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care

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Abstract: Background: There has been a dramatic increase in mobile apps

for diabetes self-care. However, their quality is not guaranteed and patients do not have the appropriate tools for careful evaluation. Objective: This work aims to propose a tool to help patients with diabetes select an appropriate app for self-care. Methods: After identifying the conceptual framework of diabetes selfcare, we searched Apple US app store and reviewed diabetes self-care apps, considering both generic and diabetes-specific features. Based on an existing tool for representing the benefits and weaknesses of medical apps, we created the Pictorial Identification Schema/Diabetes Self-care tool, which specifically identified medical apps in the diabetes domain. Results: Of the 952 apps retrieved, 67 were for diabetes self-care, while 26 were excluded because they were not updated in the last 12 months. Of the remaining 41, none cost more than 15 USD, and 36 implemented manual data entry. Basic features (data logging, data representation, and data delivery) were implemented in almost all apps, whereas advanced features (e.g., insulin calculator) were implemented in a small percentage of apps. The pictorial identification schema for diabetes was completed by one patient and one software developer for 13 apps. Both users highlighted weaknesses related to the functionalities offered and to their interface, but the patient focused on usability, whereas the software developer focused on technical implementation. Conclusions: The Pictorial Identification Schema/Diabetes Self-care is a promising graphical tool for perceiving the weaknesses and benefits of a

diabetes self-care app that includes multiple user profile perspectives.

# **Conflict of Interest Statement**

# **Statement on conflicts of interest**

Andrea Basilico, Francesco Pinciroli, Stefano Bonacina, and Sara Marceglia declare no financial affiliation/interest in the subject matter, materials, or products mentioned in this manuscript.

#### **Cover Letter**

Dear Dr Ciaccio,

I submit the revised version of the paper "Advising patients on selecting trustful apps for diabetes self-care" by A. Basilico, S. Marceglia, S. Bonacina, and F. Pinciroli for possible publication in Computers in Biology and Medicine.

The manuscript was submitted to a professional editing service for full language and style revision. The changes made by professional editors are shown in the version of the manuscript with all the corrections highlighted.

I hope that the manuscript is now suitable for publication in your Journal.

With kind regards

Sara Marceglia

### **REPLY TO REVIEWERS**

#### MS N. CBM-D-15-00634

### **Reviewer #4:**

Title Advising patients on selecting trustful apps for diabetes self-care Summary The aim of the revised manuscript is to propose and test a Pictorial Identification Schema to help patients identify strengths and weaknesses of diabetes self-management apps. The authors do so by: 1) defining a conceptual framework for diabetes self-care that can be supported by mobile health applications; 2) reviewing available diabetes self-care apps; and 3) using the conceptual framework and available apps to define the PIS. As stated in the initial review, the manuscript is intriguing, as the need to develop better tools to help patients identify evidence-based and useful self-management apps is clear. The authors appear to have carefully reviewed this reviewer's comments. As requested, they expanded their description of the PIS, provided an improved summary of their methodology, justified their reasons for not re-evaluating apps after initially downloading them in April 2014, discussed why the diabetic patient and software developer were asked to test the PIS, etc. At this time, the authors have responded to this reviewer's major concerns. As such, this reviewer finds the manuscript acceptable for publication, pending other reviewers' comments.

**Reply**: We thank the Reviewer for the positive consideration of our effort.

### **Editor-In-Chief**

The manuscript needs to be refined for English grammatical structure and phraseology. The manuscript should be polished by an English linguist or an English language service could be used. Details of author-pays services can be found, for example, at: <a href="http://www.proof-reading-service.com/">http://www.proof-reading-service.com/</a>, <a href="http://www.proof-reading-service.com/">http://www.proof-

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an organization that gathers about 230 hundred national diabetes an organization that includes about 230 hundred national diabetes

was shown to improve glycemic control [4-6] and decreasing glycosylated was shown to improve glycemic control [4-6] and to decrease glycosylated

**Reply**: The manuscript and the figures/tables were revised by a professional editing service

# HIGHLIGHTS

- A proposed method to help patients identify trustful apps for diabetes self-care.
- A pictorial identification schema is used to review diabetes self-care apps.
- This method does not require specific skills.
- Two different profiles apply the tool on the selected apps and discuss the results.

# Advising patients on selecting trustful apps for diabetes self-

### care

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Running title: Identifying apps for patients with diabetes

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#### **ABSTRACT**

Background: There has been a dramatic increase in Mmobile apps for diabetes self-care-are dramatically increasing. However, neither their quality is not guaranteed and nor the patients do not have the appropriate tools for careful evaluation.

Objective: This work aims to propose a tool to <u>helpadvise</u> patients with diabetes selecting an <u>appropriate</u> their app for self-care.

Methods: After having-identifyinged the conceptual framework of diabetes self-care, we searched the U.S. Apple.S <u>US</u> <u>Aapp</u> <u>Ss</u>tore and reviewed the <u>diabetes self-care</u> apps, for diabetes self-care considering both generic and diabetes-specific features. <u>Based on an existing Starting from an already existing</u> tool for representing the benefits and weaknesses of medical apps, we created the <u>and used Pictorial Identification Schema/Diabetes Self-care tool, whichapictorial identification schema/diabetes\_specifically for identifyieding medical apps in the diabetes domain.</u>

Results: Of the 952 apps retrieved, 67 were for diabetes self-care, while 26 were excluded because they were not updated in the last 12 months. Of the remaining 41, none cost more than \$15 USD, and thirty six 36 implemented manual data entry. Basic features (data logging, data representation, and data delivery) were implemented in almost all apps, whereas advanced features (e.g., insulin calculator) were implemented in a small percentage of apps. The pictorial identification schema for diabetes Pictorial Identification Schema/Diabetes was completed filled in by one patient and one software developer for 13 apps. Both users highlighted weaknesses related to the functionalities offered and to their interface, but the patient focused on usability, whereas the software developer focused on technical implementation.

Conclusions: The Pictorial Identification Schema/Diabetes Self-care is a promising graphical tool for perceiving the weaknesses and the benefits of an app for diabetes self-care app that, also includesing the viewpoint of multiple user profile perspectives.

# **MeSH**-Keywords<u>:</u>

Medical informatics computing\_\*[L01.700.568]

Data **<u>Dd</u>**isplay\_\*[F02.784.412.221]

Mobile Aapplications [L01.224.900.685]

Diabetes <u>Mm</u>ellitus [C18.452.394.750]

Self\_-care [N02.421.784.680]

### 1. Introduction

Diabetes Mellitus (DM) is a major public health concern worldwide. A recent report from the International Diabetes Federation (IDF), an organization with that gathers about 2300,000 hundred national diabetes association members, notestateds that about 387 billions people is are affected by DM globally, and that related health expenditures were estimated to be at least USD 612 billion in 2014 [1].

Th DM, the concept of DM patient self-care at that also involves including the use of mobile applications or "apps,", has proved to be beneficial for patients [2]. While an agreedagreement on the definition of self-care is still under being discussed [3], the concept of self-care is about the active involvement of the patients in their own care and modifying their lifestyle behaviors. Patient self-care, including regular monitoring of blood glucose, was shown to improve glycemic control [4–6] and decreaseing glycosylated hemoglobin values.

Recent evidence shows that the use of mobile smartphone interventions to support self-care and blood glucose monitoring have beneficial effects that are; even better than those obtained with other computer-based tools [7,8]. Support from mobile technologies is effective in promoting physical activity in patients with diabetes [9], and is associated with a better control of the progression of ketosis to diabetic ketoacidosis in young people [10]. Even though thise evidence is has yet still to be confirmed [11], mobile smartphone applications that provideing reminders, disease monitoring, management, and education tools are thought to benefit both patients and health\_care professionals [12,13], especially if combined with a telemonitoring approach [14–16].

However, <u>coming from</u> the literature <u>shows that</u>, these results were based on apps and mobile interventions evaluated in controlled environments, using safe and reliable mobile tools and applications. Conversely, <u>at present</u>, the <u>app</u> market <u>of apps</u> is <u>currently</u> exploding [17], and about 100,000 thousands of health mobile apps are available oin the major <u>app</u> stores [18],

safety of such apps is still <u>being</u> underestimated [19–27] and there is a huge gap between <u>the</u> scientific results <u>on-for</u> the development and use of medical apps and the apps available in the stores [28]. In this scenario, <u>the-patients</u>, searching for an app to assist in <u>their diabetes</u> self-care <u>are</u>, is-likely to find hundreds of <u>options and experience difficulties results</u>, and faces the <u>problem of selecting the appropriate right-one for their needs</u>.

The problem of app selection is not only is related to the cost of the app, but also the it requires need to carefully evaluate ion of: the functionalities made available, ; theits responsiveness to the patients's needs, the reliability of the underlying information sources, and its; the usability and understandability [29,30]. Also, mMobile apps also suffer from several limitations -that are not easily detectable by an the inexperienced user, including the poor underlying clinical evidence, and its the integration with health-care information systems [31]. Regulatory bodies, despite the recent publication of Food and Drug Administration (FDA) guidelines on medical mobile apps [32]-, are still far from providing valuable tools that are able to identify, in an easy and understandable way, the weaknesses and benefits associated withto a single app, and helping the patients in selecting the best-best-suited or the least-ss-risky app [33]. Scientific reviews [26entific re, the opinions on reviewing site opinions (see http://medicapp.info/appmediche/ and http://www.imedicalapps.com), and some attempts from by UK National Health Services (NHS) to catalogue medical apps (http://www.nhs.uk/pages/healthappslibrary.aspx) are the only available choices for patients to perform a responsible decision-making on about the appropriate apps to download and use. Reviewing initiatives like iMedicalApps and MedicApp provide app ranking and evaluations from health\_care professionals or healthcare students who tested and used the app. They categorize apps according to their medical specialty and the operating system, and the apps are ranked by specialized health-care professionals ranked them by mapps are em (see http://www.imedicalapps.com). Even though this information is useful for the patients, they are

written from <a href="mathe-lealth\_care">athe</a> health\_care</a> professional\_<a href="mathe-perspective">perspective</a> projective</a> projective health may not have the same focus. In addition, it seems that the NHS catalogue is under discussion for improvements. The new objective for the catalogues is to provide the consumers/patients an endorsed set of health and social care mobile apps (https://www.gov.uk/government/publications/national-information-boards-workstreams).

Furthermore, at presenta few apps are <u>currently</u> available in the catalogue for diabetes self-care.

The "Ppictorial lidentification schema Schema (PIS)" for medical apps [35] proposes a one-shot user-oriented identity card able to represent the weaknesses and benefits associated to with an app. The pictorial identification schema PIS was thought designed as an evaluation tool that can be filled in-completed by any user profile (such as patients, health-care professionals, mHealth app developers, mHealth app promoters, or students, etc.) according to their specific skills and experience. The refore, the value of the pictorial identification schema PIS is hence related to the ""signature" of the author who filled incompleted the schema forms. The pictorial identification schema PIS identifies six attributes families (responsible promoters, offered services, searching methods, application domains, envisaged users, and qualifier and quantifiers) that each of them containing attributes defined from the review of the available apps. The schema uses a traffic -light color code to represent whether the implementation of a certain attribute represents a strength (green) or a weakness (red) for the app that is under evaluation. In its present stage, the pictorial identification schema PIS is still under being validatedion and the its dissemination strategies have yet are still to be exploited [35]. However, the pictorial identification schema PIS was designed by reviewing the apps in three medical domains: cardiology, oncology, and pharmaceutical. Even though the pictorial identification schema PIS included attributes that are relevant for all medical apps, it still needs to include some specialized focuses ations for other relevant medical conditions, including diabetes. Despite this limitation, given its graphical and intuitive interface, the concepts and the

practicalities belonging toof the pictorial identification schema PIS could be well suited for to give patients advice advising the patient in the selection of appropriate apps for diabetes self-management. This requires that the schemaires appropriate be submitted to a validation and revision process.

In this work, we propose and test a <u>Pictorial Identification Schema/Diabetes self-care</u>, <u>specialized for pictorial identification schema for diabetes</u> apps that can be used as a simple and easily understandable graphical tool to represent the strengths and the weaknesses related to apps for the self-care of diabetes. This specialized identification schema is created by adapting the previously\_proposed <u>pictorial identification schema PIS</u> [35], building on a model for diabetes self-care [36], and reviewing the <u>diabetes-related</u> apps <u>about diabetes</u> available on <u>the U.S. Apple 'pps -S.US Aapp</u> store, to extract the <u>app</u> characteristics of the <u>apps</u>. The schema is intended to be used to <u>give</u> advices <u>to patients willing to select an app for their diabetes self-care</u>.

### 2. Research design and methods

To define the specialization of the <u>pictorial identification schema-PIS</u> for diabetes self-care, we <u>proceeded followeding</u> an approach similar to that adopted for the definition of the original version of the schema [35]:

- 1\_- Definition of the conceptual framework for diabetes self-care, which aimed to identify the critical patient's actions that can be supported by functionalities in mobile health applications;
- 2<u>.</u>- <u>FR</u>eview of the available apps (in <u>the US</u>-Apple's <u>US aApp Ss</u>tore) for diabetes selfcare according to a set of defined characteristics;
- 3<sub>.</sub>- matching Matching between the diabetes self-care conceptual framework using mobile health apps to and the characteristics identified in the available apps aimed to define the specific attributes for of the Pictorial Identification Schema/Diabetes self-care tool one-shot pictorial schema/diabetes self-care app;
- 4<u>.</u>- <u>eE</u>xemplary use of the "one-shot pictorial schema/diabetes self-care" <u>toolapp</u> by two user profiles (a patient and a developer) for the evaluation of a small sample of apps.

