Applying ISO/IEC 25010 on Mobile Personal Health Records

Sofia Ouhbi\textsuperscript{1}, Ali Idri\textsuperscript{1}, José Luis Fernández-Alemán\textsuperscript{2}, Ambrosio Toval\textsuperscript{2} and Halima Benjelloun\textsuperscript{3}

\textsuperscript{1}Software Project Management research team, ENSIAS, Mohammed V University, Rabat, Morocco
\textsuperscript{2}Department of Informatics and Systems, Faculty of Computer Science, University of Murcia, Murcia, Spain
\textsuperscript{3}Autonomic Nervous System research team, Faculty of Medicine, Mohammed V University, Rabat, Morocco

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Abstract: Software product quality requirements reflect the stockholders’ needs in terms of quality. They play a central role in the success of the system and the software product quality. This paper lists mobile personal health record (mPHR) requirements extracted from literature and identifies the requirements which should be included in the mPHR quality evaluation. Moreover, the ISO/IEC 25010 software product quality model is used to present a checklist with which to calculate the influence of the mPHR requirements on software product quality. Furthermore, the degrees of influence of mPHR requirements on software product quality are calculated and analyzed. A set of recommendations for mPHR developers and stakeholders is provided.

\section{INTRODUCTION}

Personal health records (PHRs) provide users with the possibility of managing their own health data. Many patients are using PHRs to communicate with doctors in order to improve healthcare quality and efficiency (Fernández-Alemán et al., 2013). An mPHR is a mobile application that allows users to access and coordinate their lifelong health information through their smartphones and to make appropriate data available to those who need it. MPHRS are very useful for people with chronic diseases (Chang et al., 2010). A large number of companies have emerged to provide consumers with the opportunity to use MPHRS within a healthcare platform (Kharrazi et al., 2012). An increasing number of studies have been published discussing different mPHR characteristics, functionalities and requirements (Chang et al., 2010; Simon and Seldon, 2012; Kharrazi et al., 2012; Al-Habsi and Seldon, 2013; Dohan et al., 2014). General inherent property requirements should be taken into consideration before the development of an mPHR. These requirements include functional requirements and software quality requirements (SQR). An SQR represents a target value of the software quality (SQ) measure (ISO/IEC-25030, 2007). A previous research work (Ouhbi et al., 2013) has shown that an increasing amount of attention has been paid to SQR since 2007.

Defining SQR is a critical stage in the software requirements process and SQR can be used in the process of software product quality requirements elicitation or as input for an evaluation process (ISO/IEC-25010, 2011). The ISO/IEC 25030 standard (ISO/IEC-25030, 2007) presents guidelines concerning the definition and the evaluation of SQR. This standard is part of the international research standardization project SURaRe which developed the ISO/IEC standard series 250nn for software product quality, evaluated from the viewpoint of users and stakeholders. The ISO/IEC 25010 standard (ISO/IEC-25010, 2011), which has replaced the ISO/IEC 9126-1 (ISO/IEC-9126-1, 2001), defines a software product quality model along with a system quality in use model. The ISO/IEC 25010 software product quality model is composed of eight characteristics, which are subdivided into sub-characteristics that can be measured internally or externally. The use of a software product quality model is essential in the quality requirement definition process (ISO/IEC-25030, 2007). The aim of this paper is to propose a general set of mPHR requirements reported in literature and to identify which requirements should be involved in the software product quality evaluation of an mPHR. This paper also aims to suggest a checklist for mPHR SQR and to evaluate the degrees of influence of mPHR requirements on software product quality characteristics by using the ISO/IEC 25010 standard (ISO/IEC-25010, 2011).

The remainder of this paper is organized as follows: Section 2 extracts general requirements for
an mPHR from literature. Section 3 presents an overview of the ISO/IEC 25010 standard. Section 4 provides an analysis of the influence of mPHR requirements on software product quality. The results are presented in Section 5 and discussed in Section 6. Section 7 shows the conclusions of this study and an overview of future work.

2 MPHRS REQUIREMENTS

This section presents the general requirements for an mPHR that should be taken into consideration during the requirements elicitation phase. The following requirements were extracted from several studies on mPHRs and also from the evaluation of existing mPHRs in app repositories. The study by (Kharraz et al., 2012) attempted to identify the data elements and application features implemented in current mPHRs in order to define the common components of a typical mPHR. The paper by (Simon and Seldon, 2012) has also presented some mPHR functionalities while discussing an exchange data method for mPHRs. Some requirements were extracted from a study concerning diabetics’ mPHR (Chang et al., 2010) and requirements for web-based PHRs were also taken into consideration (Fernández-Alemán et al., 2013). The general requirements for an mPHR were selected and gathered in six blocks: app’s accessibility, user’s personal information, user’s physical body quantitative data, user’s health information, user’s actions, and app’s features.

