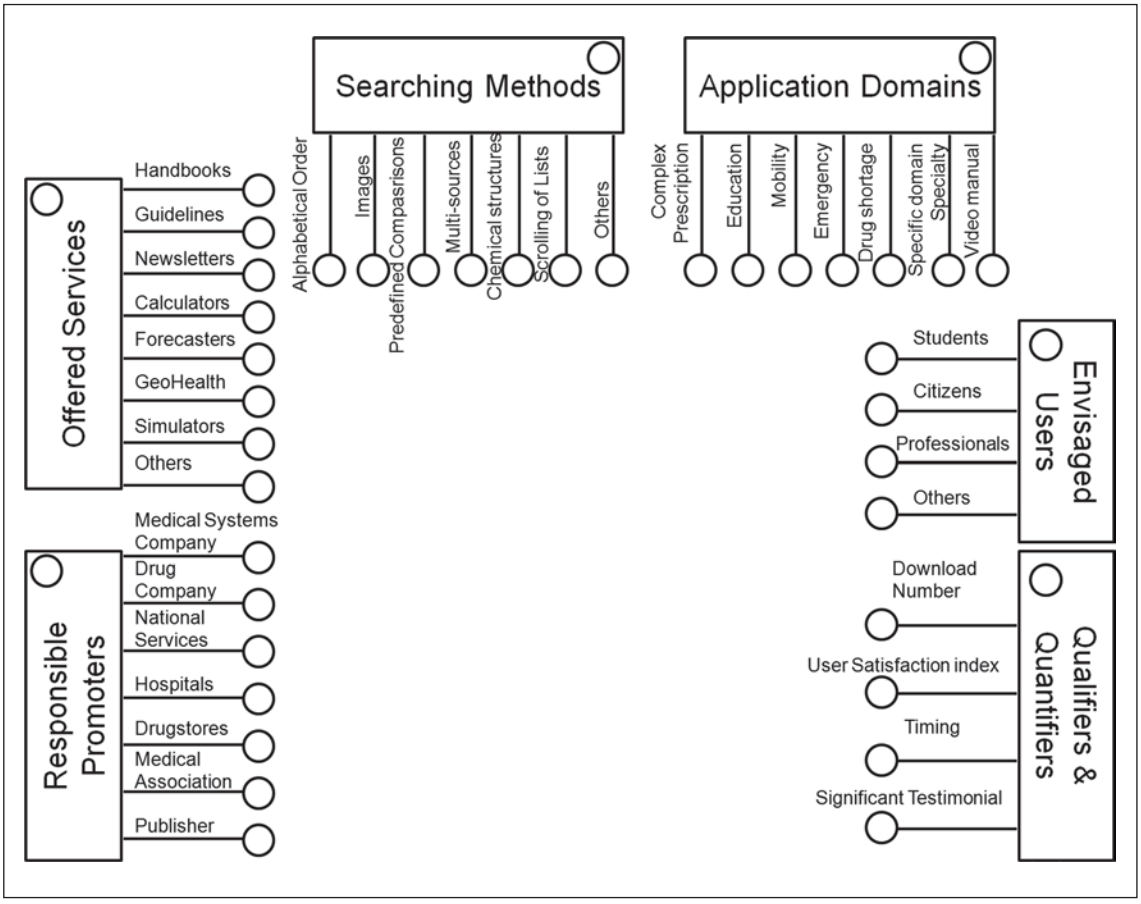

Fig. 2
The Pictorial Schema for the assessment of the Apps

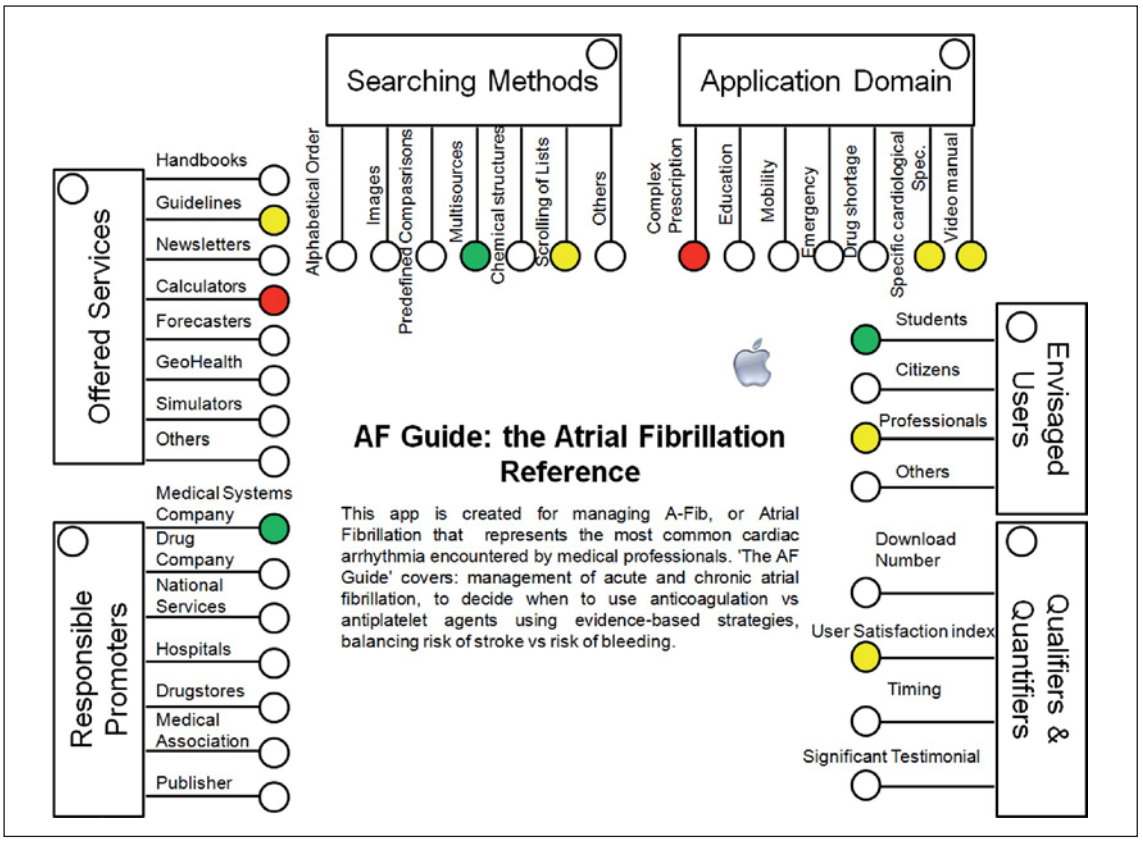

Figure 3
Assessment of the "AFGuide: the Atrial Fibrillation Reference" app

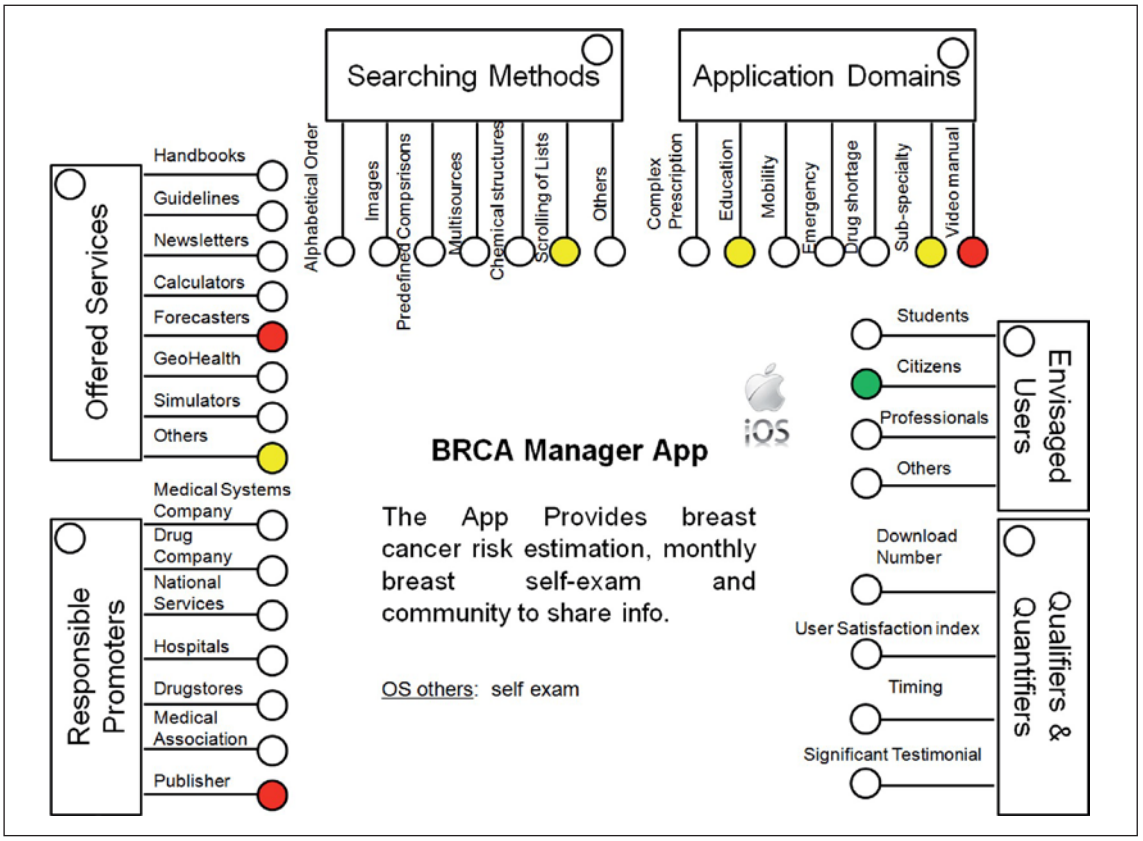

Figure 4
Assessment of the "BRCA Manager" app

main, 24 for the oncology domain, and 40 for the pharma domain.

Figure 3 and Figure 4 show examples of single app one-shot identification pictorial schema for two Apps, one from the cardiology domain, and one for the oncology domain.

As reported in the center of Figure 3, the App "AF Guide" provides information/answers for the management of drugs and behaviors in atrial fibrillation (AF). The responsible promoter is QxMD Software Inc, a company that produces certified medical devices. Since this promoter is trusted and active in the medical field, the