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E-health internationalization requirements for audit purposes

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ABSTRACT

Background and objective: In the 21st century, e-health is proving to be one of the strongest drivers for the global transformation of the health care industry. Health information is currently truly ubiquitous and widespread, but in order to guarantee that everyone can appropriately access and understand this information, regardless of their origin, it is essential to bridge the international gap. The diversity of health information seekers languages and cultures signifies that e-health applications must be adapted to satisfy their needs.

Methods: In order to achieve this objective, current and future e-health programs should take into account the internationalization aspects. This paper presents an internationalization requirements specification in the form of a reusable requirements catalog, obtained from the principal related standards, and describes the key methodological elements needed to perform an e-health software audit by using the internationalization knowledge previously gathered.

Results: *S Health*, a relevant, well-known Android application that has more than 150 million users in over 130 countries, was selected as a target for the e-health internationalization audit method and requirements specification presented above. This application example helped us to put into practice the proposal and show that the procedure is realistic and effective.

Conclusions: The approach presented in this study is subject to continuous improvement through the incorporation of new knowledge originating from additional information sources, such as other standards or stakeholders. The application example is useful for early evaluation and serves to assess the applicability of the internationalization catalog and audit methodology, and to improve them. It would be advisable to develop of an automated tool with which to carry out the audit method.

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1. Introduction

E-health is a process that provides health care information via electronic means and connects patients, physicians, care providers, health care delivery systems, citizens, governments and regulatory bodies through the use of information and telecommunication technologies, particularly over the Internet. The Internet has the scope, the infrastructure, and the acceptance to achieve widespread change and to drive the development and adoption of e-health applications [1]. e-health programs provide the potential for: enhanced reach at a relatively low cost; scalability; time efficiency; and the capacity to provide individual patients [2–4] including traditionally underserved populations, patients with chronic conditions [5,6] and consumers all over the world [7] with tailoring and customization. International collaborations as regards delivering and evaluating e-health programs provide many opportunities but also lead to very substantial challenges specifically related to different languages and cultures [8,9]. Developers and researchers should therefore take into account e-health internationalization requirements.

Internationalization (i18n) is the process of designing a software application in such a way that it can be adapted to various languages and regions without the need for engineering changes [10]. This aspect is particularly relevant in the case of extremely sensitive information, such as that in the health domain. Many stakeholders currently provide cross-country health care material and e-health programs for multicultural environments [1]. The amount of health related information on the worldwide Internet is rapidly increasing [11]. There are currently thousands of e-health web sites online offering general content on health and medical care, including hundreds of thousands of individual web pages

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dedicated to a broad range of topics [12]. The capabilities of i18n can make e-health systems valuable for users in different countries [13]. However, it is necessary to have an appropriate mechanism with which to check the personalization functionality of a given e-health application, in particular with regard to i18n.

According to the IEEE Standard 1028 [14], an *audit* can be defined as "an independent examination of a software product, software process, or set of software processes performed by a third party to assess compliance with specifications, standards, contractual agreements, or other criteria". Different aspects can be taken into account in a software audit, such as usability, accessibility, reliability or i18n, among others, and many health institutions, such as Pen Computer Systems (PCS) [15] in Australia and eCompliance [16] in Canada are interested in auditing e-health platforms. Furthermore, standardization in the field of e-health is a long ongoing activity in which an attempt is made to use latest technologies for the benefit of patients, health services and other interested parties [17,18]. When standards are used in the context of software development or auditing, it is very useful to adapt, refine and express their contents in the form of explicit software and system requirements [19]. This implies identifying the principal related sources, extracting the relevant text, and reinterpreting all this information in the form of precise requirements [20,21]. In spite of the relevance of the problem described, neither specific standards and guidelines for e-health software i18n nor e-health i18n audit approaches are, to the best of our knowledge, available to date.