### <u>2.1.</u> Conceptual framework

A conceptual model about for the self-care of a chronic disease, the heart failure, was presented by Riegel and Dickson [37]. In that model maintenance Maintenance and management are the main concepts in that model. The first one Maintenance relates to the monitoring of symptoms and treatment compliance in order to pursue and follow physiologic stability [37]. The second one Management relates to the patients'r decision-making actions when some symptoms occur [37]. A third component, i.e., confidence, is included in the model for representing the relationship between self-care and outcomes. Higher levels of self-care confidence relate to better patient self-care abilities [37]. In another research, thise model has been adapted for to describe DMing self-care of DM [36] with the The objective was to uncover the relationship between self-care and DM health outcomes; of DM, being the

glycaemic control was the main target and patient decision-making a crucial factor [36], in terms of maintenance and management as described by the model from Riegel and Dickson's [37] model. As we are looking for In our design of a Pictorial Identification Schema/Diabetes self-carepictorial identification schema for health mobile apps for managing diabetes, we propose a model of DM self-care that highlightsing the aspects of data collection and data analysis, as key aspects for to improving DM self-care of DM, when the process is mediated by mobile health apps.

According to the American Association of Diabetes Educators, managing diabetes includes several actions, such as making healthy food choices, being physically active, monitoring blood sugar, and taking proper medications as prescribed [38]. The rRegular communication with the diabetes care team is also important to support problem solving, to reduce risks for of complications, and to cope with lifestyle changes [38].

To this end, the mMultiple factors and activities to manage the disease properly

we concurre described on with different time scales, ranging from daily to long-term, in order to

properly manage the disease (Fig.ure 1).

These include blood-glucose tests, food intake, and physical activity management, which patients should perform that are to be performed daily by the patient him/her self, as well as their compliance to with therapies or medications for facing comorbidities, which that are conversely followed on a long-term basis. In Fig. 1, these activities are considered as input for the patients to integrate all information and decide the best actions to control their disease according to their best who, according to her/his knowledge, integrates all the information obtained and decides the best actions to control the disease (e.g., to select the proper medication). Information is tracked dDuring this decision-making process, the information is tracked: e.g. for instance, if the patient performs a blood-glucose test, thise information will be traditionally noted down oin a paper diary. O; other useful data are related to activities and food intake. This tracked information (called "logs") represents the present behavior of the patient

and is an output of the process (see\_bottom of FigureFig. 1). Some of the information collected in the logs can be part of the process inputs, which helping the patients with in their decision-making process, as represented by the "Feedback from ongoing status" arrow in the top of FigureFig. 1.

Figure 1 – Representation of the diabetes self-care process. To obtain the proper medication, thus controlling diabetes, the patient deals with daily and long-term measurements and therapies (left inputs). This information is used by the patient through his/her personal knowledge to decide the best actions to take, patient decision making (central arrow). During the whole process some information is tracked (process outputs). Also, the ongoing status is a feedback for the patient to possibly change his/her behavior (feedback arrow on the top).

More specifically, the term ""logs" refers to the fact that data are automatically stored without the human intervention and are intended to be used by a computer or another device.

For example, due to the hardware characteristics of smartphones, some mobile applications are able to record the smartphone ownercorphysical activityactivity—done by the smartphone owner, and their related calories consumption. In FigureFig. 1, the patients's ongoing status acts as a feedback, which and influences their decision about of the patient regarding the action to take.

Comparing our model (FigureFig. 1) with the DM self-care of DM in [36], patients decision-making about their self-care is affected by their his/her current health status, the daily evidence (self-care maintenance), and the long-term evidence (self-care management). Process logs are used to for support ing the patients decisions about their self-care. At each iteration, composed by the pairs of "decision" and "caction to take." pair, the patients self-care ability to self-care increases (self-care confidence).

Hence Therefore, a mobile application for diabetes self-management must, at the very least, implement data logging for heterogeneous types of data (blood-glucose, medication, activity, nutrition) [34]; however, when considering mobile devices, we also expect some additional functionalities, such as, for instance, graphically representing that the data collected

are both graphically represented on the screen (e.g., graphs, charts, etc.) and delivering it using ed (e-mail, text messages, or cloud services, etc.). These other functionalities can be summarized as data representation and data-delivery. The above-mentioned functionalities do not include any kind of "algorithm" or "algorithm" devoted to the interpretation or analysis of the data collected, represented, or delivered. An insulin dose calculator is an example of such "intelligence" Since decision-making models for the automatic interpretation of patient-related data in diabetes are still under being developedment [39], we considered functionalities that provide direct advice to patients as "advanced" features and did not include them in the "absice" features expected for a mobile app for diabetes.

HenceC, considering the framework shown in FigureFig. 1, we identified the basic features that a mobile app for diabetes self-management must implement, which are:

- 1. Delata logging: , store storing data in a permanent way for later use;
- 2. data Data representation, reliably representing the previously stored data on the deviceously sto the previously stored data; and 3.

<u>dD</u>ata delivery: <u>,</u> allowing <u>data</u> to <u>be</u> share <u>d</u> <u>data</u> with other people (e.g., family member, health\_care professional) <u>under in</u> multiple forms (e.g., text message, e-mail, cloud file).

## 2.2. Apps selection workflow

The Our research began started by considering all the related iPhone apps available in the Apple app.S. Aapp Sstore on April 1, 2014 being returned by searchquerying the the Apple Aapp Sstore using with the keyword "diabetes.". Since the keyword was generic, but the main target of our study was ere multi-featured apps dedicated to diabetes management both for both patients and health\_care professionals, we introduced some exclusion criteria. Apps were excluded from our analysis by the following criteria if: they :

- \* were a limited version (i.e., lite or free app) of an available fully\_-featured version; they were
  - \* supported only a single feature (e.g., insulin calculator only); they
- did not support any diabetes-specific data collection, archiving, and analysis for time-monitoring (e.g., glycated hemoglobin converter, pills reminder, etc.);
- their target was not diabetes self-management (e.g., generic health trackers, activity trackers, cooking apps, educational apps, etc.) or if diabetes self-management was an incidental-only element within the app; or if they
- \* were a content\_content\_consumption\_consumption\_only app (e.g., magazine, journal, etc.)\_;

Then, eConsidering the fast evolution of the app market, we also excluded apps that did not receive any up-dates during the 12twelve months prior to the search (i.e., from April the-1st, 2013 to March 31st, 2014). All the aApps meeting the inclusion criteria were used for our review. Then, aAmong these apps selected for our study, the a sub-set including the apps freely available for free and also available infrom the the Italian Appletal Italian Apple Aapp sStore wereas downloaded to let a direct test of the apps directly lication. We decided to download only the free apps available for free to let the users participate to in the study without incurring additional costs.

### 2.3. Reviewed attributes

According to our conceptual framework, we reviewed all the apps meeting our inclusion criteria <u>by</u> considering general features related to the mobile market (<u>such as app</u> pricing, app updates, etc.), and diabetes-specific features including basic features (data logging, data representation, and and data delivery), and advanced features (e.g., community services, insulin calculators, etc.) [26,34]. Then, www.

of the known reviewing initiatives (www.imedicalapps.com, http://medicapp.info/appmediche/,

 $\underline{\text{or}}\,\text{http://apps.nhs.uk/}). \text{ The full list of the}\underline{\text{se}}\,\text{ attributes is reported in Table 1}.$ 

The 2.4. The ".Pictorial Identification Schema/Diabetes self-care One shot pictorial schema for /diabetes self-care"

The one shot pictorial schema<u>PIS</u> is a graphical classification tool for mHealth apps that we proposed previously [35].

It defines six main families, which each include ing different attributes:

- Responsible promoters (medical systems companiesy, drug eompanycompanies, national services, hospitals, <u>pharmaciesdrugstores</u>, medical associations, <u>publisherspublishing companies</u>), representing who holds the major perceived responsibility on the app, <u>which and it does</u> not necessarily <u>be mean</u> the developer.
- Offered services (handbooks, guidelines, newsletters, calculators, forecasters,
   GeoHealth, simulators, others), representing the type of services/functionalities
   available in the app.
- 3. Searching methods (alphabetical order, images, predefined comparisons, multiple sources, chemical structures, <u>list</u> scrolling-of-lists, others), representing the tools for <u>""</u>consuming contents<sup>22</sup> available in the app.
- 4. Application domains (complex prescriptions, education, mobility, emergency, drug shortage, specific domain specialty, video manual), representing, besides the medical area, the domain in which the app is intended to be used.
- Envisaged users (students, citizens, professionals, others) that are the main user sategories.
- 6. Qualifiers and q& Quantifiers (download number, user satisfaction index, timing, significant testimonial), representing the factors that are mostly considered by non specialized users in evaluating the app evaluation.

To classify an app, a traffic light color-coded score has to beis assigned to each attribute. Attributes coded as red are to caveats for the potential user, whereas those coded as green are the strengths of the app. The yellow code means "something-in-between". The interpretation of the green and the red coding depends on the attribute family. For instance, ""offered services" are coded green when they are useful and appropriate for the field, whereas "searching methods" are coded green when they are not trivial and the result-set presentation is effective [35]. This implies that the schema was not intended to describe only what is provided by the app, but also to provide a judgment, from the viewpoint of the signee, on whether or not the feature/attribute is appropriate/works well. The pictorial identification schema can be filled in by any potential user type, who is required to what is provided by Any potential user type, who is required to "sign" the filled-in schema, can fill in the pictorial identification schema. The This signature is important because since-different profiles can judge the app differently (e.g., developer vs patient vs therapist).

A more detailed description of the Ppictorial identification schema, including the rules for color coding, is provided in [35].

According to the methodology developed in [35], starting from the review of the apps selected for our work, we defined new attributes specific to the diabetes domain and removed those that were not relevant to it. For example, in the "csearching methods" family, the "chemical structures" attribute is not relevant for diabetes self-care. That attribute indicates the possibility to browse chemical structures of drugs or other entities, e.g. e.g., proteins.

We then asked to a patient with diabetes and to a software developer to evaluate the subset of apps downloaded for free from the the Italian Apple'sane, the Italian Aapp sStore, and to fill incomplete the PISpictorial schema forms specific to for diabetes. As for the color-coded score, we adopted the same methods as described in [35]. For instance, as we considered an app the update of an app, a red label will be assigned if the app has not been updated for more

than the average updating time we defined above, a green label will be assigned if the updating time is equal to or less than the average (updates are more frequent), and a yellow label if the updating time is somewhere thing in the middle of the earlier or later times.

### 3. Results

### <u>3.1.</u> *App review*

The search ofn the U.S. Apple.S. <u>US</u> Aapp <u>s</u>Store using the keyword <u>""</u>diabetes <u>""</u> returned <u>sulted in-952</u> apps. Of those, <u>we identified 67 (7.03%)</u> the apps for <u>diabetes self-care-of</u> diabetes we identified were 67 (7.03%). However, 26 apps were excluded because <u>they were not</u> updated in the last 12 months, from April the 1<sup>st</sup>, 2013 to March the 31<sup>st</sup>, 2014- (<u>FigureFig. 2A</u>). <u>Forty-one apps were selected Aafter applying our exclusion criteria 41 apps were selected</u> (4.31%). The <u>se</u> 41 apps, which were updated in the <u>12twelve</u> months prior to our search, received, on average, 3.6 updates <u>on average</u>. Thisat means <u>that</u> an active (<u>""</u>living") application is <u>updated approximately updated every</u> 3 to 4 months.

Regarding Considering appthe pricing, in the set of the 41 selected 41 apps, there were none costing more than USD\$\_15. Twenty-seven apps (about 66%) were free; 8 apps -(about 20%) cost less than \$5, and 6 apps (about 14%) cost between \$5 and \$15 (FigureFig. 2B).

Regarding the data\_entry procedure, which is how the data is-was inserted into the application, the vast majority (36 apps) implementeds a manual data entry (FigureFig. 2C).

Seven percent; 7%-of apps (3 apps) supporteds data input from a wired glucose meter and 5% (2 apps) supportsed a wireless connection (via Bluetooth) between the glucose meter and the smart-phone.

FigureFig. 2D shows that the basic features that we defined in FigureFig. 1 (data logging, data representation, data and delivery) are were implemented in, at least, 50% of the apps. Other advanced features, like an insulin calculator or the presence of a community behind

the app, are were actually implemented in a really very small percentage of all the apps (17% and 12%, respectively).