corresponding lollipop is green. Whereas the guidelines provided are told to be referenced by "Evidence-based strategies", the App does not provide in-depth answers to questions regarding AF (attribute "Guidelines" in the "Offered services" yellow). Conversely, the risk calculator uses a too simplistic approach, as noted by the reviewers in iMedicalApps, thus making the calculator attribute in the "Offered Services" as well as the "Complex prescription" attribute in the "Application Domains" red. Except the navigation tabs helping the user to navigate causes, clinical presentation, classification, symptoms, etc., information are mainly presented as lists, with a sub-optimal visualization effectiveness ("Scrolling of list" attribute yellow). In the "Application Domains" family, since the app addresses the AF "Specific sub-specialty" with some missing information (it does not provide in-depth answers to the questions regarding AF) the scoring was set to yellow. For the same reason, the video-manuals to explain AF main characteristics that are available in the App are scored yellow. Even though not well declared in the App description, contents are well suited for students (green scoring) but incomplete for professionals (yellow scoring). Patients/citizens are not included among Envisaged Users. We could not retrieve any satisfaction index/rating for this App, neither in iMedicalApps nor in the Apple Store, but we could find some users' comments. Among them, some were positive (students) and some were negative (professionals). For this reason, the scoring for this attribute was set to yellow.

Figure 4 shows the application of the pictorial schema to the BRCA Manager, an App in the oncology domain for the breast

