

A Requirements Catalog of Mobile Personal Health Records for Prenatal Care

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Abstract. Mobile Personal Health Records (mPHRs) for prenatal care are mobile health applications that allow pregnant women manage, access and share their health data with healthcare providers. In this paper, a requirements catalog was developed, according to standards, guidelines and relevant literature. The catalog covers requirements about Sustainability, Internationalization (i18n), Operability, Reliability, Functional suitability and Performance efficiency. The usefulness of this catalog consists in conducting audit evaluations of prenatal care mPHRs, in addition to helping stakeholders and developers identify potential requirements for their mPHRs.

Keywords: mPHRs · Requirements · Catalog · Prenatal care · Sustainability · ISO/IEC 25010 · i18n

1 Introduction

Mobile health is experiencing a growth trend as consumers request more accessibility to the medical health professionals and transparency in healthcare becomes more important. Moreover, the health, fitness and medical industries have been identified as the top three fields to accelerate the growth of mobile devices [1].

Mobile Personal Health Records (mPHRs) for prenatal care are mobile health applications used by pregnant women, which allow them to access and coordinate their health information using mobile devices and track their pregnancy until the day of delivery [2]. The mPHRs for prenatal care also store personal and health data recorded by the pregnant women, which can also be accessed by their healthcare providers [3].

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The mPHRs for prenatal care are currently available in the leading mobile applications stores: Apple App store and Google Play store. In fact, Android and iOS platforms are currently the prominent and adopted mobile operating systems for health apps development [4].

The health data collected using prenatal care mPHRs usually include [2]: (i) Personal information such as name, telephone number, marital status and insurance details; (ii) Physical body information such as height, weight, waist size and blood pressure; (iii) Personal medical history such as blood group, allergies, medication use and family health history; and (iv) Obstetrical history such as last menstrual period, estimated due date, gynecological history and contraception method prior to pregnancy. In addition to the specific functionalities, expected for these kinds of mobile applications, a number of non-functional requirements can be considered, either for development or auditing purposes, which can be gathered in a requirements catalog.

To target a large number of pregnant women, the content of the mPHRs for prenatal care should be conceived with consideration of diverse languages and regions [5]. Thus, requirements for internationalization (i18n) should be determined at early stages of the development lifecycle of prenatal care mPHRs.

According to the findings of our previous study [2], Operability, Performance efficiency, Reliability and Functional suitability are the most influenced quality characteristics, of the ISO/IEC 25010 [6] product quality model, by the requirements of mPHRs for prenatal care. ISO/IEC 25010 defines: Operability is the degree to which the product has attributes that enable it to be understood, learned and attractive to the user, when used under specified conditions. Performance efficiency is the performance relative to the amount of resources used within stated conditions. Reliability is the degree to which a system performs specified functions under specified conditions for a defined period of time. Finally, functional suitability is the degree to which the product provides functions that meet stated needs under specified conditions. Hence, requirements related to these quality characteristics should be delineated.

Moreover, according to the United Nations (UN), sustainability is defined as "the ability to meet the needs of the present without compromising the ability of future generations to satisfy their own needs" [7]. There are five dimensions of sustainability [8]: economic, social and environmental, in addition to two dimensions that have been identified for software sustainability, which are: individual (human) and technical dimensions [9, 10]. Endorsing the sustainability of mPHRs for prenatal care is necessary to expand their adoption by the users. Therefore, requirements about sustainability should be considered.

To the best of our knowledge, a requirement catalog for prenatal care mPHRs has not yet been developed. This paper aims to develop a requirements' catalog for the inherent properties of mPHRs for prenatal care. According to the ISO/IEC 25010 Standard [6], software product properties are divided into inherent properties and assigned properties. Inherent properties determine the capabilities of a software product, and they are permanent features; they can be classified as either functional

properties or quality properties. Functional properties determine what the software is able to do, while quality properties show the degree to which the software is able to provide and maintain its specified services. Assigned properties are not considered as quality characteristics of the software, as they can be changed without changing the software [6]. This catalog mainly focuses on i18n, sustainability and the quality characteristics of the ISO/IEC 25010 product quality model: Operability, Reliability, Functional suitability and Performance efficiency for prenatal care mPHRs.