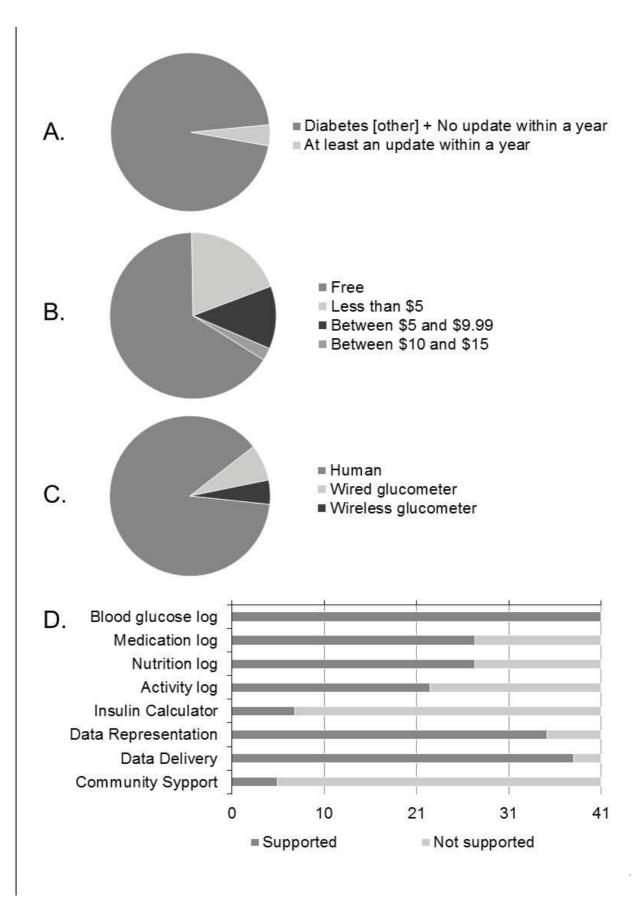


Figure 2—Results of the app review. A—Distribution of apps for diabetes self-management updated in the last year compared to the whole set of apps retrieved by the Apple's U.S. App Store using the "diabetes" keyword. B—Distribution of prices in the apps meeting the inclusion criteria. C—Distribution of the input methods in the apps meeting the inclusion criteria. D—Implemented features (light grey = function supported; dark grey = function not supported) in the apps meeting the inclusion criteria.

The full results on for all the 67 applications for diabetes self-care found in the US

AppleS iUS aApp sStore (before excluding those not updated) are available as in-a table in the

Supplementary Table 1 Material, in a table in which each row is dedicated to a single app that passed the selection workflow, and each column represents an attribute (see Section

2.3.Methods each row is dedicate).

3.2. The "Pictorial Identification Schema/Diabetes self-care one-shot pictorial schema for /diabetes self-care"

After reviewing the available apps, we identified the attributes relevant for diabetes self-care to be included in the <a href="mailto:new-Pictorial">new-Pictorial Identification Schema-/-Diabetes Self-care tool</a>.

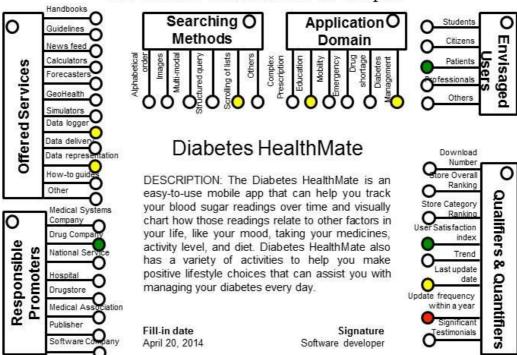
Since many of the apps reviewed were not promoted by a specific stakeholder (e.g.-e.g., hospital, scientific society); within the "responsible promoters" family, we added the attribute "private/independent/third?" party, "y. Wwithin the "offered services" family, we added those attributes identified in Fig. 1, namely "data logger, "data representation, "rand and delivery, and "sawell as the other attributes identified in the review ("community services" and "how-to guides"). In the "offered services" family, the "multiple source-modal queries" and "structured queries" attributes were added. In the "application domains" family, the "specific domain subspecialty" attribute was replaced by "diabetes management, "rand, we added the "patients" attribute in the "envisaged users" family. Finally, in the "qualifiers and & quantifiers and we replaced the "timing" attribute with

those related to the last update and the frequency of update. We added also the ranking attributes available in the Apple's butAapp store (""overall ranking" and ""category ranking").

The final setup of the <u>Pictorial Identification Schema/Diabetes self-care specialized</u>

pictorial identification schema specialized for diabetes self-care is represented in <u>FigureFig.</u> 3.

# A. Review of a software developer



# B. Review of a patient

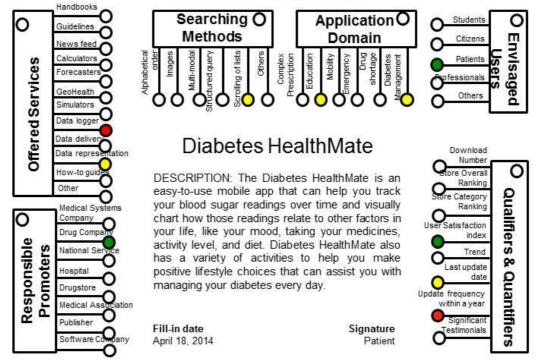


Figure 3 The Pictorial Identification Schema/Diabetes filled in for a sample app (Diabetes Health Mate). The schema defines six families, each with different attributes. An attribute colored in red means that the feature/function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if not pertaining to the examined app. In the center, the schema reports the name of the app, its description as available on the Apple Store, the date in which it was filled in and the signature of the author, in terms of user profile. A Pictorial Identification Schema/Diabetes filled in by a software developer. B

Pictorial Identification Schema/Diabetes self care filled in by a patient. Note the different colors chosen for the Data Logger attribute in the "Offered Services" family.

Using this specialized version of the <u>PISpictorial identification schema</u>, we asked to two different users with different profiles profiles (one patient and one developer) to evaluate some apps by completing filling in the schema forms. To this end, weWe asked them to download, among the 41 apps reviewed, the 13 apps freely those available in the the Italian AppletalItalian Apple Aapp Sstore for free from among the 41 apps reviewed(13 apps). Figure Fig. 3A and 3B show the schema filled incompleted by the two profiles for a sample app called "Diabetes HealthMate", i Thise app is meant to supports diabetic patients in managing their disease mainly through the logging of relevant data and the ability to inspect them on a chart. The app supports tracking and visualizing blood sugar readings tracking and visualization together with other information on the patient lifestyle and provides some suggestions for positive lifestyle choices.

These two profiles provided a different evaluation in the "offered services" family. In FigureFig. 3A, the ""data logger" attribute in the "offered services" family is colored in yellow, because even if all the data logs were ging are implemented, some of them are incomplete and not contextual with each single-blood-glucose test. Conversely, in FigureFig. 3B, the same attribute is red because the patient highlighted the fact that the interface is overloaded with information and the correct steps for adding a new data log are it is not immediately clear—which are the correct steps to perform in order to add a new data log.

When the two user profiles, a patient and a developer, reviewed the remaining 12 apps using the Pictorial Identification Schema/Diabetes self-carepictorial identification schema, their major disagreements were again in the "offered services" family (FigureFigs 4, 5, and Figures S1 and S2 in the Supplementary Material). Specifically, the "data logger" attribute is colored red 5 times out of 13 (according to the patientng assessment by the Patient), and 9 times out of 13 according to the developerme assessment by the Developer). In addition, another attribute that was frequently given obtained frequently thea red label is the "update frequency within a year" in the "qualifiers and quantifiers" family (for both of the assessments), asbecause some of the apps were updated a number of times less frequently than the average. The apps that were given obtained a red label for the "update frequency within a year" attribute were the same for the two profiles.

Assesment by the

Scrolling Lists Structured Query

bant - A diabetes app for the ePatient	DiabetesConnect - Diabetes Management	Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes
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Responsible Promoters										Attribute	Red	Yellow	Green
Responsible Promoters										occurrences		Label	Label
Medical Systems Company										0	0	0	(
Drug Company			3			- 12				1	0	0	
National Service					•					0	0	0	(
Hospital			3			in.				1	0	1	(
Drugstore										0	0	0	(
Medical Association			- N			66				1	0	1	(
Publisher										1	0	1	
Private/Independent/3rd-party										9	2	7	(
										Attribute	Red	Yellow	Green
Offered Services										occurrences	Label	Label	Label
Handbooks		2 8	8			S		8	12	0	0	0	(
Guidelines			8	8 8		2		8	10	0	0	0	(
News feed		2 8	8			5		8		0	0	0	(
Calculators			8			8			100	0	0	0	(
Forecasters		2 8	8	2 8		Š		8		0	0	0	
GeoHealth		3		8 8	100	8.			10	0	0	0	(
Simulators		9 5				8				0	0	0	(
Data Logger			U							12	9	1	- 2
Data Delivery			1.0							7	- 1	2	- 4
Data Representation										9	3	3	
Community Support		2 8			12	60				1	0	1	(
Multi-modal how-to guides										0	0	0	(
Others			-						- 8	0	0	0	(
Searching Methods										Attribute	Red	Yellow	Green
										occurrences		Label	Label
Alphabetical Order										0	0	102	(
Images		ž Ú				10				0	0		(
Multi-modal										0	0	0	(
	4	201		200		100	100		- 3	10			

Attribute

Red

Yellow

Green

Figure 4—The Pictorial Identification Schema/Diabetes Self-care filled-in for all the 13 apps by the Developer. The schema reports the six families, each with different attributes, filled in for each app. An attribute colored in red means that the feature/function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if not pertaining to the examined apps.

Assesment by the Patient	bant - A diabetes app for the ePatient	DiabetesConnect - Diabetes Management	Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes				
Responsible Promoters	1													Attribute	Red	Yellow	Green
	<u> </u>													occurrences 0	Label 0	Label	Label
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National Service			C - S					0. 8		0 0		5	2	0			
Hospital														1	0	1	0
Drugstore														0	1500	(67)	275
Medical Association														1			0
Publisher														1	- 22		0
Private/Independent/3rd-party					g 9			2 2						9	2	7	0
Offered Services														Attribute	Red		Green
Handbooks														occurrences 0		Label 0	Label
Guidelines		Š										8		0	0	0	
News feed		2										2	S 8	0			
Calculators		Š.	î î				5	î		ï		Š		0	0	0	
Forecasters		2	8				2	8 8				2	8 8	0	5 700	0	
GeoHealth		Q Q												0	. 03	0	
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Data Logger							-			t - 4				7		2	
Data Representation								2 3		9		2	8 3	9	5 633	2	
Community Support														1	. 200		
Multi-modal how-to guides														0	0	0	0
Others														0	0	0	0
Searching Methods														Attribute	Red	Yellow	Green
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Multi-modal			* -					*					* -	0		A	
Scrolling Lists										9			50	12	4	6	
Structured Query														0	953	0	1.00
Others														0	0	0	0
Application Domains																	Green
37.77														Attribute	Red	Yellow	
Complex Prescription	1 -											-		occurrences	Label	Label	Label
Education														occurrences 0	Label 0	Label 0	0
Education Mobility														occurrences	Label 0	Label 0	0
Education Mobility Emergency														occurrences 0 1	Label 0 0 0	Label 0	0
Mobility			20 2 20 2 20 2 20 2 20 2					22 3 25 3 45 3 45 3 45 3						occurrences 0 1 0 0 0	0 0 0 0 0	0 1 0 0 0	0 0 0
Mobility Emergency														occurrences 0 1 0 0	0 0 0 0 0	0 1 0 0	0 0 0
Mobility Emergency Drug shortage														0 0 0 0 12	0 0 0 0 0 0 4	0 1 0 0 0 0	000000000000000000000000000000000000000
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Mobility Emergency Drug shortage Diabetes Management  Envisaged Users Students Citizens														occurrences 0 1 0 0 0 12 Attribute occurrences 0 0	Label	Label	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Mobility Emergency Drug shortage Diabetes Management  Envisaged Users Students Citizens Patients Professionals Others														occurrences 0 1 0 0 0 12 Attribute occurrences 0 11 1 0	Label	Label	Green Label 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
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Mobility Emergency Drug shortage Diabetes Management  Envisaged Users Students Citizens Patients Professionals Others  Qualifiers & Quantifiers Download Number Store Overall Ranking Store Category Ranking User Satisfaction Index Timing frame / trend / temporal pattern Seasonality				N.A.										Occurrences	Label	Label	Green Label

Figure 5—The Pictorial Identification Schema/Diabetes filled-in for all the 13 apps by the Patient. The schema reports the six families, each with different attributes, filled in for each app. An attribute colored in red means that the feature/function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if not pertaining to the examined apps.

### **Discussion**

In this work, we proposed and tested a <u>Pictorial Identification Schema/Diabetes self-care that can be carepictorial identification schema</u> for apps addressing diabetes self-care that can be <u>cfilled-inompleted</u> by heterogeneous profiles, users (<u>e.g. e.g., patients, and health-care professionals</u>) and <u>smart mobile device experts of the mobile domain (e.g. e.g., developers, and interface designers), and can <u>serve to advisegive advice to patients about in selecting the appropriate app to be confident in under the advice of <u>her/histheir</u> therapist.</u></u>

When we reviewed the apps available on the US-Apple we US Aapp Sstore for diabetes self-management, we found that only 7% of all the apps under identified using the "diabetes" keyword were intended for to supporting the patients's management of the disease. On Following this their review, we based the identified some cation of new attributes to specialize fy the pictorial identification schema. The results of our review showed that, interestingly, no single application costs more than \$15. Even though the mobile app market is usually cheap, diabetes is a specific condition in which patients are also motivated also to spend money to improve their quality of life. Hence, we could have expected an app market including with apps more expensive than \$15, but this was not the case, and app prices were affordable for all users. Moreover, data entry was manual in the majority of the reviewed apps, even though it is prone to human errors. For example, Let us make the case of a patient tests his blood -glucose when as he wakes up in the morning and finds that the value is 250 mg/dL, which indicates (hyperglycaeemia), but he erroneously inserts 150 mg/dL into the application. That single value is going towould severely impact not only the daily average, but also the weekly average and possibly more. Another possible error would be to insert 250 mg/dL for a different another time or date than the testit was tested; again, that would is going to compromise the validity of the data. Automatic data entry is only possible when the app directly communicates with a glucose meter, but this procedure is subject to compatibility issues, including those between the app and the operating system, M: mobile operating systems (such as iOS, Android and the rest of operating environments, Windows) usually receive a major update once a year and possibly

minor updates throughout the rest of the year. This means that <u>unless either</u> the developer of the <u>app for diabetes self-care app</u> is as fast as Apple, Google, and Microsoft and the rest, in releasing an updated version of the app <u>on</u> the very same day an operating system update is released, <u>or</u> the app\_lication is may be s-subject to possible compatibility issues and might <u>cause</u> malfunctioning, <u>where cC</u>rashes and incorrect behaviors cannot be excluded <u>in these</u> circumstances.