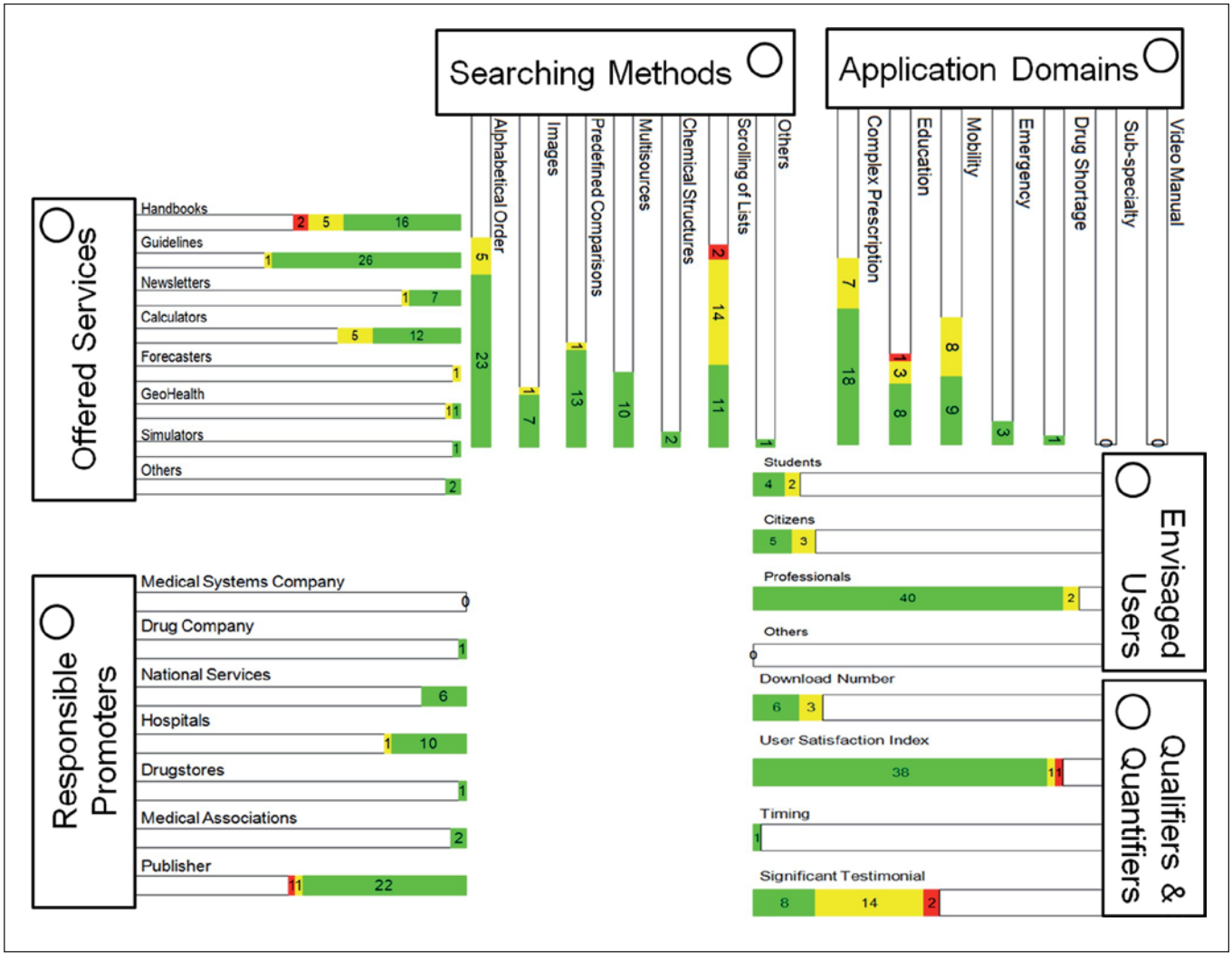

Figure 5 Aggregated results for the assessment of the Apps belonging to Pharma Domain