The paper is structured as follows: Sect. 2 presents the related work on developing requirements catalogs for mobile health applications. Section 3 describes the method used to develop the present catalog. Section 4 reports the results of an illustration example on the use of this catalog on an mPHR for prenatal care. Section 5 discusses the findings of this illustration. The conclusion and future work are presented in Sect. 6.

2 Related Work

According to the standard ISO/IEC/IEEE 29148 [11], software requirements specification is defined as "a structured collection of the requirements (functions, performance, design constraints, and attributes) of the software and its external interfaces". Hence, collecting these requirements in the Software Requirements Specification (SRS) document is essential to clearly disclose the requirements to stakeholders and define them accurately to developers.

Previous studies have established requirements catalogs, such as the study of Zapata et al., which proposes a SRS that specifies the usability requirements for mobile health applications, in addition to an audit method [12]. The requirements of this catalog were extracted from recommended standards, popular guidelines and literature. The proposed catalog was designed to be reused and adapted to different projects. Moreover, a study of Ouhbi et al. defined a reusable requirements catalog for blood donation applications with regards to i18n and sustainability [13] . The requirements identified in this catalog were derived from the main related software engineering and e-health standards and literature. Another study of Ouhbi et al. defined a reusable requirements catalog for sustainable connected health applications [14]. This catalog provides requirements that cover the individual, social, environmental, and technical dimensions of sustainability, and can be adapted to specific m-health applications.

Furthermore, Jensen et al. identified reusable technical security requirements for healthcare applications, which were extracted from legislation applicable to the healthcare domain [15].

In our previous work [2], a framework was developed in order to evaluate the software quality of prenatal care mPHRs according to the ISO/IEC 25010 quality standard. The aim of this framework was to study the influence of the common requirements of mPHRs for prenatal care, which were extracted from literature and existing mobile apps on the market, on the software quality characteristics and

sub-characteristics of the ISO/IEC 25010. These requirements were classified according to 7 blocks: App's accessibility, the expectant woman's personal details, the expectant woman's physical body information, the expectant woman's personal medical history, the expectant woman's obstetrical and pregnancy information, user's actions, and app's components.

The findings of this study stated that the quality characteristics most influenced by the mPHRs for prenatal care requirements are Functional suitability, Reliability, Operability and Performance efficiency.

3 Method

3.1 Requirements Specification of mPHRs for Prenatal Care

The limited adoption of Personal Health Records (PHRs) by individuals is a real issue [15, 16], due to several reasons such as the use of medical terminologies that are usually difficult to understand by users [17], the lack of multi-language support, in addition to socio-cultural barriers [18, 19]. Moreover, PHRs for pregnancy are an intriguing focus because of the high attention paid to health information by pregnant women [20]. The adoption of mPHRs for prenatal care is also influenced by software quality [2]. Hence the requirements related to i18n, software quality and sustainability should be taken in consideration when developing an mPHR for prenatal care.

In order to identify the requirements of mPHRs for prenatal care to be included in the catalog, the present study relied on : (i) An analysis of the features and functionalities of mPHRs for prenatal care [21]. (ii) Previous studies about the software quality evaluation of mPHRs for prenatal care [2, 22]. (iii) A requirements catalog related to usability [12]. And (iv) Requirements catalogs related to i18n [5, 13] and sustainability [13, 14]. Furthermore, the following standards were used to extract requirements [14]:

- ISO/IEC 25010 standard for system and software product quality requirements and evaluation [6].
- ISO/TR 14292 standard for the definition, scope and context of PHRs [23].
- ISO/TR 20514 standard for the definition, scope and context of Electronic Health Records (EHRs) [24].
- The W3C standards for Web and mobile devices [25].
- ISO/TS 14265 standard for the classification of purposes for processing personal health information [26].
- ISO/TR 18307 standard for interoperability and compatibility in messaging and communication standards – Key characteristics [27].
- ISO/HL7 27931 standard for data exchange in health care environments [28].
- ISO 21090 standard about harmonized data types for information interchange [29].