Regarding the available app features, our results showed that only basic features (i.e., data logging of data, data representation, and data delivery) are were implemented in all of the reviewed the apps we reviewed, whereas advanced features (e.g., insulin calculator, community support) awere rare. Hence Therefore, at present, the mobile applications for diabetes self-care that which constantly receive updates currently implement only basic features, which are still effective for a proper management of the disease, but do not really exploit the full potential of the mobile technology by offering users an advanced multi-featured experience to the user. For the sake of the truth, wWe have to note mention that some people may use multiple, single single-function apps to suit their different needs (e.g. e.g., they may have a data data-logging app, an insulin dose calculator, and a peer communication app in their collection), but this selection of applications would require the hand transcription of some data, which may that may become a source of typos, with unexpected consequences.

Schema/Diabetes Self-care toolPictorial Identification Schema for Diabetes Self-care, we asked to two different user types user profiles to fill it in to complete their profiles. The first user profile was the patient, who is the natural target of the schema. The second one-was the developer. We chose these profiles because This choice was based on the fact that both regulatory bodies (such as the FDA; [32]) and scientific framework proposals of frameworks to ensure medical app quality [27] are based on the declarations of the app developers regarding their apps. Hence Therefore, after the adoption of the pictorial identification schema PIS and in the light of a "fresponsible app development" [27], the app developers would will-likely

provide the an evaluation of their his/her apps. Another possible user profile to be involved would have been a the diabetes expert. However, he/shethe diabetes expert would have provided a judgment similar to that one ose available in on the peer-reviewing sites and, for this reason, we decided not to include the this profile in theis preliminary testing.

Even though with a limited sample size of potential users, our exploratory testing on 13 apps showed that different user profiles have different approaches to their judgments about what action to take to manage their disease, and, as for the original pictorial identification schema, the profile of the user who completes fills in the schema is relevant. In our experiment, the strategy used by the two profiles differed because since the developer had a greater consideration of the function of the appearsidered more the functional viewpoint (which features are implemented and whether they work the way they are supposed to) whereas the patient had a viewpointwas focused on the usability and interfaces of the app (how the features are presented and the overall user experience). HoweverIn fact, the main differences in the user judgments were in the "coffered services." the The patient tended to highlight criticisms in the developer tended to highlight whether or not a specific functionality works. Interestingly, both user profiles provided a red label for the "cupdate frequency within a year" attribute for the same apps, thus which suggests that both evaluators perceive the perception of this attribute as a critical factor is the same for both evaluators.

The possibility to haveof multiple evaluations from different profiles would enrich the information and knowledge grounding the patients's decision-making process. Each app should will be associated with to more than one pictorial identification schema, according to the number of reviews that it will receive. The multiple viewpoints expressed by the different filled incompleted schemas will let the patients having an idea on understand the different weaknesses or strengths of the app and, in turn, perform a more informed and responsible choice.

Our search of the Apple Apple Apple store was done performed on the April 1st, 2014.

As more than a year has passed, we considered repeating the our search so that we could. In

that way we could have included updated results in the paper-some updated results. However,
Apple has since changed something has changed in the way search the results of a search oin the
Apple Aapp'p store are retrieved and presented. A limit to the number of results has been set
according to the application program interface (API) for executing searches in the Apple'ps
aApp'p store [40], a limit to the number of results has been set. The default limit value of the
limit isfor search results is 50, while a value from 1 to 200 can be assigned to it [40]. It This
means that less—popular apps will not be included and displayed in the result—set. As a
consequenceConsequently, a lower number of apps could be retrieved and analyzed., while
oQur original search using the keyword "diabetes" resulted in 952 apps. On November 9,
2015, we performed a keyword search using "diabetes self-care" as a key search on the US
Apple'pples aApp'p Sstore and found two Two apps have been found.

The issue of an effective dissemination strategy for the schema remains open. As already discussed in [35], the most important point is how to reach the users and how to make the pictorial identification schema PIS rapidly known to the general public quickly. The way of the Using standardization bodies was recognized as being innot effective because of their due to the different scales; in terms of time, but also paperwork, between the definition of a norm, the certification process, and the app development market. Conversely, the possibility of creating specific repositories guided by pictorial identification schemas, in which the patient can choose medical apps, guided by Pictorial Identification Schemas seems more feasible. These might be ad-hoc repositories, organized as pharmacy shelves, where the patient can find only apps already tested and evaluated through the pictorial identification schema PIS that will serves to guide their choices as a guide for the choice. However, this idea currently has no This is however only an idea that, at present, does not have any practical applications.

Finally, the pictorial identification schema Pictorial Identification Schema/Diabetes self-care is an easily understandable way to map all of the apply underthe features so they can be seen at a glance for the user in an at a glance view regarding each single app. One of the strengths of this approach is the possibility of to have multiple stakeholders completing the

schemafilling it in, which provides different perspectives on thus providing different viewpoints on the app, as, e.g. for instance, the functional or the usability viewpoints. This implies that the user who is searching for a trustful app can use the wishing to download the app can have, through the pictorial identification schema\_Pictorial Identification Schema/Diabetes self-care to see the arreviews of the app by from multiple profiles, including that from other users.

### 5. Conclusion

In conclusion, www e showed that there are several available apps for patients with diabetes are many, but that those supporting diabetes self-management only implemented basic, and someway non-risky, functions, whereas the more-advanced functions that are more useful for patient self-care in a context in which the uncertainties and the traceability are unavoidable, are have not been not implemented yet. In this arena, our proposed the Pictorial Identification Schema/Diabetes Self-care tool pictorial identification schema we propose is an easy and intuitive tool to for potential patient users to be guided into guide the patient, as possible user, in perceiving the weaknesses and the benefits of the apps and ultimately makeing a responsible choice.

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The results of the study were partially presented to the Conference Apps for Medicine Health and Home Care Market. Conversely, the possibility of creating specific repositoriesity issues meeting the inclusioy. (http://www.ehealth.polimi.it/appqa.asp). This research received no specific grant from any funding agency in the public, commercial, or not for profit sectors.

# AUTHOReh received nConflict of interest-STATEMENT

The authors report nNo competing financial interests exist.

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## **TABLES AND FIGURES CAPTIONS**

## Table 1

-Full list of the attributes considered for reviewing each selected app.

Table 1 - Full list of the attributes considered for reviewing each selected app.

<u>Attributes</u>		<u>Definitions</u>							
		The date of last update. If the date of last update is							
	<u>Last update</u>	prior to 12 months ago, then the app —is discarded							
		from further analysis.							
	<u>Frequency</u>	The total number of updates the app received within							
	within last 12	the last 12 months.							
	<u>months</u>	the last 12 months.							
	<u>SApp store</u>	In which international store (United States, Italy or							
	<u>orthington</u>	both) the app is available for download.							
<u>General</u>		Which price tier the app falls into ("Free", " "Less							
<u>Aattributes</u>	Price tier	than \$5"-," -"Between \$5 and \$9.99"-," -"Between \$10							
		and \$15", or "More than \$15").							
	<u>In-app</u>	The app offers additional features through an in-app							
	<u>P</u> purchase	<u>purchase-or-not.</u>							
	Optimization	The app is supported by and optimized both-for							
	for iPad (iOS	iPhone and but also for iPad.							
	<u>Universal)</u>	in Herio							
	<u>Android</u>	The app is also available for Android in the Google							
	<u>r maroid</u>	Play app sStore.							
<u>Diabetes</u>	<u>Diabetes type-</u>	Whether the app supports "type 1" diabetes, "type							
Diabetes	<u>1 vs. 2</u>	2" diabetes or "both"."							

<u>Aattributes</u>		A dDiabetes-related data can be entered into a mobile
	Data-entry	app in different ways ( <u>""human"</u> , " <u>""wired</u>
	procedure	glucometer", " "wireless glucometer", " "continuous
		glucose monitoring — CGM-system".").
		Diabetes can be treated with different therapies so
	Therapy mode	apps can implement different alternatives. (-"insulin
	THEIRPY HIOGE	pen"," ""insulin pump"," "oral pills"," ""multiple
		<u>modes",," ""N-A."")</u>
		Blood_glucose log: logging of blood glucose readings:
		Medication log: logging of medications adopted to
		manage diabetes:
		Nutrition log: logging of nutrition parameters:
		Activity log: logging of physical activity:
		Insulin calculator;
	<u>Features</u>	Data representation: the app allows to represent at
		least some of the data previously logged:
		Data delivery: the app implements the ability to share
		data:
		Community sSupport: the app is built around a
		community.
		NHS: the app was reviewed by the ""UK NHS"
Contributing		(http://apps.nhs.uk);
Contributing	Reviewing	iMedicalapps: the app was reviewed by
quality	<u>s</u> Sites	<u>""iMedicalapps"</u> (http://www.imedicalapps.com):
<u>initiatives</u>		Medicapp: Specifies whether the app was reviewed
		by ""Medicapp" (http://medicapp.info/appmediche/).

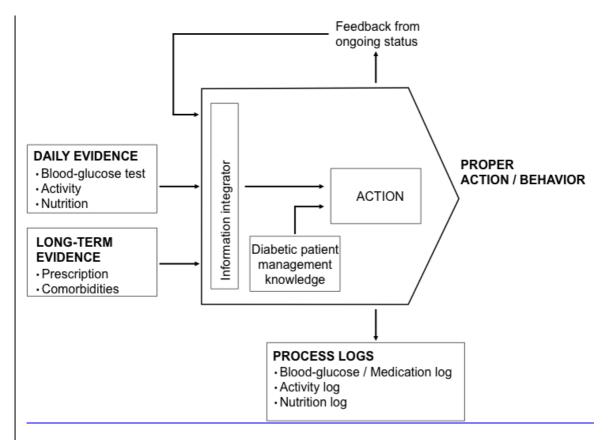


Figure Fig. 1.—Representation of the diabetes self-care process. To obtain the proper medication, thus controlling diabetes, the patients deals with daily and long-term measurements and therapies (left inputs). This information is used by the pPatients through use his/hertheir personal knowledge to assess this information and decide the best actions to take during their, patient decision-making (central arrow). During the whole processprocess, some information is tracked (process outputs). Also, the ongoing status gives patients is a feedback for the patient toso that they can possibly change his/hertheir behavior (feedback arrow on the top).

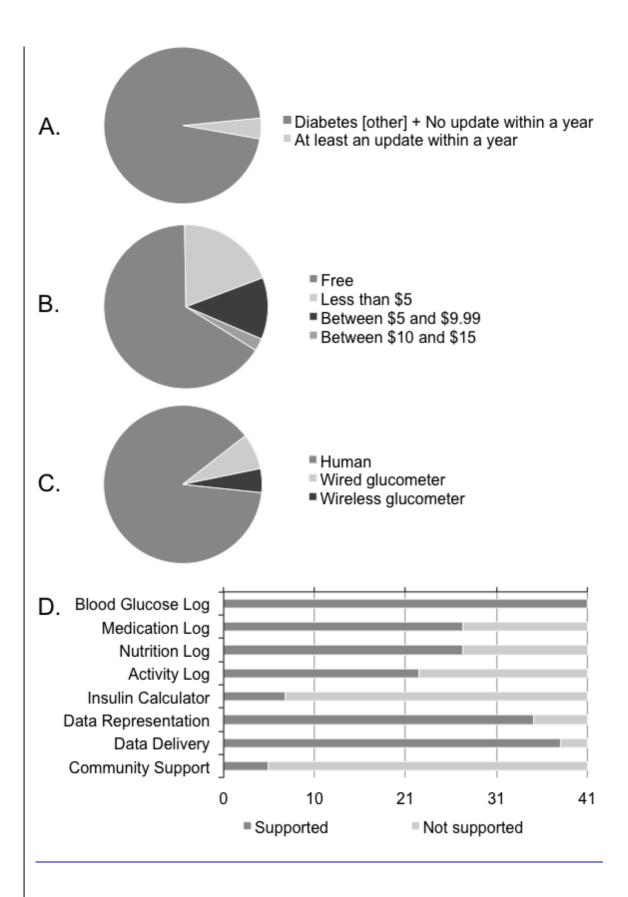
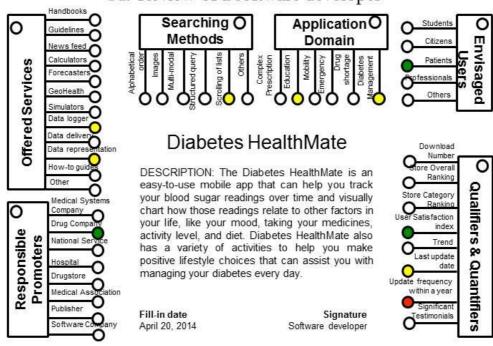
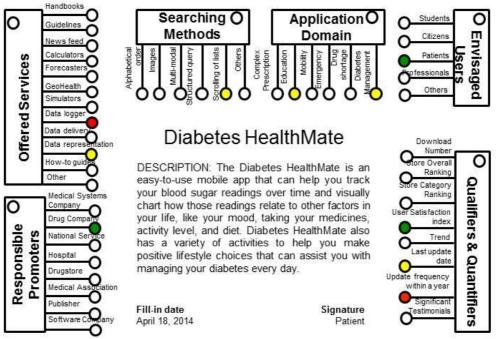


Figure Fig. 2.— Results of the a pp review results. (A)— Distribution of apps for diabetes self-management updated in the last year compared with to the complete whole set of apps retrieved from by the Apple's US a.S. App Sstore using the keyword, ""diabetes." (keyword. B)— Distribution of prices in the apps meeting the inclusion criteria. (C)— Distribution of the input methods in the apps meeting the inclusion criteria. (D)— Implemented features (light grey = function supported; dark grey = function not supported) in the apps meeting the inclusion criteria.