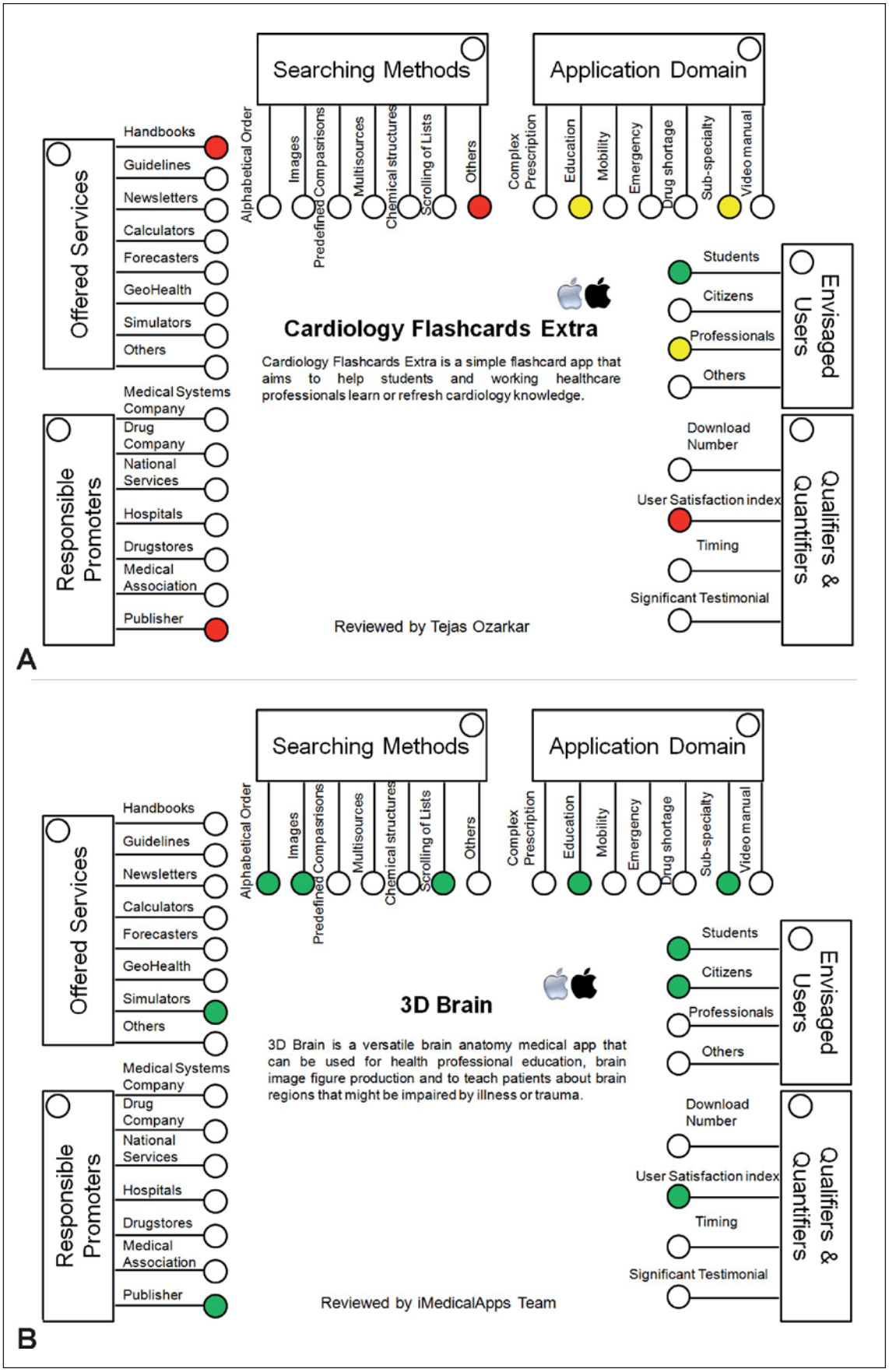

Figure 6
Assessment of three Apps not included in the Apps selected to create the pictorial schema: A – the "Cardiology Flash-card Extra" app; B – the "3D Brain" app