2.1 App’s Accessibility

App’s accessibility (AA) refers to the availability of the mPHR for users either before or after installation in the user’s smartphone. AA1: OS type. This requirement for the operating system (OS) type concerns the availability of the mPHR in app repositories. Is it limited to a specific store? The well-known OS types are: Android, iOS, Blackberry and Windows Phone. AA2: OS version. This requirement is important as regards the accessibility of the mPHR. An agreement should be reached as to whether the app will be accessible to a certain OS version or it should be available for all smartphones using the same OS. AA3: cost. Is the mPHR free or does it cost money? This requirement should be taken into consideration by stakeholders as free apps are more popular (Petas et al., 2013) but paid apps might have a more advanced set of functionalities (d’Heureuse et al., 2012). AA4: target audience. This requirement should specify whether the mPHR targets a certain audience type, such as people suffering from a chronic disease, or it is open for all users. AA5: geographical limitation. It is necessary to define whether the app should be available for a certain geographic area, or should have an open access for users from all over the world. AA6: network operator’s limitation. In some cases, the network operator sponsors apps which will be available only for its users.

2.2 User’s Personal Information

An mPHR should contain a profile section which contains the user’s personal information (PI). The user’s profile can be of great importance if s/he wishes to share information with another party. The user profile requirements should therefore cover the following data: PI1: full name, PI2: age, PI3: marital status, PI4: insurance type, PI5: phone number, PI6: email and PI7: address.

2.3 User’s Physical Body Quantitative Data

The role of the mPHR is to help the user keep track of his/her physical body quantitative data (QD). The following data should figure in any mPHR to help users with different kinds of health problems track their measurements: QD1: height, QD2: weight, QD3: temperature, QD4: heart frequency, QD5: glucose and QD6: blood pressure.

2.4 User’s Health Information

The user’s medical record should contain some or all of the following health information (HI): HI1: illness history. HI2: family illness history. HI3: blood group. HI4: medication list. HI5: allergies. HI6: fertility. HI7: surgical procedures. HI8: social history such as: alcoholism, drug addiction and tuberculosis. HI9: immunizations. HI10: psychological disorders. HI11: emotional disorders.

2.5 User’s Actions

Different user’s actions (UA) should be specified in the requirements document. UA define the set of actions that the user can take while using the mPHR. It should be specified whether the user can or cannot: UA1: add information, UA2: remove information, UA3: modify information, UA4: be authenticated. An authentication method can be a login/ password or a two-factor authentication or biometric authentication, UA5: import data UA6: export data UA7: share information and UA8: backup data.
2.6 App’s Features

An app’s features (AF) are the functionality of the app. Requirements for AF may contain: AF1: health advice. This could help the user to improve his/her way of life. AF2: social media. AF3: images. AF4: alarm system. Alarms can be set for medication intake or appointments with doctors. AF5: notification messages. Messages can be push notifications or short message service SMS which are sent by another party in order to notify the user. AF6: internationalization. Is the mPHR available in more than one language? International access is reflected by the nationalization. AF7: is the mPHR available in more than other party in order to notify the user.

AF8: emergency contact. In the case of an emergency, the user should have an easy access to the phone numbers to be contacted. AF9: connection with EHR. EHR stands for Electronic Health Record. AF10: connection with labs. AF11: connection with hospitals. AF12: connection with health devices. AF13: connection with other PHRs.

3 ISO/IEC 25010 STANDARD

The ISO/IEC 25010 quality model defines: (i) quality in use, which is a measure of the overall quality of the system in its operational environment for specific users, for carrying out specific tasks, (ii) software product quality, which is composed of eight characteristics that are further subdivided into sub-characteristics that can be measured internally or externally: (1) external SQ addresses properties related to the execution of the software on computer hardware and the application of an OS; (2) internal SQ addresses properties of the software product that are typically available during the development. Internal SQ has an impact on external SQ which again has an impact on SQ in use (ISO/IEC-25010, 2011). Note that the ISO/IEC 25010 standard has replaced the ISO/IEC 9126 standard in 2011. The ISO/IEC 25010 quality model differs somewhat from the ISO/IEC 9126 quality model: security becomes a characteristic in ISO/IEC 25010 rather than a sub-characteristic for functionality as it was in ISO/IEC 9126, compatibility is added as a new characteristic in ISO/IEC 25010 and quality in use has five characteristics instead of the four characteristics of ISO/IEC 9126.