# A. Review of a software developer



# B. Review of a patient



FigureFig. 3.— The Pictorial Identification Schema/Diabetes Self-care tool completed filled in for a sample app (Diabetes Health-Mate). The schema defines six families, each with different attributes. An attribute coloured in red means that the feature or function is implemented in the app with strong weaknesses, whereas the green colour means that the implementation has no weaknesses. An attribute is not coloured if not pertaining to the examined app. In the centere, the schema reports the name of the app, its description as available on the Apple's app Setore, the date in which it was completed filled in, and the signature of the author, in terms of user profile. (A)—Pictorial Identification Schema/Diabetes Self-care tool completed by filled in by a software developer. (B)—Pictorial Identification Schema/Diabetes Self-care tool completed filled in by a patient. Note the different colours chosen for the data logger attribute in the ""offered services" family.

FigureFig.

developer fi

each with d

Assesment by the Developer

bant - A diabetes app for the ePatient DiabetesConnect - Diabetes	<u>a</u>	Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes
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Responsible Promoters								Attribute occurrences	Red Label	Yellow Label	Green Label
Medical Systems Company								0	(	) (	) (
Drug Company				8				1	(	) (	
National Service			•					0	(	) (	
Hospital				5			į.	1	. (	)	1
Drugstore								0	(	) (	
Medical Association								1	(	)	
Publisher								1	(	)	1
Private/Independent/3rd-party							T (	9	1	2	7

Offered Services				 				Attribute occurrences	Red Label	Yellow Label	Green Label
Handbooks		5 8		2	3 8			0	0	C	0
Guidelines	10	2 8		ă	3 3	8		0	0	C	0
News feed		5 5			5 5			0	0	C	0
Calculators	18	9 8	8	8	9 1	8	1	0	0	C	0
Forecasters		3 8			3 3			0	0	C	0
GeoHealth	18	2 8		5	3 3		18	0	0	C	0
Simulators		3 3		Š				0	0	0	0
Data Logger								12	9	1	2
Data Delivery		0 0 0 0						7	1	2	4
Data Representation								9	3	3	3
Community Support	25	8 8						1	0	- 1	0
Multi-modal how-to guides								0	0	C	0
Others	10							0	0	0	0

Searching Methods	100	 		100			100	Attribute occurrences	10000000	Yellow Label	Green Label
Alphabetical Order						1		0	0	(	0
Images	- 1			- 1				0	0	(	0
Multi-modal								0	0	(	0
Scrolling Lists			- 1					12	- 4	(	3 2
Structured Query								0	0	(	0
Others	- 15		- 3					0	0	(	0

Application Domains						Attribute occurrences	Red Label	Yellow Label	Green Label
Complex Prescription						0	(	) (	) (
Education						1	(	)	1 0
Mobility						.0	(	) (	) (
Emergency						0	(	) (	) (
Drug shortage						0	(	) (	0
Diabetes Management						12			3 2

Envisaged Users									Attribute occurrences		Charles and the Control	Green Label
Students		8	9 1	8	ă.	2 :	8		0	0	0	0
Citizens		2			2				0	0	0	0
Patients									11	0	0	11
Professionals		9	8 8	0 0 R 8	9				1	0	0	1
Others									0	0	0	0

colored in r weaknesses

attribute is 1

Qualifiers & Quantifiers								Attribute occurrences	Red Label	Yellow Label	Green Label
Download Number								0	0	) (	)
Store Overall Ranking								0	C	) (	)
Store Category Ranking	- 1	100						0	C	) (	)
User Satisfaction Index		N.A.						7	1	10	
Timing frame / trend / temporal pattern		- S			ii .			0	C	) (	)
Seasonality								0	C	) (	)
Last Update Date								13	C	10	)
Update Frequency within a year								13	8	3	3
Significant Testimonials						-		0	C	) (	)

Assesment by the Patient	bant - A diabetes app for the ePatient	DiabetesConnect - Diabetes Management	Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes					
Responsible Promoters														Attribute occurrences	Red Label	Yellow Label	Green Label	1
Medical Systems Company		Г			Г	Г				Г	Г			0	-	_	-	1
Drug Company														1		0	0	1
National Service														0				
Hospital													1	1		-	1 (	
Drugstore						<u> </u>				_				0		100	0 0	
Medical Association Publisher	5 5				4 6				4 2		_	g - 2		1			1	-
Private/Independent/3rd-party						-								9				
r ivate/independent/ord-party																-1	11	1
Offered Services					110 so			-5		v				Attribute occurrences	Red Label	Yellow Label	Green	Ī
Handbooks								-						0		0	0 (	4
Guidelines														0				2
News feed											_			0			0 0	_
Calculators Forecasters	2 8 2 8									$\vdash$	$\vdash$			0	_		0 0	2
GeoHealth	-		1			_			-	$\vdash$	$\vdash$		-	0		-		1
Simulators											$\vdash$			0		_	_	5
Data Logger														12		5	5 :	2
Data Delivery														7		2		3
Data Representation														9	_			3
Community Support											_			1			12	)
Multi-modal how-to guides										<u> </u>	_			0	_		0 0	
Others						_							7			U	0	1
Searching Methods														Attribute occurrences	Red Label	Yellow Label	Green	Ì
Alphabetical Order				Ť –	г	Г				$\overline{}$				0			0 (	1
Images														0		0	0 (	0
Multi-modal														0		0		9
Scrolling Lists														12				2
Structured Query											_			0			00	2
Others				,						Ь.		2 2		0		0	0	1
Application Domains														Attribute occurrences	Red Label	Yellow	Green	Ī
Complex Prescription	-				П					$\Box$				Occurrences		_	0 (	1
Education														1		0	1 (	7
Mobility														0		~	-	9
Emergency														0	_		0 (	4
Drug shortage														0	_		0 0	4
Diabetes Management														12		4	6	2
Environed Hoors														Attribute	Red	Yellow	Green	1
Envisaged Users														occurrences		Label	Label	ļ
Students						_					<u> </u>			0			0 (	2
Citizens Patients		- 1												11	_		0 1	4
Professionals														1				1
Others														0				
														Attribute	Red	Yellow	Green	Ī
Qualifiers & Quantifiers														occurrences		Label	Label	1
Qualifiers & Quantifiers				_	_	$\overline{}$	$\overline{}$					1				O.		
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Download Number Store Overall Ranking														0		0	0 (	2
Download Number				N.A.										0		0	0 (	9
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Download Number Store Overall Ranking Store Category Ranking User Satisfaction Index Timing frame / trend / temporal pattern Seasonality				N.A.										0 0 7 0		0 0 1 0 0 0	0 0 0 1 1 5 0 0 0 0 0 0 0 0 0 0 0 0 0 0	5
Download Number Store Overall Ranking Store Category Ranking User Satisfaction Index Timing frame / trend / temporal pattern				N.A.										0 0 7 0		0 0 1 0 0 0	0 0 0 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0

**FigureFig. 5.**— The Pictorial Identification Schema/Diabetes Self-care tool completed by the patient filled in for all the 13 apps by the Patient. The schema reports the six families, each with different attributes, which have been completed filled in for each app. An attribute colored in red means that the feature or function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if it does not pertaining to the examined apps.

## HIGHLIGHTS

- A <u>proposed</u> method to help patients identify <u>trustful</u> apps for diabetes self-care is <u>proposed</u>.
- This method is based on a pictorial identification schema is used to and on a revieww of existing apps for diabetes self-care apps.
- This method does not require specific skills.
- The method has been applied by tTwo different user profiles apply the tool on the a set of selected apps and discuss the the results discussed.

Advising patients on selecting trustful apps for diabetes self-

care

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**Running title:** Identifying apps for patients with diabetes

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#### **ABSTRACT**

Background: There has been a dramatic increase in mobile apps for diabetes self-care.

However, their quality is not guaranteed and patients do not have the appropriate tools for careful evaluation.

*Objective:* This work aims to propose a tool to help patients with diabetes select an appropriate app for self-care.

*Methods:* After identifying the conceptual framework of diabetes self-care, we searched Apple US app store and reviewed diabetes self-care apps, considering both generic and diabetes-specific features. Based on an existing tool for representing the benefits and weaknesses of medical apps, we created the Pictorial Identification Schema/Diabetes Self-care tool, which specifically identified medical apps in the diabetes domain.

Results: Of the 952 apps retrieved, 67 were for diabetes self-care, while 26 were excluded because they were not updated in the last 12 months. Of the remaining 41, none cost more than 15 USD, and 36 implemented manual data entry. Basic features (data logging, data representation, and data delivery) were implemented in almost all apps, whereas advanced features (e.g., insulin calculator) were implemented in a small percentage of apps. The pictorial identification schema for diabetes was completed by one patient and one software developer for 13 apps. Both users highlighted weaknesses related to the functionalities offered and to their interface, but the patient focused on usability, whereas the software developer focused on technical implementation.

Conclusions: The Pictorial Identification Schema/Diabetes Self-care is a promising graphical tool for perceiving the weaknesses and benefits of a diabetes self-care app that includes multiple user profile perspectives.

Keywords:

Medical informatics computing [L01.700.568]

Data display [F02.784.412.221]

Mobile applications [L01.224.900.685]

Diabetes mellitus [C18.452.394.750]

Self care [N02.421.784.680]

#### 1. Introduction

Diabetes mellitus (DM) is a major public health concern worldwide. A recent report from the International Diabetes Federation, an organization with about 230 diabetes association members, noted that about 387 billion people are affected by DM globally, and that related health expenditures were estimated to be at least USD 612 billion in 2014 [1].

The concept of DM patient self-care, including the use of mobile applications or "apps," has proved to be beneficial for patients [2]. While agreement on the definition of self-care is still being discussed [3], the concept of self-care is about the active involvement of patients in their own care and modifying their lifestyle behaviors. Patient self-care, including regular monitoring of blood glucose, was shown to improve glycemic control [4–6] and decrease glycosylated hemoglobin values. Recent evidence shows that the use of smartphone interventions to support self-care and blood glucose monitoring have beneficial effects that are even better than those obtained with other computer-based tools [7,8]. Support from mobile technologies is effective in promoting physical activity in patients with diabetes [9], and is associated with a better control of the progression of ketosis to diabetic ketoacidosis in young people [10]. Even though this evidence has yet to be confirmed [11], smartphone apps that provide reminders, disease monitoring, management, and education tools are thought to benefit both patients and health-care professionals [12,13], especially if combined with a telemonitoring approach [14–16].

However, the literature shows that these results were based on apps and mobile interventions evaluated in controlled environments using safe and reliable mobile tools and applications. Conversely, the app market is currently exploding [17] and about 100,000 health mobile apps are available in the major app stores [18], including apps for diabetes self-management. In addition, the problem of the reliability and safety of such apps is still being underestimated [19–27] and there is a huge gap between the scientific results for the development and use of medical apps and the apps available in the stores [28]. In this scenario, patients searching for an app to assist in their diabetes self-care are likely to find hundreds of options and experience difficulties selecting the appropriate one for their needs.

The problem of app selection is not only related to the cost of the app, but also the need to carefully evaluate the functionalities made available, its responsiveness to the patients' needs, the reliability of the underlying information sources, and its usability and understandability [29,30]. Mobile apps also suffer from several limitations that are not easily detectable by an inexperienced user, including poor underlying clinical evidence and its integration with healthcare information systems [31]. Regulatory bodies, despite the recent publication of Food and Drug Administration (FDA) guidelines on medical mobile apps [32], are still far from providing valuable tools that are able to identify, in an easy and understandable way, the weaknesses and benefits associated with a single app, and helping patients in selecting the best-suited or the least-risky app [33]. Scientific reviews [26], reviewing site opinions (see http://medicapp.info/appmediche and http://www.imedicalapps.com), and some attempts by UK National Health Services (NHS) to catalogue medical apps (http://www.nhs.uk/pages/healthappslibrary.aspx) are the only available choices for patients to perform responsible decision-making about the appropriate apps to download and use. Reviewing initiatives like iMedicalApps and MedicApp provide app ranking and evaluations from health-care professionals or students who tested and used the app. They categorize apps according to their medical specialty and operating system, and the apps are ranked by specialized health-care professionals (see http://www.imedicalapps.com). Even though this information is useful for patients, they are written from a health-care professional perspective, which may not have the same focus. In addition, it seems that the NHS catalogue is under discussion for improvements. The new objective for the catalogues is to provide the consumers/patients an endorsed set of health and social care mobile apps (https://www.gov.uk/government/publications/national-information-boards-workstreams). Furthermore, a few apps are currently available in the catalogue for diabetes self-care.

