

A Review on Usability Features for Designing Electronic Health Records

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Abstract— Health professionals should record clinical care information in order to provide adequate patient assistance. Such recording process requires an Electronic Health Record (EHR) with complete and integral information adjusted to treatments performed on a patient. Moreover, availability and access to EHR are key features supporting decision making and improve patient care. Nevertheless, designing an EHR fulfilling a set of quality attributes is not an easy task. In fact, an EHR with low usability causes deficient clinical services and poor data quality on medical records. In this paper, an interpretation of the ISO 9241-210 standard, in the context of patients' care in an emergency situation, is presented. It considers three mid-level objectives: understanding, designing and evaluating. In this way, an alignment between high-level guidelines, offered by usability standards, and low-level activities to be followed during an EHR design, is achieved.

Keywords— *Electronic Health Record, Usability, User Centered Design (UCD), e-Health.*

I. INTRODUCTION

The possibility of timely access to patients' clinical information, independently of where they are, or the type of treatment they require, constitutes a fundamental difference on provided health care. It has encouraged and motivated the implementation of Electronic Health Records (EHR) allowing access, management, and querying medical information. Nevertheless, EHR design and implementation have been mainly focused on administrative and financial aspects, in order to bring billing support, instead of concerning on patient care. This focus has left in background issues related to EHR usability, making difficult querying and recording clinical information by medical staff. In fact, uncertainty in medical staff regarding easiness of access to medical records is a barrier for EHR adoption [1]. Consequently, ignoring EHR usability during the design and the implementation phases, may impact on the adoption of an entire e-Health system [2].

There are several usability standards and characteristics which can be used as guidelines for designing an EHR under a user-centered approach, as well as for incorporating quality principles looking patient safety, within a usable and effective e-Health system. In this paper, EHR usability standards and characteristics are reviewed, discussed and interpreted by considering three steps: understanding, designing and

evaluating. These steps aim to guide an EHR design process, looking forward to decrease the resistance of physicians for adopting an EHR in a daily basis. Presented interpretation is conducted on patients care in an emergency situation. This paper is structured as follows. The most recognized standards associated with usability are outlined in Section II. EHR usability characteristics, as well as usable design, are summarized in Section III. Methods for evaluating EHR usability are described in Section IV. A review on EHR usability features regarding patients care in an emergency situation is presented in Section V. Final remarks are stated in Section VI.

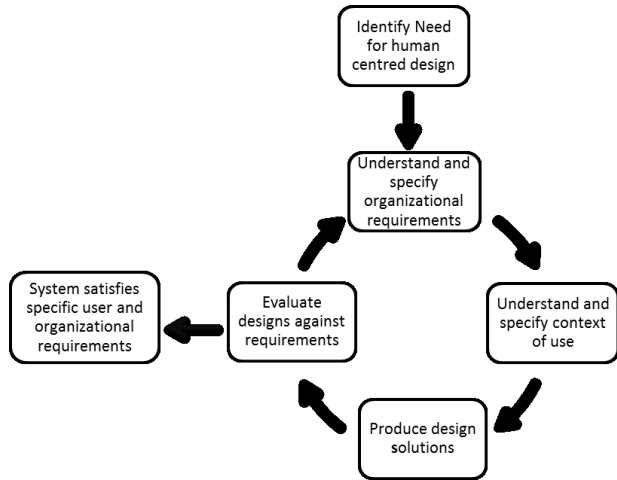
II. USABILITY STANDARDS

Usability is defined by the ISO as the effectiveness, efficiency and satisfaction with which users can achieve their tasks in a context intended product use [3]. Usability is a quality attribute of software, which sometimes tends to be confused with utility. Utility, in turn, refers to the existence of a feature to perform a particular activity, regardless of aspects such as the degree of difficulty to execute the process. Efforts on EHR have been focused on improving utility, ignoring aspects such as user satisfaction, simplicity, context preservation and efficient user interaction, among others. In fact, many EHR implementations may have failed due to usability problems [4]. The lack of access to secondary functions, information loss, and navigability issues on graphical user interfaces are among these problems [1]. Taking this into account, organizations such as the National Institute of Standards and Technology (NIST), the Office of the National Coordinator for Health Information Technology and the Agency for Healthcare Research and Quality (AHRQ), have established guidelines for improving EHR usability. These guides are based on ISO standards such as ISO 9241-210, ISO 9241-11, and ISO/TR 16982.

A. ISO 9241-210

The ISO 9241-210 standard replaced the ISO 13407, in order to upgrade and integrate requirements and recommendations related to User Centered Design (UCD) principles and activities [5]. The main activities considered in this standard are depicted in Figure 1[6]. Such activities have to be initiated early in the process and performed iteratively.

Fig. 1. ISO 9241-210 standard [6].