The SQ measures defined in ISO/IEC 2502n are useful for formalizing stakeholder SQR. Software product requirements are divided into inherent and assigned property requirements. The inherent properties are composed of function and quality properties. “Functional properties determine what the software is able to do, while quality properties determine how well the software performs” (ISO/IEC-25010, 2011).

4 MPHR REQUIREMENTS

INFLUENCE ANALYSIS

This section presents the analysis process used to calculate the influence of the mPHRs requirements defined in this study on software product quality, along with an illustration example. The analysis process is based on that of (Idri et al., 2013) but was adapted to our needs in order to answer the following questions:

Q1 Which mPHR requirements should be considered when evaluating mPHR quality?
Q2 What influence do mPHR requirements have on software product quality?

In order to answer Q1, the mPHR requirements are analyzed and SQR are identified by using the definition from ISO/IEC 25030. In order to answer Q2, three steps are carried out in the analysis process:

Step 1. Analysis of the product quality characteristics and sub-characteristics. The product quality model ISO/IEC 25010 was analyzed in order to understand the meaning of each external sub-characteristic. In order to obtain a better idea of the meaning of the mPHR SQR, the ISO/IEC 25023 standard should be used. However, the standard for the measurement of system and software product quality ISO/IEC 25023 is under development and the metrics from the ISO/IEC 9126-2 external metric technical report were therefore studied. All the compliance quality sub-characteristics were discarded owing to the fact that conventions and compliance with regulations are not relevant to this study.

Step 2. Checklist of mPHR requirements using ISO/IEC 25010 software product quality model. The potential influence of an mPHR requirement on an external sub-characteristic is checked. A software product quality sub-characteristic is considered to be influenced by a requirement if the variables used in the calculation of the external metric are influenced by this requirement. The unavailability of ISO/IEC 25023 led us to use the external metrics defined in ISO/IEC 9126-2. In the case of the new sub-characteristics of ISO/IEC 25010, whose previous model did not provide external metrics, we analyzed the definitions provided by ISO/IEC 25010 in order to estimate the influence of mPHR requirements on them.

Step 3. Calculation of degree of influence of mPHR requirements on software product quality.
Three degrees of influence are calculated:

1. \( DI(EC, B) = \sum DI(EC,R) / N(R) \), where \( DI(EC, B) \) is the degree of influence of a block of requirements B on an external characteristic EC and \( N(R) \) is the total number of requirements in that block.

2. \( DI(EC, R) = N(EC, R) / N(EC) \), where \( DI(EC, R) \) is the degree of influence of a requirement R on an external characteristic EC, \( N(EC, R) \) is the number of sub-characteristics EC of EC that are influenced by that R, and \( N(EC) \) is the total number of sub-characteristics of EC.

3. \( DI(EC, B) = \sum DI(EC,R) / N(R) \), where \( DI(EC, B) \) is the degree of influence of a block of requirements B on an EC and \( N(R) \) is the total number of requirements in that block.

\( N(EC, R) \), \( N(EC) \), and \( N(R) \) are calculated from the checklist defined in Step 2. According to the result, each degree of influence is classified into five groups: Very high if the result is between 0.90 and 1.00; High if the result is between 0.7 and 0.89; Moderate if the result is between 0.4 and 0.69; Low if the result is between 0.2 and 0.39; and Very low if the result is between 0 and 0.19.

**Illustration Example.** In this example we focus on the degree of influence of block AA, which contains six requirements, on the Transferability (T) characteristic. In order to calculate \( DI(T, AA) \) it is necessary to calculate the degree of influence of each AA requirement on Transferability: \( DI(T, AA) = \sum_{i=1}^{6} DI(T, AAi) / 6 \). The requirement AA1 influences three Transferability sub-characteristics: Portability, Adaptability and Installability. Thus, \( DI(T, AA1) = (1+1+1)/3 = 1 \). Following the same logic, we obtain that: \( DI(T, AA2) = 1 \); \( DI(T, AA3) = 0 \); \( DI(T, AA4) = 0 \); \( DI(T, AA5) = 1/3 \); and \( DI(T, AA6) = 1/3 \). So, \( DI(T, AA) = (1+1+0+0+1/3+1/3)/6 = 0.44 \).

In this example we also calculate the degree of influence of block AA on the Portability (P) sub-characteristic: \( DI(P, AA) = \sum_{i=1}^{6} DI(P, AAi) / 6 \). Portability is influenced by AA1 and AA2, thus \( DI(P, AA1) = 1 \); \( DI(P, AA2) = 1 \); and \( DI(P, AA3) = DI(P, AA4) = DI(P, AA5) = DI(P, AA6) = 0 \). So, \( DI(P, AA) = (1+1+0+0+0+0)/6 = 0.33 \). The results show that \( DI(T, AA1) \) and \( DI(T, AA) \) are moderate while \( DI(P, AA) \) is low.