3.2 Requirements Catalog for Prenatal Care mPHRs

The present requirements catalog is developed according to: (i) The guidelines provided by SIREN (SImple REuse of software requirements), which is an approach based on software engineering standards that can be used to create, select and specify the requirements of a software, in addition to promoting the reuse of requirements. This approach was firstly introduced by Toval et al. [30]. (ii) Recommendations from the IEEE 29148 standard [11], which provides a definition of the normative content of the SRS. This standard contains provisions for the processes and products related to the engineering of requirements for systems and software products and services throughout the life cycle. (iii) Guidelines from the IEEE 1233 guide for the development of the set of requirements, System Requirements Specification that satisfy an expressed need. It also covers the necessary characteristics and qualities of individual requirements and the set of all requirements [31].

The development of the present catalog is focused on providing a complete, consistent and valid set of requirements for prenatal care mPHRs. The generation process of the catalog is divided into four steps, as described in Fig. 1: (i) The identification of sources, which are the relevant studies and standards previously presented. (ii) The extraction of requirements from the identified sources. (iii) The generation of the catalog from the extracted requirements by adopting the SIREN approach. (iv) The maintenance of the catalog by regularly updating it due to changes to the standards used or to the mPHRs for prenatal care. The structure of the catalog is adapted to the general SRS structure from the IEEE 29148:2011 standard [11] as shown in Table 1.

The aim of the present catalog is to cover the mPHRs for prenatal care requirements related to: Sustainability, i18n, Reliability, Performance efficiency, Functional suitability and Operability (named Usability in the IOS/IEC 9126-1 standard [32]). As shown in Table 1, the Functional suitability requirements are in the subsection 3.2, the Usability requirements are in the subsection 3.3, the Performance efficiency requirements are in the subsection 3.4, the Reliability requirements are in the subsection 3.7.1, and finally two subsections have been integrated in the SRS structure: 3.7.6 and 3.7.7 for i18n and Sustainability requirements, respectively, according to [13]. Each requirement identified has a set of predefined attributes that describes it, such as: a unique Project Unique Identification (PUID), source, description, priority, current state, version history, date and rationale.

4 Results

Based on the existing mPHRs for prenatal care for both iOS and Android, previous studies [33, 2] and scientific literature related to pregnancy [34, 35, 36] (Step 1 in Fig. 1), the requirements of mPHRs for prenatal care have been extracted (Step 2 in Fig. 1). Note that the requirements related to i18n and Sustainability have been slightly adapted to mPHRs for prenatal care according to [13] and [5].

The requirements of mPHRs for prenatal care are presented in Table 2.