The ISO 9241-210 standard also defines six key principles for UCD [7], which are shown in Table I.

B. ISO 9241-11

The ISO 9241-11 was created for regulating the quality of usability and ergonomics of hardware and software. The eleven chapter of this standard defines usability and how to appraise it, taking in to account performance and user satisfaction, as well as measures of effectiveness and efficiency [3].

C. NISTIR 7741

The NISTIR 7741 is a UCD guide for EHR developers looking for efficient and effective designs. It aims to improve user satisfaction and quality of experience by guiding implementation of usable interfaces. It also provides guidance on UCD methods and essential elements to be considered during EHR usability validation [8].

D. ISO/TR 16982

The ISO/TR 16982 provides high-level information on UCD usability methods which can be used for design and evaluation. It deals with specific advantages and drawbacks of each method [9].

TABLE I. KEY PRINCIPLES OF UCD.

No.	UCD Principles
1	Design based on an explicit understanding of users, tasks and environments.
2	Users are involved in design and development.
3	Design is targeted and refined by focusing on user evaluations.
4	The process is iterative.
5	Design is addressed at the entire user experience.
6	Design team includes multidisciplinary skills and perspectives.

III. USABILITY OF ELECTRONIC HEALTH RECORDS

EHR quality can be understood as the degree on which medical records meet certain requirements [10]. Thus, an agreement on what will be understood as EHR quality should be stated and documented. Moreover, coordinated and guided efforts in the design of clinical information systems are required in order to achieve a significant progress in the adoption of EHRs. Improved levels of usability might turn medical staff to adopt EHR, and e-Health systems, as well as lead institutions to invest on innovation [11]. EHR usability relates characteristics and design.

A. Usability Characteristics

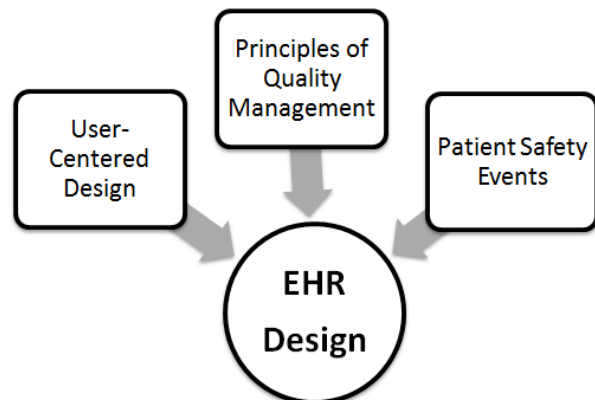
Usability characteristics can be outlined as follows [12]:

- Learnability: Degree to which the software product allows users to learn its application.
- Operability: Degree to which users find the product easy to use and control.
- Protection against user errors: Degree to which the system protects users from making mistakes.
- Aesthetics of the user interface: Extent to which the interface allows an enjoyable and satisfying user interaction.
- Intelligibility: Extent to which the software product allows users to recognize whether the software is suitable for your needs.
- Accessibility: Ease of use and safety for users with specific disabilities.

B. Designing Usable EHR

Three main components, related to patients care, should be considered during the design and implementation of an EHR [13]. These components are illustrated in Figure 2 and outlined below.

Fig. 2. EHR design



1) *EHR User Centered Design*

The fundamental principles for creating usable systems are based on a systematic understanding of users and their environments, system design and iterative testing of performance targets users. Such principles are mentioned in Table II.

2) *Principles of Quality Management of Health Records*

Quality management involves reviewing medical records, identifying gaps and defining correction plans.

There are two main types of reviews:

- Quantitative: It considers compliance and ordering of medical record data.
- Qualitative: Assessment performed to analyze medical record information content. It requires a medical audit by experts.

3) *Patient Safety Events*

Safety events are associated to patient risks due to introduced errors on the medical record. Lack of clarity on information to be recorded by medical staff, or on meaning of shown data by an interface, will lead to confusion. Such confusion may in turn, lead to a misinterpretation of medical records and therefore, to a wrong decision-making by physicians, jeopardizing patient integrity.

IV. EHR USABILITY EVALUATION

EHR quality should be evaluated in order to ensure medical records completeness and adequacy. Usability evaluation outcomes will improve EHR navigation, screen design, interaction or visual design, among other concerns, for which it is not necessary to test the entire application at a time, except at the end of the cycle design, and before the implementation of the EHR. Usability evaluation should be conducted in early stages of the development cycle, using wireframes or paper prototypes.