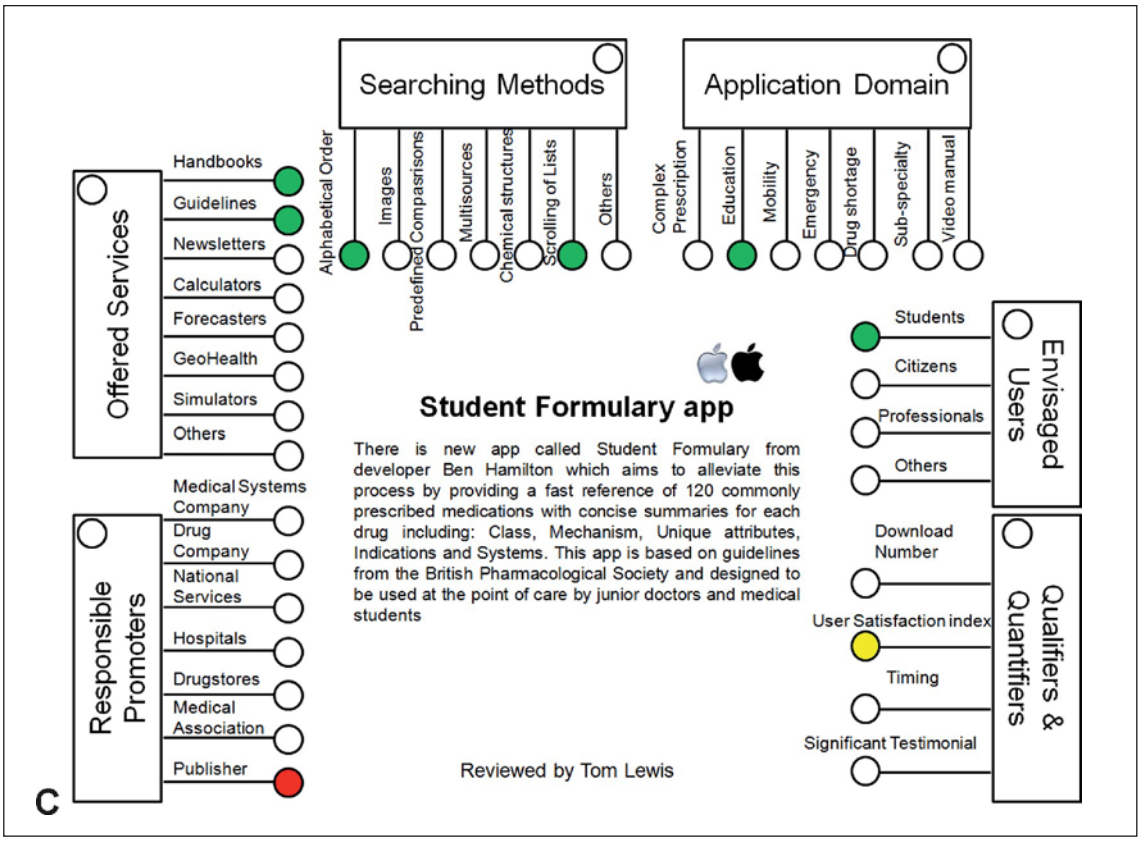

Figure 6
Assessment of three Apps not included in the Apps selected to create the pictorial schema: C – the "Student Formulary app" app

cancer risk assessment and advices for monthly breast exam. BRCA Manager was developed by Geference Inc, a medical publisher, that, to our knowledge and without other specific investigations, seems new and not yet ranked in the medical domain ("publisher" attribute red). The provided risk calculator, that falls into the "Forecaster" category, is declared to be based on the model proposed by Gail et al. [33, 34] (BCRA tool developed by the National Cancer Institute) but there are two important drawbacks: first, the Gail model should be used by the patient together with a clinician, and, second, the model adopted is not complete. These drawbacks produced the red lollipop in the "Forecaster" attribute ("Offered Services"). Because the App offers also other services, including for instance a community to share experiences, the attribute "Others" was scored. The yellow color is due to the fact that the community service is not monitored by the developer. No specific "Searching Methods" are implemented in the App, except the list scrolling, which is however not highly effective (yellow "Scrolling of lists" attribute). For the lack of evidence based sources, and the superficial application of clinical models, the attributes in the "Application Domains" were scored yellow or even red. Citizens (not yet patients, since it is aimed to prevention) are the declared "Envisaged Users" and the App is designed to meet their requirements.

We also tested whether our pictorial schema was able to show the quality of a group of Apps. The representative case of Pharma domain is represented in Figure 5. Note that Figure 5 summarizes the results shown in Table 5. In Figure 5, the scores of all the Apps enrolled for the pharma domain were joined to obtain an overall domain perception.

3.4 Application of the One-shot Pictorial Schema to the other Apps

The application of the pictorial schema to other Apps did not reveal any inconsistency. For two of the three Apps, the schemas could be completely filled in by an independent user (biomedical engineer, PhD candidate) by using the available reviews. For the other App, the user faced the need to download and use the App. Figure 6 shows the three pictorial schemas for the chosen Apps.

4. Discussion

Our results show that it is possible to define a properly descriptive and structured pictorial schema, to be used as ID card for any medical app, independent from the specific medical domain. The schema provides a synthetic view on the strengths and on the risks related to a single App for different user's types. Attribute scores are provided in a common code (traffic-light code) to facilitate the perception on the App advantages/usefulness (green lights) as well as its caveats (red lights).