## 5. RESULTS

This section presents the results of the mPHR requirements influence analysis.

### 5.1 Requirements Used to Evaluate mPHR Software Product Quality

The software product quality of an mPHR on a smartphone with an OS should be evaluated using external requirements. “External software quality requirements are used as the target for technical verification and validation of the software product” (ISO/IEC-25010, 2011). Requirements in block AA for cost and OS version are ”assigned property requirements” (ISO/IEC-25030, 2007). These requirements cannot therefore be used as SQR as they can be changed without changing the software. The remaining mPHR requirements identified in this study should be included in the evaluation of the mPHR’s software product quality. Each requirement should be specified with a target quality measure in the requirements document approved by the mPHR stakeholder.

### 5.2 Influence of mPHR Requirements

Table 1 shows the results of the software product quality model checklist. This checklist contains 30 software product quality sub-characteristics. Only a few mPHR requirements are concerned with more than 50% of the external SQ sub-characteristics, while 60% are not dealt with. UA8 influences half of the sub-characteristics. UA4, AF9, AF10, AF11 and AF13 have an impact on 16 external sub-characteristics, while AF12 impacts on 17 sub-characteristics. The requirements in block AA have a very low impact on SQ. Figure 1 presents the degree of influence of the blocks of requirements on the external characteristics. The impact of the blocks PI, QD, HI, UA and AF on Reliability and Performance efficiency is very high. In fact these blocks are the only blocks which have an impact on these two characteristics. The UA influence on Functional Suitability is also very high. All the blocks have a very low influence on Compatibility and Maintainability.
Transferability is influenced moderately by AA. All the blocks have a low influence on Security. They have a moderate influence on Operability except AA which has a very low influence on this characteristic.

Figure 2 presents the degree of influence of the mPHR requirements on the external characteristics. All requirements have an influence on Functional suitability. Operability is influenced by 92% of mPHR requirements, while 88% of the requirements affect Reliability and Performance efficiency. Security and Maintainability are respectively influenced by 69% and 63% of the mPHR requirements, while Compatibility and Transferability are affected by only 18% and 8% respectively. Figure 3 shows the degree of influence of the blocks of mPHR requirements on the external sub-characteristic. This figure provides a detailed view on the impact of mPHR requirements on each external characteristic by identifying which of its components is concerned. The sub-characteristic Appropriateness of Functional suitability.
appropriateness is influenced by all the mPHR requirements. The sub-characteristics of Reliability and Performance efficiency are equally influenced by all the blocks except AA. Learnability and Helpfulness, which are sub-characteristics of Operability, are influenced by only one mPHR requirement in block AF. The Security sub-characteristic that is most influenced by mPHR requirements is Confidentiality. Compatibility is mainly influenced through the sub-characteristic Interoperability. None of the mPHR requirements has influenced the following Maintainability sub-characteristics: Analyzability, Changeability, Modification stability, and Testability. Installability, which is a sub-characteristic of Transferability, is moderately influenced by block AA.

6 DISCUSSION

This section summarizes the principal findings of this study and presents their implications for mPHR stakeholders and developers.

6.1 Principal Findings

The requirements listed in this study were extracted from literature and from a compilation of existing mPHRs. Requirements such as Medication (HI4) and Allergies (HI5) exist in all the mPHRs evaluated by (Kharrazi et al., 2012) and the absence of these requirements may severely affect mPHR market penetration (Kharrazi et al., 2012). The mPHR requirements identified were analyzed in order to select those that should be included in the evaluation of software product quality. Software product quality is evaluated by using SQR (ISO/IEC-25040, 2011). Apart from requirements concerning cost and OS version in block AA, the other requirements can be translated to SQR by assigning a quality attribute that can have a target measure to each requirement. The influence analysis results show that the requirements UA4, UA8, AF2, and AF9–AF13 have a great influence on software product quality:

Authentication (UA4) has a great influence on mPHR software product quality. Information security in mobile devices is a serious limitation and threat to the users’ personal data (Wasserman, 2010). Protecting users’ health information is one of the aspects that may distinguish one mPHR from another. Various biometric authentication methods are being developed for smartphones (Klonovs et al., 2013; Meng et al., 2013), which may enhance the protection of mPHR users’ personal medical records. The mPHR user who is willing to back up his/her data (UA8) is confronted with mobile limitations. Compared with computers, smartphones have a limited memory, which will limit their ability to store images and large data files (Wasserman, 2010). One solution to this is the use of a cloud service, which can act as a storage mechanism and an intermediary for data transfer.
However, an Internet connection is required, and the user may once again confront some serious mobile environment limitations such as frequent disconnection and variable bandwidth (Peng, 2013). Moreover, the study by (Ion et al., 2011) has shown that smartphone users do not trust the cloud as a data-storage environment and prefer to use home-based storage solutions, such as storing data on their laptops.