The Pictorial Identification Schema (PIS) for medical apps [35] proposes a one-shot user-oriented identity card able to represent the weaknesses and benefits associated with an app. The PIS was designed as an evaluation tool that can be completed by any user profile (such as

patients, health-care professionals, mHealth app developers, mHealth app promoters, or students) according to their specific skills and experience. Therefore, the value of the PIS is related to the "signature" of the author who completed the schema forms. The PIS identifies six attribute families (responsible promoters, offered services, searching methods, application domains, envisaged users, and qualifier and quantifiers) that each contain attributes defined from the review of the available apps. The schema uses a traffic light color code to represent whether the implementation of a certain attribute represents a strength (green) or a weakness (red) for the app under evaluation. In its present stage, the PIS is still being validated and its dissemination strategies have yet to be exploited [35]. However, the PIS was designed by reviewing the apps in three medical domains: cardiology, oncology, and pharmaceutical. Even though the PIS included attributes that are relevant for all medical apps, it still needs to include specialized focuses for other relevant medical conditions, including diabetes. Despite this limitation, given its graphical and intuitive interface, the concepts and the practicalities of the PIS could be well suited to give patients advice in the selection of appropriate apps for diabetes self-management. This requires the schema's attributes be submitted to a validation and revision process.

In this work, we propose and test a Pictorial Identification Schema/Diabetes self-care, specialized for diabetes apps that can be used as a simple and easily understandable graphical tool to represent the strengths and the weaknesses related to apps for the self-care of diabetes. This specialized identification schema is created by adapting the previously proposed PIS [35], building on a model for diabetes self-care [36], and reviewing the diabetes-related apps available on Apple's US app store to extract the app characteristics. The schema is intended to be used to give advice to patients willing to select an app for their diabetes self-care.

#### 2. Research design and methods

To define the specialization of the PIS for diabetes self-care, we followed an approach similar to that adopted for the definition of the original version of the schema [35]: 1. Definition

of the conceptual framework for diabetes self-care, which aimed to identify the critical patient actions that can be supported by functionalities in mobile health applications; 2. Review of the available apps (in Apple's US app store) for diabetes self-care according to a set of defined characteristics; 3. Matching the diabetes self-care conceptual framework using mobile health apps to the characteristics identified in the available apps to define the specific attributes for the Pictorial Identification Schema/Diabetes self-care tool; 4. Exemplary use of the one-shot pictorial schema/diabetes self-care tool by two user profiles (a patient and a developer) for the evaluation of a small sample of apps.

#### 2.1. Conceptual framework

A conceptual model for the self-care of a chronic disease, heart failure, was presented by Riegel and Dickson [37]. Maintenance and management are the main concepts in that model. Maintenance relates to the monitoring of symptoms and treatment compliance to pursue and follow physiologic stability [37]. Management relates to the patients' decision-making actions when some symptoms occur [37]. A third component, i.e., confidence, is included in the model for representing the relationship between self-care and outcomes. Higher levels of self-care confidence relate to better patient self-care abilities [37]. In other research, this model has been adapted to describe DM self-care [36] with the objective to uncover the relationship between self-care and DM health outcomes; glycemic control was the main target and patient decision-making a crucial factor [36] in terms of maintenance and management as described by Riegel and Dickson's [37] model. In our design of a Pictorial Identification Schema/Diabetes self-care, specialized for, we propose a model of DM self-care that highlights the aspects of data collection and analysis as key to improving DM self-care when the process is mediated by mobile health apps.

According to the American Association of Diabetes Educators, managing diabetes includes several actions, such as making healthy food choices, being physically active, monitoring blood sugar, and taking proper medications as prescribed [38]. Regular

communication with the diabetes care team is also important to support problem solving, to reduce risks of complications, and to cope with lifestyle changes [38].

Multiple factors and activities to manage the disease properly were described on different time scales ranging from daily to long-term (Fig. 1). These include blood-glucose tests, food intake, and physical activity management, which patients should perform daily, as well as their compliance with therapies or medications for comorbidities, which are conversely followed on a long-term basis. In Fig. 1, these activities are considered as input for patients to integrate all information and decide the best actions to control their disease according to their best knowledge (e.g., to select the proper medication). Information is tracked during this decision-making process; e.g., if the patient performs a blood-glucose test, this information is traditionally noted in a paper diary. Other useful data are related to activities and food intake. This tracked information (called "logs") represents the present behavior of the patient and is an output of the process (see bottom of Fig. 1). Some of the information collected in the logs can be part of the process inputs, which help patients with their decision-making process, as represented by the "Feedback from ongoing status" arrow in the top of Fig. 1.

More specifically, the term "logs" refers to the fact that data are automatically stored without human intervention and are intended to be used by a computer or another device. For example, due to the hardware characteristics of smartphones, some mobile apps are able to record the smartphone owners' physical activity and their related calorie consumption. In Fig. 1, the patients' ongoing status acts as feedback, which influences their decision about the action to take. Comparing our model (Fig. 1) with DM self-care [36], patients decision-making about their self-care is affected by their current health status, daily evidence (self-care maintenance), and long-term evidence (self-care management). Process logs are used to support patients' decisions about their self-care. At each iteration, composed by the pairs of "decision" and "action to take," patients self-care ability increases (self-care confidence).

Therefore, a mobile application for diabetes self-management must, at the very least, implement data logging for heterogeneous types of data (blood-glucose, medication, activity,

nutrition) [34]; however, when considering mobile devices, we also expect some additional functionalities, such as graphically representing the data collected on the screen (e.g., graphs, charts) and delivering it using e-mail, text messages, or cloud services. These other functionalities can be summarized as data representation and delivery. The above-mentioned functionalities do not include any kind of "algorithm" or "intelligence" devoted to the interpretation or analysis of the data collected, represented, or delivered. An insulin dose calculator is an example of such "intelligence." Since decision-making models for the automatic interpretation of patient-related data in diabetes are still being developed [39], we considered functionalities that provide direct advice to patients as "advanced" features and did not include them in the "basic" features expected for a mobile app for diabetes.

Considering the framework shown in Fig. 1, we identified the basic features that a mobile app for diabetes self-management must implement, which are: 1. Data logging, storing data in a permanent way for later use; 2. Data representation, reliably representing the previously stored data on the device; and 3. Data delivery, allowing data to be shared with other people (e.g., family member, health-care professional) in multiple forms (e.g., text message, e-mail, cloud file).

### 2.2. App selection workflow

Our research began by considering all related iPhone apps available in Apple app store on April 1, 2014 returned by searching the Apple app store using the keyword "diabetes." Since the keyword was generic, but the main target of our study was multifeatured apps dedicated to diabetes management for both patients and health-care professionals, we introduced some exclusion criteria. Apps were excluded from our analysis by the following criteria: they were a limited version (i.e., lite or free app) of an available fully featured version; they were supported only a single feature (e.g., insulin calculator only); they did not support any diabetes-specific data collection, archiving, and analysis for time-monitoring (e.g., glycated hemoglobin converter, pills reminder); their target was not diabetes self-management (e.g., generic health

trackers, activity trackers, cooking apps, educational apps) or if diabetes self-management was an incidental-only element within the app; or if they were a content-consumption-only app (e.g., magazine, journal). Considering the fast evolution of the app market, we also excluded apps that did not receive any updates during the 12 months prior to the search (i.e., from April 1, 2013 to March 31, 2014). All apps meeting the inclusion criteria were used for our review. Among these apps selected for our study, a subset including the apps freely available from the Italian Apple app store were downloaded to test the apps directly. We decided to download only the free apps to let the users participate in the study without incurring additional costs.

## 2.3. Reviewed attributes

According to our conceptual framework, we reviewed all the apps meeting our inclusion criteria by considering general features related to the mobile market (such as app pricing, app updates), diabetes-specific features including basic features (data logging, representation, and delivery), and advanced features (e.g., community services, insulin calculators) [26,34]. We considered whether the app was reviewed by one of the known reviewing initiatives (www.imedicalapps.com, http://medicapp.info/appmediche/, or http://apps.nhs.uk/). The full list of these attributes is reported in Table 1.

## 2.4. The Pictorial Identification Schema/Diabetes self-care

The PIS is a graphical classification tool for mHealth apps that we proposed previously [35]. It defines six main families, which each include different attributes:

 Responsible promoters (medical systems companies, drug companies, national services, hospitals, pharmacies, medical associations, publishing company), representing who holds the major perceived responsibility on the app, which does not necessarily mean the developer.

- Offered services (handbooks, guidelines, newsletters, calculators, forecasters,
   GeoHealth, simulators, others), representing the type of services/functionalities
   available in the app.
- 3. Searching methods (alphabetical order, images, predefined comparisons, multiple sources, chemical structures, list scrolling, others), representing the tools for "consuming contents" available in the app.
- 4. Application domains (complex prescriptions, education, mobility, emergency, drug shortage, specific domain specialty, video manual), representing, besides the medical area, the domain in which the app is intended to be used.
- 5. Envisaged users (students, citizens, professionals, others) that are the main user categories.
- Qualifiers and quantifiers (download number, user satisfaction index, timing, significant testimonial), representing the factors that are mostly considered by nonspecialized users in evaluating the app.

To classify an app, a traffic light color-coded score is assigned to each attribute. Attributes coded as red are to caveats for the potential user, whereas those coded as green are the strengths of the app. The yellow code means "something-in-between." The interpretation of the green and the red coding depends on the attribute family. For instance, "offered services" are coded green when they are useful and appropriate for the field, whereas "searching methods" are coded green when they are not trivial and the result-set presentation is effective [35]. This implies that the schema was not intended to describe only what is provided by the app, but also to provide a judgment, from the viewpoint of the signee, on whether or not the feature/attribute is appropriate/works well. Any potential user type, who is required to "sign" the filled-in schema, can fill in the PIS. This signature is important because different profiles can judge the app differently (e.g., developer vs patient vs therapist).

A more detailed description of the PIS, including the rules for color coding, is provided in [35].

According to the methodology developed in [35], starting from the review of the apps selected for our work, we defined new attributes specific to the diabetes domain and removed those that were not relevant to it. For example, in the "searching methods" family, the "chemical structures" attribute is not relevant for diabetes self-care. That attribute indicates the possibility to browse chemical structures of drugs or other entities, e.g., proteins.

We then asked a patient with diabetes and a software developer to evaluate the subset of apps downloaded for free from the Apple's Italian app store, and to complete the PIS forms specific to diabetes. As for the color-coded score, we adopted the same methods as described in [35]. For instance, considering an app update, a red label will be assigned if the app has not been updated for more than the average updating time we defined above, a green label will be assigned if the updating time is equal to or less than the average (updates are more frequent), and a yellow label if the updating time is somewhere in the middle of the earlier or later times.

#### 3. Results

#### 3.1. App review

The search of Apple's US app store using the keyword "diabetes" returned 952 apps. Of those, we identified 67 (7.03%) apps for diabetes self-care. However, 26 apps were excluded because they were not updated in the last 12 months, from April 1, 2013 to March 31, 2014 (Fig. 2A). Forty-one apps were selected after applying our exclusion criteria (4.31%). These 41 apps, which were updated in the 12 months prior to our search, received 3.6 updates on average. This means that an active ("living") app is updated approximately every 3 to 4 months.

Considering app pricing, in the set of 41 selected apps, none cost more than USD 15. Twenty-seven apps (about 66%) were free; 8 apps (about 20%) cost less than \$5, and 6 apps (about 14%) cost between \$5 and \$15 (Fig. 2B).

Regarding the data-entry procedure, which is how data was inserted into the application, the vast majority (36 apps) implemented manual data entry (Fig. 2C). Seven percent of apps (3 apps) supported data input from a wired glucose meter and 5% (2 apps) supported a wireless connection (via Bluetooth) between the glucose meter and the smartphone.

Fig. 2D shows that the basic features that we defined in Fig. 1 (data logging, representation, and delivery) were implemented in at least 50% of the apps. Other advanced features, like an insulin calculator or the presence of a community behind the app, were implemented in a very small percentage of all the apps (17% and 12%, respectively).

The full results for all 67 applications for diabetes self-care found in AppleS iUS app store (before excluding those not updated) are available in a Supplementary Table 1, in which each row is dedicated to a single app that passed the selection workflow, and each column represents an attribute (see Section 2.3.).