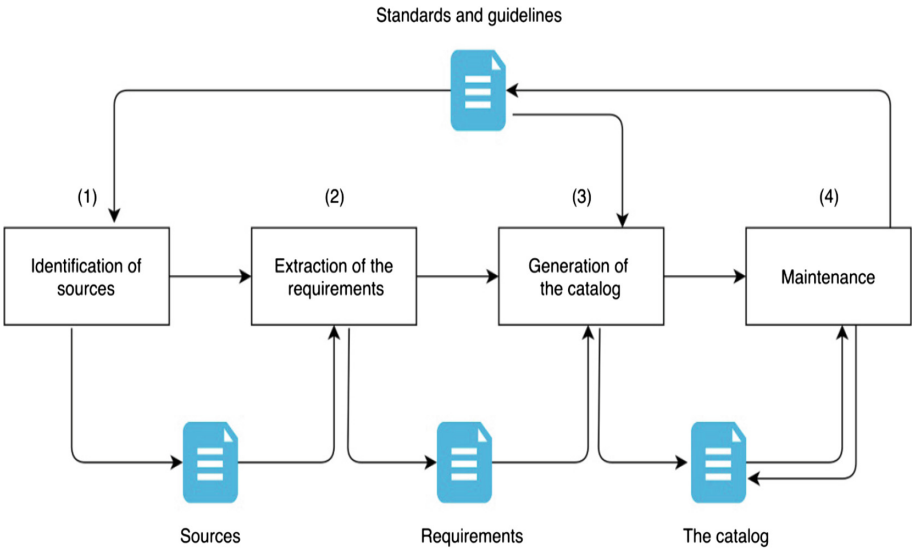

Fig. 1. Generation process of the catalog

4.1 Illustration Using an mPHR for Prenatal Care: Pregnancy +

In order to illustrate how to apply the developed catalog to evaluate an mPHR for prenatal care, we selected Pregnancy +, which is the most downloaded, best reviewed and free mPHR in Google Play store. Pregnancy + is available for both Android and iOS mobile operating systems. However, the Android version has been considered in this study since the popularity of Android: in December 2018, Android had a world-wide market share of 75.16 percent, according to [37].

The review score of this app is 4.6 of 5 stars, which is considered as very high, and the number of total installs exceeds ten millions. Note that these information were extracted in March 2019.

A questionnaire including 30 questions has been generated from the developed catalog. This questionnaire has been used in the evaluation of the app "Pregnancy +", and contained only questions related to relevant requirements in the case of this app.

After installing the app "Pregnancy +", the first author conducted the evaluation on the 1st March 2019. The answers to the questions were either: Yes (1 point), No (0 point) or Partially (0.5 point). The questionnaire of this evaluation is presented in Table 3.

The answers to the questionnaire for the evaluation of the "Pregnancy +" app, as shown in Table 3, are as follows: 2 Partially (6.67%), 15 Yes (50%) and 13 No (43.33%). The questions that got "Partially" as an answer are Q21 and Q28. The reason for which Q21 got this answer, is because the app only provides a weight tracker but

not a blood pressure tracker. Moreover, for the question Q28, the app includes the baby trackers (contraction timer and kicks counter); however, the app should be upgraded to the premium version so that the user can use these features. Hence the total score of this app is: (2*0.5 + 15*1)/30 = 53.33%, which is considered as a good score, since more than half of the answers are positive. Nevertheless, there is still room for improvement, as it can be deduced from the answers that are not positively validated.

Table 1. Table of contents (IEEE 29148:2011) [11]

1. Introduction
   - 1.1 Purpose
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5 Discussion

According to the findings of the evaluation that has been conducted on the app "Pregnancy +", most of the main requirements are included in this app. However, some of the questions that got "No" as an answer remain very important for an mPHR for prenatal care, such as:

- Q2: It should be stated in the description of an mPHR in the app store that it supports multiple languages, even identifying which are them, in order to encourage users around the world to download and use the app.

Table 2. Requirements identified for prenatal care mPHRs

I18n requirements
1) The tool shall be designed for cultural diversity and multilingual use.
1.1) The mPHR shall adapt its content to the user language preferences.
1.2) The mPHR shall be available in several languages, by providing an easy and clear way to switch them.
1.3) The mPHR shall adapt the help, privacy policy and disclaimer sections to the user language preferences.
1.4) The mPHR shall adapt the pregnancy related terminology to user language preferences.
1.5) The mPHR shall display the text with the correct text align depending on the user language preferences. (From left or right)
2) The mPHR shall use pictures to express ideas.
3) The mPHR shall illustrate the content with icons.
4) The mPHR shall use graphs to present the measurements history (e.g blood pressure, weight).
5) The mPHR shall use appropriate formats, units of measurement and currency for an international audience.
5.1) The mPHR shall adapt the number formatting to the user language preferences.
5.2) The mPHR shall adapt the currency to the user geographic location.
5.3) The mPHR shall adapt the units of measurements to user geographic location.
5.4) The mPHR shall adapt the date and time formatting to the user preferences.
5.5) The mPHR shall adapt the phone numbers to user geographic location.
5.6) The mPHR shall adapt the address to user geographic location.
6) The mPHR shall take into account the first day of the week by geographic location.
7) The mPHR shall adjust the advertisements displayed to the user to avoid cultural discrepancies.
8) The mPHR shall allow the user to manage personal information, such as different countries' specific legislation or regulations regarding user ownership of personal information.
8.1) The user should be able to adjust personal information in accordance with different countries' specific legislation or regulations regarding user ownership of personal information.
8.2) The user should be able to control personal information in accordance with different countries' specific legislation or regulations regarding user ownership of personal information.
8.3) The user should be able to process personal information in accordance with different countries' specific legislation or regulations regarding user ownership of personal information.
Sustainability requirements
1) The mPHR shall have a positive individual impact.
1.1) The mPHR shall respect security and privacy of the user.
1.2) The mPHR shall promote personal health and well-being of the user.
2) The mPHR shall have a positive social impact.
2.1) The mPHR shall allow interaction among users (e.g forums).
2.1.1) The mPHR shall connect to social networks.
2.2) The mPHR shall promote social solidarity and share among users.
3) The mPHR shall have a positive environmental impact.
3.1) The mPHR shall reduce transportation means to find obstetrics and gynecology health centers.