Social media (AF2) usage highly influences mPHR software product quality. Using social networks implies privacy and security issues, particularly as regards sharing information related to health data. Despite the lack of privacy in social media, the mPHR users of social networks can obtain support and information from the social network community which could help them to confront their health condition (Fernández-Alemán et al., 2013). Block AF includes requirements for mPHR app’s features that have a great influence on mPHR software product quality, particularly requirements concerning mPHR connections with other parties, such as EHR, laboratories and medical devices. According to (Al-Habsi and Seldon, 2013), the lack of a standardized form of data exchange is one of the most common problems in medical data exchange. (Al-Habsi and Seldon, 2013) have used free tools and open source software to develop a communication module between mPHRs and web-based PHRs. Their module uses a common message standard Continuity of Care Record (CCR), and message vocabulary standards.

The results also show that the external characteristics which are highly influenced by mPHR requirements are Reliability and Performance efficiency. A previous study (Idri et al., 2013) has shown that Reliability is influenced by frequent disconnection, variable bandwidth, and limited energy autonomy, while Performance efficiency is influenced by lower bandwidth and limited storage capacity. In the requirements elicitation phase, the mPHR requirements should be specified by taking into consideration these mobile environment limitations. Functional suitability through Appropriateness, Operability through Ease of use, Attractiveness and Technical accessibility, and Security through Confidentiality are also influenced by the mPHR requirements. The Operability characteristic in ISO/IEC 25010 refers to the Usability characteristic in ISO/IEC 9126 and was renamed to avoid conflict with the definition of usability in (ISO/IEC-25062, 2006). Operability may confront the limited user interface of smartphones (Idri et al., 2013). The study by (Zapata et al., 2014) has analyzed 24 mPHRs (Android and iOS only) and has concluded that these mPHRs are not suitably structured in compliance with Android and iOS usability guidelines. Security is influenced by authentication and interoperability with other parties. A cloud service can overcome problems of security in smartphones and (Zonouz et al., 2013) has proposed a cloud-based comprehensive and lightweight security solution for smartphones.

6.2 Implications and Advice for mPHR Stakeholders and Developers

This study provides a general view of mPHR requirements. It is up to stakeholders, developers and evaluators to translate them to SQR. The mPHR SQR can be used by those responsible for specifying and evaluating software product quality. Software product quality evaluation can be performed “during or after the development process or acquisition process by the developer organization, the acquirer organization or an independent evaluator” (ISO/IEC-25040, 2011). The mPHR requirements for external software quality characteristics should be stated quantitatively in the quality requirements specification using external measures and then used as criteria when the mPHR is evaluated (ISO/IEC-25010, 2011). A checklist of mPHR requirements and their influence on software product quality may be of great use to mPHR developers. Stakeholders could formulate their mPHR requirements by taking into consideration the suggestions made in this study.

6.3 Limitations

This study may have some limitations such as: (i) Other mPHR requirements, which do not figure in our list, may have been relevant to this study. However, the mPHR requirements presented in this study were extracted from a large and relevant collection of mPHR literature. (ii) The use of the definition of software product quality characteristics rather than their metrics. This limitation is owing to the fact that the ISO/IEC 25023 standard is unavailable since it is still under development. The ISO/IEC 9126-2 technical report has therefore been used to alleviate this threat. These limitations may have slightly affected the results of our study. Nevertheless, we believe that our findings may be used in future works on mPHRs.

7 CONCLUSION AND FUTURE WORK

This paper has extracted and analyzed 51 mPHR requirements from literature. A list of mPHR requirements that should be included in the mPHR quality
evaluation is suggested. The ISO/IEC 25010 software product quality model has been applied to the mPHR requirements identified in this study. A checklist containing 30 external sub-characteristics has been presented to calculate the influence of mPHR requirements on software product quality. The degrees of influence of mPHR requirements on a software product are calculated and analyzed. The results of this study have shown that some characteristics, through certain sub-characteristics, are more influenced by the mPHR requirements than others, particularly, Functional suitability, Reliability, Performance efficiency, Operability and Security characteristics. As future work, we intend to use the results from this study as a basis to carry out an empirical evaluation of an mPHR. We intend also to express the disparity and variability in the degree of influence of the various mPHR requirements.

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