Our schema can be compiled or updated at any time window of the life of an App. It can be filled after its release, or after months. This is in line with the fast development rate that characterizes the mobile App arena, in which every day thousands

of new Apps are released, and even more are updated or dismissed.

The "pictorial ID for Medical App" compiling can be carried out by a variety of user types, each of them forwarding the strength and weaknesses related to their role. A generically interested citizen, a healthcare provider, a doctor, a nurse, the app manufacturer, a declared cohort of users, a scientific society, a governmental body: all of these are examples of possible compilers. Each of them is widely interested in avoiding any risk, firstly for the patient, as well as for its own envisaged role. This implies that, for the same App, more than one identification schemas can be compiled, depending on the specific user, thus allowing a new user to understand when and where to use the App, with positive expectations. Since the scores given by the author of the pictorial schema strongly depend on their background, knowledge, and role, the "signature" of the author must accompany the one-shot pictorial schema.

Our results also showed that, in addition to providing a synthetic view on the single App, the pictorial schema is able to represent weaknesses and strengths of all the Apps in a single domain. These weaknesses and strengths can be due either to the uncertainty of the domain per se, or to a drawback still to be solved by mobile Applications.

4.1 Limitations

Our work was based on available medical professional reviews of Apps in three clinical domains (i.e., cardiology, oncology, and pharma). This choice allowed us to define a set of attributes that will be likely suited also to other clinical domains. However, the attribute set may be enriched by adding to the attributes we already identified other attributes coming from the personalized eHealth domain. For example, an App that provides a diary to be filled in by a diabetic patient, or by a patient suffering from migraine, is not well represented in the present attribute set. We may need to add the category of "enhancers", representing those tools that boost the communication between the patient and his/her physicians when the patient's condition requires frequent monitoring.

Also, we cannot exclude that, considering other types of App reviews, the pictorial schema should be improved. A step forward to our schema can be found in the recent FDA guidelines [16]. In fact, Apps that are not (or may be not) medical devices are listed in categories of services. These categories already include all the attributes of our "Offered Services" and "Searching Methods" families, but some others are defined that can be used to enrich the schema.

4.2 Dissemination Strategy

One of the main drawbacks of the HON code project was the scares resonance it had on the general public. Whereas e-health professionals know well the initiative, patients are poorly informed on it: less than 1% of people searching health information on the Internet use the HONcode seal to verify the medical information they retrieved [35]. This suggests that the dissemination strategy of any new attempt to identify/evaluate/represent Apps should impact the widest possible population. We made a first attempt to catch the professional public by presenting the pictorial schema at the National Congress of the the Italian College of Hopsital Cardiologists (Associazione Nazionale Medici Cardiologi Ospedalieri, ANMCO) that involves more than 5000 cardiologists in Italy [36]. The idea was well accepted by the public that recognized the need of such a user-oriented approach. The next step in this direction will be the definition and administration of a questionnaire regarding the value of the families of attributes and of the attributes themselves that will be launched by our laboratory to all the main clinical, scientific, and patient associations in Italy, but also at the European level through the mediation of the European Federation of Medical Informatics (EFMI).

This action will contribute both to support the approach and to widen its diffusion among users. Other actions, likely in the direction of standardization bodies, should be planned to ensure wider diffusion not only to the manufacturers, but also to the governance and to those that run the big App market stores.

5. Conclusion

Despite the resulting schema is only a first-step towards an overall representation of strength and weaknesses of apps from the user's viewpoint, it appears reasonably transparent to be filled in and read. The usefulness and effectiveness of the "pictorial ID for Medical App" come both from its architecture and from the declared signature of its compiler. As a first step, the schema can be used as a "best practice" behavior adopted by the interested parties, for example by providing it together with the App description on the market store. Then, the schema can be proposed to standardization bodies to become part of the recommendations or the rules regarding those medical Apps that are presently not covered by the FDA guidance. In addition, it has the potential for a wide dissemination, especially if promptly proposed to clinical and patients' scientific societies to obtain their contribution to the identification of appropriate attributes.

Author Contribution

All the authors contributed equally to the research and to the development of the one-shot pictorial schema, as well as to manuscript drafting and revision.

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