(*continued*)

Table 2. (*continued*)

3.2) The mPHR shall be convenient for frequent use. 3.3) The mPHR shall connect to other resources (e.g the connection to an EHR). 3.3.1) The mPHR shall back up data in data repositories, drivers or cloud systems. 3.3.2) The mPHR shall use device features such as Bluetooth, Global Positioning System (GPS), camera and fingerprint sensor. 3.3.3) The mPHR shall connect with maps applications to display locations. 3.4) The mPHR shall be energy-efficient. 4) The mPHR shall have a positive technical impact. 4.1) The mPHR shall easily adapt with future updates. 4.2) The mPHR shall shut down in idle mode.
Operability requirements
1) Appropriateness recognizability 1.1) The mPHR home page, with respect to colors, layout and content shall be attractive. 1.2) The content in the screens of the mPHR shall be well positioned. 1.3) The main menu in the mPHR shall be well structured. 1.4) The content in the different sections of the mPHR shall be well classified. 1.5) The presentation of the measurements entered in the mPHR shall be understandable. 1.6) The design and the features of the mPHR shall be compliant. 2) Ease of use 2.1) The degree of mastering the mPHR. 2.2) The degree of ease while using the mPHR. 3) User error protection 3.1) The mPHR shall display dialog boxes if the user enters wrong or missed data. 4) User interface aesthetics 4.1) The mPHR's layout shall be attractive and consistent. 4.2) The fonts used in the mPHR shall be attractive. 4.3) The colors used in the different screens of the mPHR shall be attractive. 4.4) The color theme used in the mPHR shall be consistent. 4.5) The colors used, in terms of their adequacy with each functionality/feature, and with the pregnancy theme shall be appropriate. 4.6) The fonts used in the mPHR shall facilitate the legibility. 4.7) The mPHR shall adapt to the screen orientation (horizontal and vertical). 5) Technical learnability 5.1) The mPHR shall be easy to learn. 5.2) The frequency of the support needed from a technical person to use the mPHR. 5.3) The mPHR shall include a Help/Frequently Asked Questions (FAQ) section.
Functional suitability requirements
1) Functional appropriateness 1.1) The mPHR shall include functionalities that are well integrated and complementary for a better prenatal care. 1.2) The degree of inconsistency of the functionalities/ features for prenatal care in the mPHR while executing the requested tasks, whether it gives the expected results or not. 1.3) The section about the weekly progress of pregnancy for the baby and the expectant woman shall be useful for users.

(*continued*)

Table 2. (*continued*)

1.4) The pregnant woman section shall track at least weight and blood pressure, with the possibility to browse the history of the measurements taken. 1.5) The baby section shall include at least a contraction timer and kicks counter with the possibility to browse the history of the values entered. 1.6) The appointments feature shall include the full details about the appointment, a reminder and the possibility to add notes / questions to the doctor. 1.7) The features and functionalities of the mPHR shall be very clear and simple to access and use. 2) Accuracy 2.1) Any measurement entered to the mPHR shall be accurate and valid.
Reliability requirements
1) The mPHR shall keep the measurements, already taken, available and shall provide the possibility to restore and check them any time while using the app. 2) The mPHR shall provide the option to restore the preferences/ settings each time it is used.
Performance efficiency requirements
1) The navigation between hierarchical screens, in terms of response time, shall be consistent in the mPHR. 2) The user shall be able to make a call from the mPHR to a contact from the phone repository in case of an emergency. 3) The user shall be able to connect the mPHR to an external device. 4) The user shall be able to create an instant health report in the mPHR and send it to the stakeholders.