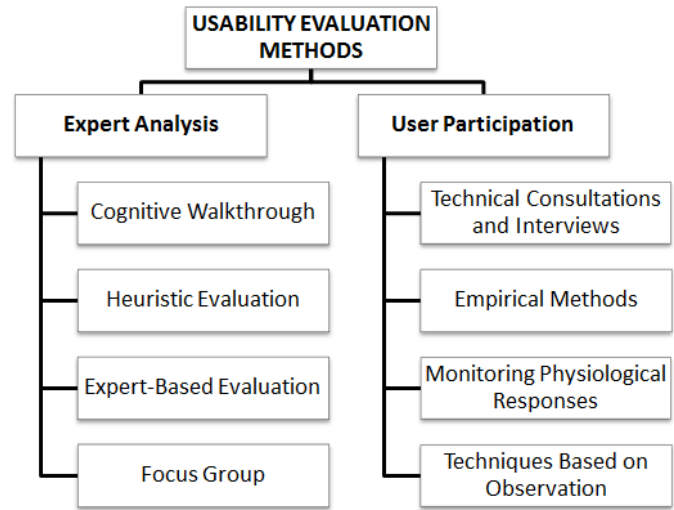
A. *Methods*

There are several methods to evaluate EHR usability. Such methods are mainly based on expert analysis, or user participation, as it is shown in Figure 3.

TABLE II: PRINCIPLES OF USER-CENTERED DESIGN [8].

No.	UCD Principles NISTIR 7741
1	Understand user needs, workflows and work environments
2	Engage users early and often
3	Set user performance objectives
4	Design the user interface from known human behavior principles and familiar user interface models
5	Conduct usability tests to measure how well the interface meets user needs
6	Adapt the design and iteratively test with users until performance objectives are met

Fig. 3. EHR usability assessment methods



An evaluation method can be chosen based on selected and incorporated EHR usability characteristics, as well as on considered risks within a specific context. It also should take into account human, physical and environmental factors. A set of considerations for properly selecting an evaluation method are shown in Table III [14].

The AHRQ establishes the importance of dedicating efforts on developing tools for system evaluation and adherence to usability principles and best practices as well as the establishment of usability certification for systems developed by suppliers [14]. The Office of the National Coordinator for Health Information Technology (ONC) published a method for testing and certification of EHR. This certification aims providers to follow a formal user-centered design and improving usability testing results in specific product areas [15].

TABLE III. USABILITY EVALUATION CONSIDERATIONS.

Characteristic	CONSIDERATIONS
Strategy	Associated to a development stage when the evaluation is performed.
Location	Related to where the evaluation is performed.
Prejudice	Subjectivity or objectivity Inherent to a method which will affect the outcome.
Measure of Usability	Type of measurement provided by a method (i.e. quantitative or qualitative).
Information	Granularity of the response provided by a method.
Immediateness of Response	Speed with which a method generates a response.
Intromission	Changes in user behavior due to an evaluation scenario.
Cost	Required resources to perform an analysis and an evaluation.

B. EHR Evaluation Usability Protocol (EUP)

The evaluation protocol for electronic medical records, proposed by the NIST, is a model for determining the usability of an EHR. The protocol is shown in Figure 4. It specifies the three steps that should be followed for validating the usability of an EHR in a specific context. These steps are performed on cases where critical risks are identified and have to be evaluated, since they can be sources of error on medical records [16].

1) Step I: Application Analysis

Applications analysis depends on the requirements of EHR. It includes a description of basic functions, and considers user characteristics, as well as interactions between them and the EHR, looking forward to identify critical tasks related to patient safety aspects. Additionally, it should provide a description of user interface design and optimization during development.

2) Step II: Expert Review of User Interface

The review should be conducted by the provider’s development team as well as by experts in usability and clinical security. The evaluators compare the design of the user interface of the EHR against standards of scientific design. Design problems that could lead to security risks are identified. Finally, the development team may choose to modify aspects of the user interface, either to eliminate problems or to adjust deviations from the best practices, according to the findings related to patient safety issues.

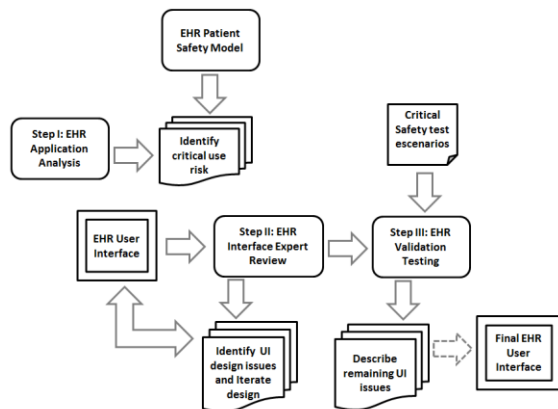
3) Step III: Validation Tests of User Interface

User performance in critical tasks, related to previously-identified patient safety risks, should be evaluated. It is done by qualified professionals who validate usability previously to the EHR implementation stage.

Measures that can be used for performance are:

- Quantity of successfully completed tasks.
- Quantity of found and fixed errors.
- Failures on successfully complete a task or an organizational procedure in a proper sequence.