This paper is concerned with i18n requirements for e-health audit purposes. In other words, we intend to provide i18n aspects for e-health resources in order to meet the needs of the users, independently of their language, culture or origin. In order to facilitate dealing with i18n in a rigorous and complete manner, we propose to collect the existing knowledge on i18n, mainly gathered from standards, in a single formal document. This document denominated as e-health Internationalization Catalog (eHI-C), has been constructed according to the best Requirements Engineering (RE) practices. Although eHI-C can be used as a conventional requirements document in an ordinary e-health software development process, in this paper we focus on its use for audit purposes. This paper therefore provides not only a secretion of the i18n sources used and the i18n requirements catalog obtained, but also the outline of an e-health audit method with which to asses this kind of properties, denominated as e-health Internationalization Audit Method (eHIA-M). The main contributions of this paper are, therefore: (1) the definition of a reusable software i18n requirements catalog based on the principal related Software Engineering (SE) standards and health standards provided by international standardization bodies and consortia that are active in e-health; and (2) the identification of the main artifacts, activities and roles involved in an effective e-health audit as regards i18n features, based on the catalog proposed in this study.

The remainder of this paper is organized as follows: Section 2 describes the process used to obtain the i18n requirements catalog, and the structure of this artifact. Moreover, this section outlines the e-health audit method. Section 3 shows an application example that serves as the validation strategy for the proposed approach. Section 4 discusses the results of this paper. Finally, Section 5 summarizes our conclusions and further work.

2. Material and methods

2.1. eHI-C: e-Health internationalization requirements catalog

In order to facilitate the widespread use of e-health, there is a need to implement standardized platforms [22]. This section presents the process used to identify i18n standards and other relevant sources, and to extract related requirements.

2.1.1. Information sources for internationalization requirements

Many international organizations are working on the standardization of e-health applications such as:

- CLSI [23]: Clinical and Laboratory Standards Institute.
- ITU-T/ITU-D [24]: International Telecommunication Union.
- eHSCG [25]: e-health Standardization Coordination Group.
- DICOM organization [26]: Digital Imaging and Communications in Medicine organization.
- OASIS [27]: Organization for the Advancement of Structured Information Standards.
- CEN/TC 251 [28]: European Committee for Standardization Technical Committee 251.
- ISO/TC 215 [29]: International Organization for Standardization's (ISO) Technical Committee (TC) on health informatics.
- CEN ISO/IEEE 11073 committee [30]: Medical device communication standards committee.
- IEC/TC 62 [31]: Technical committee for standards regarding electrical equipment in medical practice.

Each one addresses different issues related to e-health technology standards and specifications, e.g. architectures, interfaces, interoperability, accessibility, privacy, security or i18n. The names and references of the most important sources used to populate the i18n requirements catalog are provided below. More related standards, and further details on them, can be obtained from the ISO, IEEE and CEN websites and the other standardization organization websites.

- ISO/TR 18307:2001 Health informatics - Interoperability and compatibility in messaging and communication standards – Key characteristics. This standard describes the main requirements related to achieve interoperability and compatibility in trusted health information interchange between software applications and systems in health care.
- CEN/TR 15212:2006 Health informatics - Vocabulary – Maintenance procedure for a web-based terms and concepts database
- EN ISO 21090:2011 Health Informatics - Harmonized data types for information interchange (ISO 21090:2011)
- ISO/TR 20514:2005 Health informatics - Electronic health record – Definition, scope and context
- ISO/TR 14292:2012 Health informatics - Personal health records – Definition, scope and context
- ISO/TS 22220:2011 Health informatics - Identification of subjects of health care
- ISO/TS 14265:2011 Health Informatics - Classification of purposes for processing personal health information
- ISO/HL7 27931:2009 Data Exchange Standards - Health Level Seven Version 2.5 – An application protocol for electronic data exchange in health care environments
- ISO 27799:2008 Health informatics - Information security management in health using ISO/IEC 27002.
- CEN/TR 15640:2007 Health informatics - Measures with which to ensure patient safety as regards health software

General SE standards (e.g. quality, web usability), methods, guidelines, regulations or legislation on a topic of interest for e-health developers, could also be utilized as a source of useful reusable information for software development or audit activities. Standards concerning Web Information Systems (WIS), such as W3C, are also considered in this study, since many current e-health platforms are websites. Other general SE standards to be taken into account are:

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