### 3.2. The Pictorial Identification Schema/Diabetes self-care

After reviewing the available apps, we identified the attributes relevant for diabetes self-care to be included in the new Pictorial Identification Schema/Diabetes Self-care tool. Since many of the apps reviewed were not promoted by a specific stakeholder (e.g., hospital, scientific society) within the "responsible promoters" family, we added the attribute "private/independent/third party." Within the "offered services" family, we added those attributes identified in Fig. 1, namely "data logger," "data representation," and "data delivery," as well as the other attributes identified in the review ("community services" and "how-to guides"). In the "offered services" family, the "multiple source queries" and "structured queries" attributes were added. In the "application domains" family, the "specific domain subspecialty" attribute was replaced by "diabetes management." Then, we added the "patients" attribute in the "envisaged users" family. Finally, in the "qualifiers and quantifiers" family, we replaced the "timing" attribute with those related to the last update and the frequency of update.

We added also the ranking attributes available in Apple app store ("overall ranking" and "category ranking").

The final setup of the Pictorial Identification Schema/Diabetes self-care is represented in Fig. 3.

Using this specialized version of the PIS, we asked two different users with different profiles (one patient and one developer) to evaluate some apps by completing the schema forms. We asked them to download the 13 apps freely available in the Italian Apple's app store from among the 41 apps reviewed. Fig. 3A and 3B show the schema completed by the two profiles for a sample app called "Diabetes HealthMate". This app supports diabetic patients in managing their disease mainly through the logging of relevant data and the ability to inspect them on a chart. The app supports tracking and visualizing blood sugar readings together with other information on patient lifestyle and provides some suggestions for positive lifestyle choices.

These two profiles provided a different evaluation in the "offered services" family. In Fig. 3A, the "data logger" attribute in the "offered services" family is colored yellow because even if all the data logs were implemented, some of them are incomplete and not contextual with each blood-glucose test. Conversely, in Fig. 3B, the same attribute is red because the patient highlighted the fact that the interface is overloaded with information and the correct steps for adding a new data log are not immediately clear.

When the two user profiles reviewed the remaining 12 apps using the Pictorial Identification Schema/Diabetes self-care, their major disagreements were again in the "offered services" family (Figs 4, 5, and Figs S1 and S2 in the Supplementary Material). Specifically, the "data logger" attribute is colored red 5 times out of 13 according to the patient's assessment, and 9 times out of 13 according to the developer's assessment. In addition, another attribute that was frequently given a red label is the "update frequency within a year" in the "qualifiers and quantifiers" family (for both assessments) because some apps were updated less frequently than the average. The apps that were given a red label for the "update frequency within a year" attribute were the same for the two profiles.

#### 4. Discussion

In this work, we proposed and tested a Pictorial Identification Schema/Diabetes self-care for apps addressing diabetes self-care that can be completed by heterogeneous profiles, users (e.g., patients, health-care professionals) and smart mobile device experts (e.g., developers, interface designers), and can give advice to patients about selecting the appropriate app to be confident in under the advice of their therapist.

When we reviewed the apps available on Apple US app store for diabetes selfmanagement, we found that only 7% of all the apps identified using the "diabetes" keyword were intended to support patients' management of the disease. Following this review, we identified some new attributes to specialize the PIS. The results of our review showed that, interestingly, no single app cost more than \$15. Even though the mobile app market is usually cheap, diabetes is a specific condition in which patients are also motivated to spend money to improve their quality of life. Hence, we could have expected an app market including apps more expensive than \$15, but this was not the case, and app prices were affordable for all users. Moreover, data entry was manual in the majority of the reviewed apps, even though it is prone to human errors. For example, if a patient tests his blood glucose when he wakes up in the morning and finds that the value is 250 mg/dL, which indicates hyperglycemia), but he erroneously inserts 150 mg/dL into the application. That single value would severely impact not only the daily average, but also the weekly average and possibly more. Another possible error would be to insert 250 mg/dL for a different time or date than the test; again, that would compromise the validity of the data. Automatic data entry is only possible when the app directly communicates with a glucose meter, but this procedure is subject to compatibility issues, including those between the app and the operating system. Mobile operating systems (such as iOS, Android, Windows) usually receive a major update once a year and possibly minor updates throughout the rest of the year. This means that unless the developer of the diabetes self-care app is as fast as Apple, Google, and Microsoft in releasing an updated version of the app on the

very same day an operating system update is released, the app may be subject to possible compatibility issues and might malfunction. Crashes and incorrect behavior cannot be excluded in these circumstances.

Regarding the available app features, our results showed that only basic features (i.e., data logging, representation, and delivery) were implemented in all of the reviewed apps, whereas advanced features (e.g., insulin calculator, community support) were rare. Therefore, mobile applications for diabetes self-care that constantly receive updates currently implement only basic features, which are still effective for proper management of the disease, but do not really exploit the full potential of the mobile technology by offering users an advanced multifeatured experience. We note that some people may use multiple single-function apps to suit their different needs (e.g., they may have a data-logging app, an insulin dose calculator, and a peer communication app in their collection), but this selection of applications would require the hand transcription of some data, which may become a source of typos, with unexpected consequences.

As a preliminary assessment of the potentials of the Pictorial Identification

Schema/Diabetes Self-care tool, we asked two different user types to complete their profiles.

The first user profile was the patient, who is the natural target of the schema. The second was the developer. We chose these profiles because both regulatory bodies (such as the FDA [32]) and scientific framework proposals to ensure medical app quality [27] are based on the declarations of the app developers. Therefore, after the adoption of the PIS and in the light of a "responsible app development" [27], app developers would likely provide an evaluation of their apps. Another possible user profile could be a diabetes expert. However, the diabetes expert would have provided a judgment similar to those available on the peer-reviewing sites and, for this reason, we decided not to include this profile in the preliminary testing.

Even though with a limited sample size of potential users, our exploratory testing on 13 apps showed that different user profiles have different approaches to their judgments about what action to take to manage their disease, and, as for the original PIS, the profile of the user who

completes the schema is relevant. In our experiment, the strategy used by the two profiles differed because the developer had a greater consideration of the function of the app (which features are implemented and whether they work the way they are supposed to) whereas the patient was focused on the usability and interfaces of the app (how the features are presented and the overall user experience). However, the main differences in the user judgments were in the "offered services." The patient tended to highlight criticisms in the presentation of data (interface) that implies having difficulties in using the app, and the developer tended to highlight whether or not a specific functionality works. Interestingly, both user profiles provided a red label for the "update frequency within a year" attribute for the same apps, which suggests that both evaluators perceive this attribute as a critical factor.

The possibility of multiple evaluations from different profiles would enrich the information and knowledge grounding patients' decision-making process. Each app should be associated with more than one PIS, according to the number of reviews that it will receive. The multiple viewpoints expressed by the different completed schemas will let patients understand the different weaknesses or strengths of the app and, in turn, perform a more informed and responsible choice.

Our search of Apple's app store was performed on April 1, 2014. As more than a year has passed, we considered repeating our search so that we could include updated results in the paper. However, Apple has since changed the way search results in the app store are retrieved and presented. A limit to the number of results has been set according to the application program interface (API) for executing searches in Apple's app store [40]. The default limit value for search results is 50, while a value from 1 to 200 can be assigned to it [40]. This means that less-popular apps will not be included and displayed in the result set. Consequently, a lower number of apps could be retrieved and analyzed. Our original search using the keyword "diabetes" resulted in 952 apps. On November 9, 2015, we performed a keyword search using "diabetes self-care" on Apple's app store and found two apps.

The issue of an effective dissemination strategy for the schema remains open. As already discussed in [35], the most important point is how to reach the users and how to make the PIS known to the general public quickly. Using standardization bodies was recognized as being ineffective because of their different scales in terms of time, but also paperwork, between the definition of a norm, the certification process, and the app development market. Conversely, the possibility of creating specific repositories guided by PISs, in which the patient can choose medical apps, seems more feasible. These might be ad-hoc repositories, organized as pharmacy shelves, where the patient can find only apps already tested and evaluated through the PIS that serves to guide their choices. However, this idea currently has no practical applications.

Finally, the Pictorial Identification Schema/Diabetes self-care is an easily understandable way to map all of the app features so they can be seen at a glance. One of the strengths of this approach is the possibility of multiple stakeholders completing the schema, which provides different perspectives on the app, e.g., functional or usability viewpoints. This implies that the user who is searching for a trustful app can use the Pictorial Identification Schema/Diabetes self-care to see the reviews of the app by multiple profiles, including other users.

## 5. Conclusion

We showed that there are several available apps for patients with diabetes, but that those supporting diabetes self-management only implemented basic, and someway nonrisky, functions, whereas the more-advanced functions that are more useful for patient self-care in a context in which uncertainties and traceability are unavoidable, have not been implemented yet. In this arena, our proposed Pictorial Identification Schema/Diabetes Self-care tool is easy and intuitive for potential patient users to be guided into in perceiving the weaknesses and the benefits of apps and ultimately make a responsible choice.

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## **Conflict of interest**

The authors report no competing financial interests.

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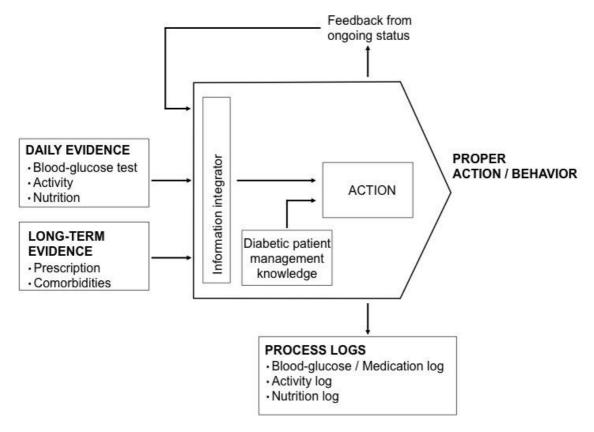
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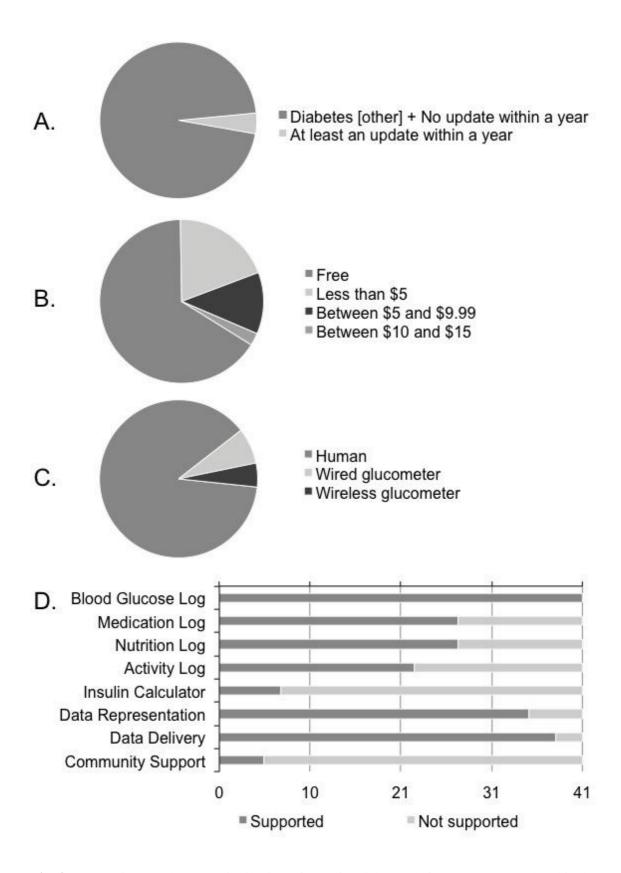
**Table 1**Full list of the attributes considered for reviewing each selected app.

Attributes		Definitions
	Last update	The date of last update. If the date of last update is prior to 12 months ago, then the app is discarded from further analysis.
	Frequency within last 12 months	The total number of updates the app received within the last 12 months.
	App store	In which international store (United States, Italy or both) the app is available for download.
General attributes	rice tier	Which price tier the app falls into ("Free," "Less than \$5," "Between \$5 and \$9.99," "Between \$10 and \$15," or "More than \$15").
	In-app purchase	The app offers additional features through an in-app purchase.
	Optimization for iPad (iOS Universal)	The app is supported by and optimized for iPhone and iPad.
	Android	The app is also available for Android in the Google Play app store.
Diabetes	Diabetes type	Whether the app supports "type 1" diabetes, "type 2" diabetes or "both."
attributes	Data-entry procedure	Diabetes-related data can be entered into a mobile app in different ways ("human," "wired glucometer," "wireless glucometer," "continuous glucose

		monitoring system").
		Diabetes can be treated with different therapies so
	Therapy mode	apps can implement different alternatives. ("insulin
	Therapy mode	pen," "insulin pump," "oral pills," "multiple modes,"
		"NA.")
		Blood-glucose log: logging of blood glucose
		readings;
		Medication log: logging of medications adopted to
		manage diabetes;
		Nutrition log: logging of nutrition parameters;
		Activity log: logging of physical activity;
	Features	Insulin calculator;
		Data representation: the app allows to represent at
		least some of the data previously logged;
		Data delivery: the app implements the ability to
		share data;
		Community support: the app is built around a
		community.
		NHS: the app was reviewed by the "UK NHS"
Contributing		(http://apps.nhs.uk);
Contributing	Reviewing sites	iMedicalapps: the app was reviewed by
quality	Treviewing sites	"iMedicalapps" (http://www.imedicalapps.com);
milialives		Medicapp: Specifies whether the app was reviewed
		by "Medicapp" (http://medicapp.info/appmediche/).