- Q9: Recovering sensitive data stored in an mPHR for prenatal care is mandatory [21]. Hence backing up data is one of the requirements that must be met.
- Q10: The mPHR for prenatal care should shut down in idle mode for security purposes and for saving the device's battery as well.
- Q24: The home page should be attractive and well structured in order to encourage users to use the mPHR.
- Q7: The presence of a community feature in the mPHR for prenatal care is very important, since users can share and ask about information related to their pregnancies [21]. This can be fostered either by implementing forums or linking social networks to the mPHR. The community feature helps pregnant women interact with each other and gain more support.

Table 3. Assessment questionnaire used for "Pregnancy +"

Question ID	Question	Answer
Q1	-Does the mPHR support multiple languages?	Yes
Q2	-Is the number of languages supported stated in the description of the mPHR in the app store?	No
Q3	-Does the mPHR provide the possibility to choose the units of measurements to be used?	Yes
Q4	-Does the mPHR use pictures / illustrations to explain ideas?	Yes
Q5	-Is there a possibility to browse the history of the measurements taken?	Yes
Q6	-Does the mPHR use graphs to illustrate data history?	Yes
Q7	-Does the mPHR promote interaction among users via social networks?	No
Q8	-Is the mPHR connected to an EHR?	No
Q9	-Is the user able to back up its data?	No
Q10	-Does the mPHR shut down in idle mode?	No
Q11	-Is the user able to find nearby healthcare centers?	No
Q12	-Does the mPHR connect to social networks?	No
Q13	-Does the mPHR adapt to both horizontal and vertical orientations?	No
Q14	-Does the mPHR include a Help or FAQ section to help understand it?	Yes
Q15	-Is the color theme consistent?	Yes
Q16	-Is it possible to connect the mPHR to an external device?	No
Q17	-Is it possible to make a call to an emergency contact from the mPHR?	No
Q18	-Are the measurements filled in the trackers stored in the mPHR?	Yes
Q19	-Does the mPHR remember the preferences / settings already set by the user?	Yes
Q20	-Is the user able to access the mPHR without Internet connection?	Yes
Q21	-Does the pregnant woman's trackers section include a weight and blood pressure trackers?	Partially
Q22	-Are the fonts styles used for the text easily legible?	Yes
Q23	-Are the colors used attractive?	Yes
Q24	-Is the home page well structured?	No
Q25	-Is the navigation between the screens consistent and quick?	Yes
Q26	-Is there a possibility to create an instant health report from the data entered in the trackers?	No
Q27	-Does the mPHR connect with maps applications to display locations?	No
Q28	-Does the baby's trackers section include a contraction timer and kicks counter?	Partially
Q29	-Are the various functionalities of the mPHR well integrated?	Yes
Q30	-Did the design suit the purpose of the mPHR?	Yes

6 Conclusion and Future Work

In this study, a requirements catalog has been developed for prenatal care mPHRs, with respect to i18n, Sustainability, Operability, Performance efficiency, Reliability and Functional suitability in order to help developers and stakeholders extract and disclose requirements for these apps. The content of the catalog was conceived based on guidelines, recommendations, standards and previous studies.

This catalog is targeting stakeholders and developers of mPHRs for prenatal care, since it will help them elicit, identify and validate their potential requirements. It can also be beneficial for the development of further mPHRs for prenatal care or improving the existing ones. The catalog can be used for audit purposes as well [5].

As future work, we intend to conduct an audit on a set of mPHRs for prenatal care, in order to analyze their degree of compliance with the requirements of our catalog. The present catalog can also be improved by covering other quality characteristics of the ISO/IEC 25010 quality model such Maintainability and Compatibility [6].

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