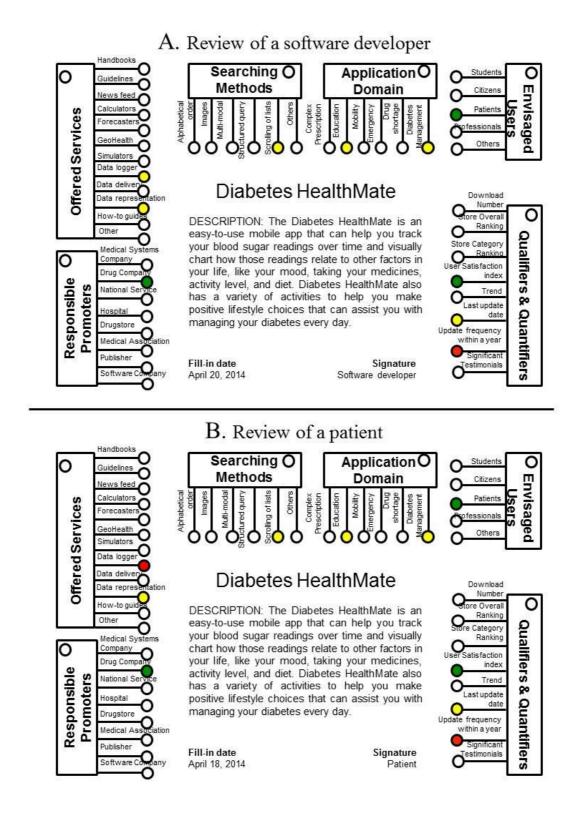
**Fig. 1.** Representation of the diabetes self-care process. To obtain the proper medication, thus controlling diabetes, patients deal with daily and long-term measurements and therapies (left inputs). Patients use their personal knowledge to assess this information and decide the best actions to take during their decision-making (central arrow). During the whole process, some information is tracked (process outputs). Also, the ongoing status gives patients feedback so that they can possibly change their behavior (feedback arrow on the top).



**Fig. 2.** App review results. (A) Distribution of apps for diabetes self-management updated in the last year compared with the complete set of apps retrieved from Apple's US app store using the

keyword, "diabetes." (B) Distribution of prices in the apps meeting the inclusion criteria. (C)

Distribution of the input methods in the apps meeting the inclusion criteria. (D) Implemented features (light grey = function supported; dark grey = function not supported) in the apps meeting the inclusion criteria.



**Fig. 3.** The Pictorial Identification Schema/Diabetes Self-care tool completed for a sample app (Diabetes HealthMate). The schema defines six families, each with different attributes. An

attribute colored in red means that the feature or function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if not pertaining to the examined app. In the center, the schema reports the name of the app, its description as available on Apple's app store, the date in which it was completed, and the signature of the author, in terms of user profile. (A) Pictorial Identification Schema/Diabetes Self-care tool completed by a software developer. (B) Pictorial Identification Schema/Diabetes Self-care tool completed by a patient. Note the different colors chosen for the data logger attribute in the "offered services" family.

**Fig. 4.** The for all 13 ap been compl

Assesment by the Developer

Danii - A diabetes app for the ePatient DiabetesConnect - Diabetes Management Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes
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Responsible Promoters								Attribute occurrences	Red Label	Yellow Label	Green Label
Medical Systems Company								0	(	(	
Drug Company	3							1	(	(	
National Service				•				0	(	(	
Hospital								1	(	8	
Drugstore								0	(	(	
Medical Association								1	(		
Publisher								1			
Private/Independent/3rd-party								9	2	7	1

Offered Services								Attribute occurrences	Red Label	Yellow Label	Green Label
Handbooks					8 8			0	0	0	0
Guidelines	10 10	- 8		10		8	15	0	0	0	0
News feed			3		8 8			0	0	0	0
Calculators		- 8		18		8	15	0	0	0	0
Forecasters	10 8							0	0	0	0
GeoHealth	15 13	8	1	18	1		18	0	0	0	0
Simulators							, i	0	0	0	0
Data Logger								12	9	1	2
Data Delivery								7	- 1	2	4
Data Representation								9	3	3	3
Community Support	10						10	1	0	-1	0
Multi-modal how-to guides								0	0	0	0
Others								0	0	0	0

Searching Methods	195					 s 180	Attribute occurrences	Red Label	Yellow Label	Green Label
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Multi-modal								0	0	)
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Structured Query								0	)	)
Others	10	2 3		5				0	)	)

Application Domains							Attribute occurrences	0.00	Yellow Label	Green Label
Complex Prescription	1	1			1		0	0	(	
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Mobility							0	0		
Emergency							0	0	(	
Drug shortage				6.5			0	0		C
Diabetes Management							12	4		2

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Citizens			10											0	0	0	(
Patients														11	0	C	11
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Qualifiers & Quantifiers							Attribute occurrences	Red Label	Yellow Label	Green Label
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Seasonality							(	) (	) (	)
Last Update Date							13	3	10	)
Update Frequency within a year							13	3 8	3	3
Significant Testimonials					-		(	) (	0	)

Assesment by the Patient	bant - A diabetes app for the ePatient	DiabetesConnect - Diabetes Management	Glooko	Diabetes UK Tracker	Diabetes Management App	Diabetes HealthMate	Diabetik	Diabetes Manager	Gluco Share	Gmate™ SMART	Diabetes App	URIGHT Diabetes Manager	Simple Diabetes				
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Hospital														1	0	1	
Drugstore						_								0	1000	0	
Medical Association					4 6				4 1					1	0	1	0
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Offered Services														Attribute	Red	Yellow	Green
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News feed														0	0	0	
Calculators														0	0	0	
Forecasters			2											0	0	0	
GeoHealth													1	0	0	0	
Simulators														0	0	0	
Data Logger	. 0													12	5	5	
Data Delivery  Data Representation													li (	9	2	2	
Community Support		-											-	1	0	1	
Multi-modal how-to guides	$\vdash$												-	0	0	0	
Others														0	0	0	0
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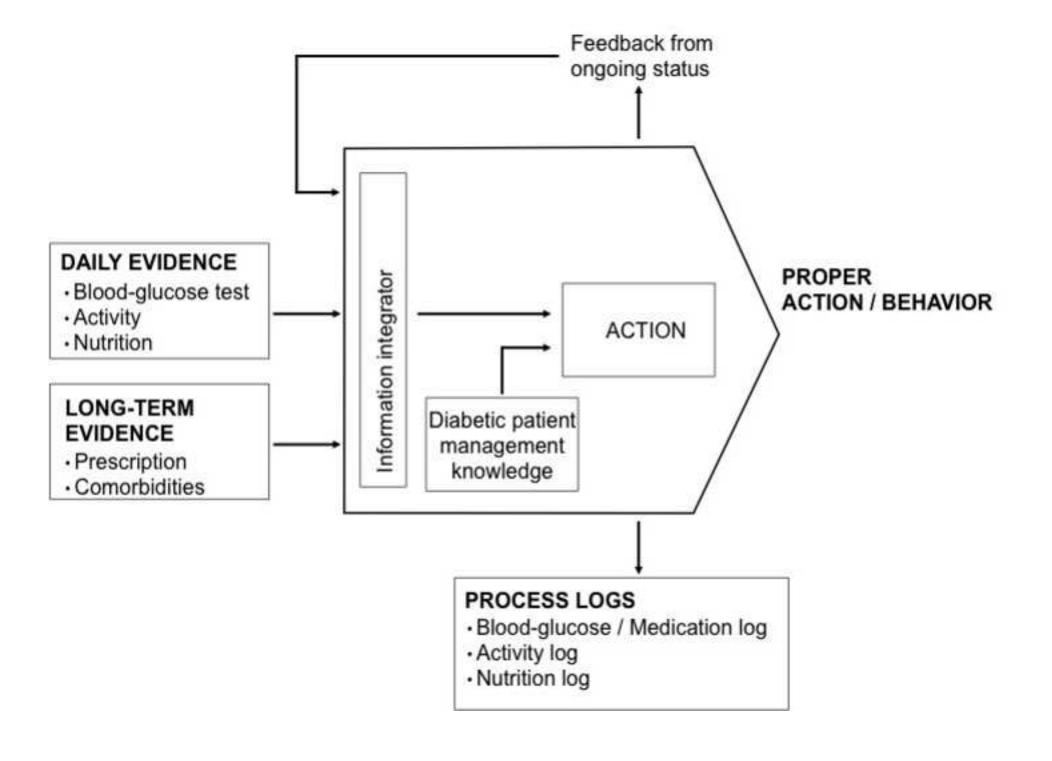
Update Frequency within a year Significant Testimonials

**Fig. 5.** The Pictorial Identification Schema/Diabetes Self-care tool completed by the patient for all 13 apps. The schema reports the six families, each with different attributes, which have been completed for each app. An attribute colored in red means that the feature or function is implemented in the app with strong weaknesses, whereas the green color means that the implementation has no weaknesses. An attribute is not colored if it does not pertain to the examined apps.

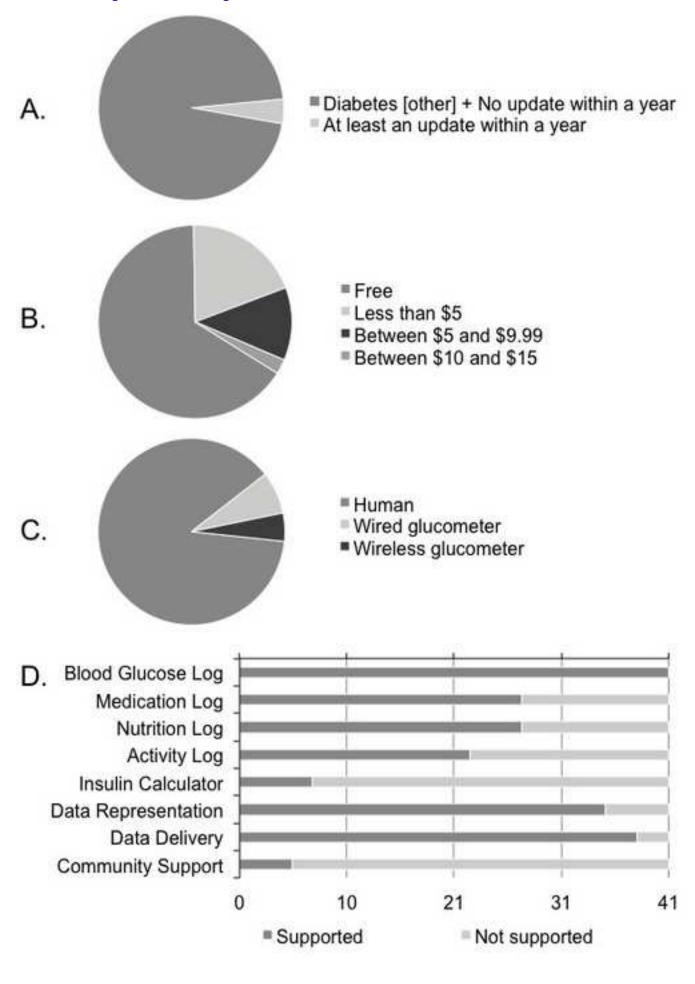
## HIGHLIGHTS

- A proposed method to help patients identify trustful apps for diabetes self-care.
- A pictorial identification schema is used to review diabetes self-care apps.
- This method does not require specific skills.
- Two different profiles apply the tool on the selected apps and discuss the results.

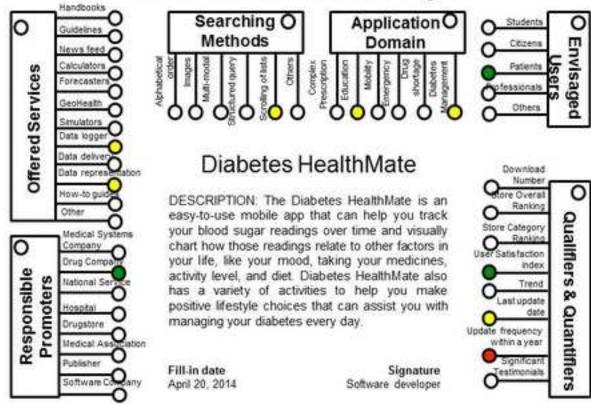
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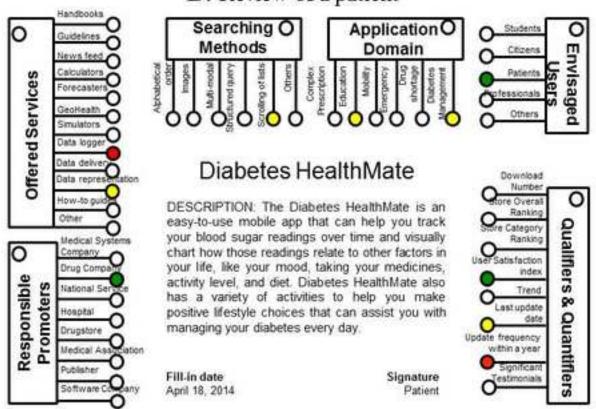
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## A. Review of a software developer



## B. Review of a patient



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# Figure(s) Click here to download high resolution image

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Supplementary Material
Click here to download Supplementary Material: S1\_Apps\_Review\_Supplementary\_Material.xlsx

Supplementary Material
Click here to download Supplementary Material: S2\_Supplementary\_Material.docx