Fig. 4. EHR Evaluation Usability Protocol [16].



The performance is evaluated by performing post-test interviews, which are focused on identifying risks due to problems on understanding or confusion expressed by users. The goal of the test is to ensure that the interface design problems do not lead to errors and impact on patient safety.

C. Usability Maturity Model

The Usability Maturity Model (UMM) defines maturity levels according to organizations’ processes and capacity [17]. Maturity levels are described in Table IV. The UMM allows to measure the degree to which a construction process of usable experiences is systematized.

V. A DISCUSSION ON USABILITY STANDARDS REGARDING PATIENTS CARE IN EMERGENCY SITUATIONS

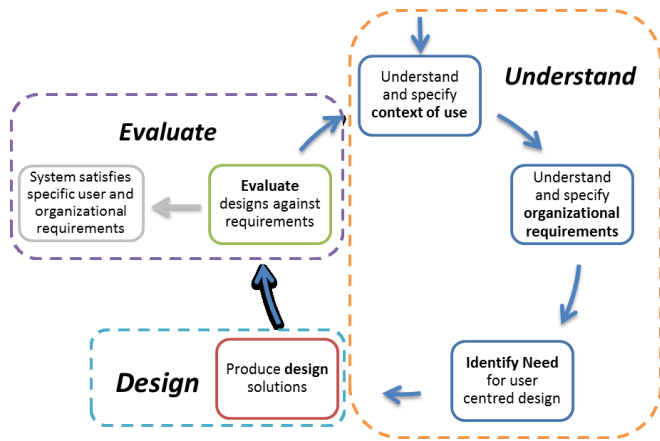
A. Proposed Interpretation of the ISO 9241-210 standard

Usability is an important attribute in design and implementation of e-Health systems due to the diversity of devices, programs and interfaces that should be integrated. Although the relevant standards to be considered in this effort are clearly identified and well documented, an interpretation is required in order to guide an EHR development team. In fact, a standard can be described as a set of high level guidelines of what should be done, but not of how to do it. Thus, in addition to consider a set of standards, mid-level objectives should be defined. In this paper, these objectives are addressed as: understand, design, and evaluate. These steps are depicted in Figure 5, illustrating our interpretation of the ISO 9241-210 standard. It differs from the interpretation shown in Section II, since brings more relevance to the specific context and organizational requirements during the understanding-step. Moreover, proposed mid-level objectives will require a set of low-level activities. These activities, as we just already highlighted and illustrated in Figure 5, cannot be accomplished without defining a specific context. Above discussion is focused on mid-level objectives and low-level activities, in the context of designing a usable EHR for supporting patients care in an emergency situation.

TABLE IV: UMM LEVELS [17].

Level	Usability Maturity Levels
0 Incomplete	Not able to carry out the process.
1 Executed	People carry out the process
2 Managed	The quality requirements, time and resources are known and controlled.
3 Established	The process is carried out as specified by the organization, the resources are defined.
4 Predictable	The performance of the process within the limits of resources and quality estimates.
5 Optimized	The organization can measured reliably process.

Fig. 5. Proposed interpretation of the ISO 9241-210 standard.



1) Step I: Understand

In the presented interpretation, the first step involves the following ordered activities: understand and specify context of use, understand and specify organizational requirements, and identify needs for UCD.

a. Understand and specify context of use

It requires information gathering and documentation of stakeholders, laws and critical factors such as treatment conditions and constraints, as well as inherent patients' and users' risks, among others. For instance, regarding EHR content, the current legislation has to be considered and enforced.

b. Understand and specify organizational requirements

Business requirements should be identified in order to ensure that EHR design, implementation and deployment are aligned with organizational goals. Organizational requirements should be properly documented in order to prioritize EHR usability characteristics [18].

c. Identify needs for user centered design

This is a main factor for accomplish a successful EHR implementation. Multiple users' perspectives, expectations, and opinions should be gathered and documented. As a human factor, users should perceive that the EHR design process is conceived and guided by them, instead of be imposed to them.

2) Step II: Design

The components shown in Figure 2 will allow an articulation between this step and the previous one. Such articulation will guide the design process by itself. In this way, the usability characteristics outlined in Section III have to be prioritized regarding each one of the EHR design components.

3) Step III: Evaluate

An assessment should involve operational and technical levels. The technical level is concerned with how an EHR is being used, whilst the operational level is concerned about in which degree the EHR is fulfilling organizational goals. Moreover, these levels involve critical factors, which should be

considered within planned evaluation scenarios. Finally, each type of medical care has particular conditions, which impacts on considered usability characteristics. These particularities should be also assessed.

B. EHR Usability in the Emergency Context

Some deliverables of applying proposed steps are shown below. The discussion is emphasized in particular issues due to space constraints of the paper.

1) Understand

A usable EHR for supporting patients care on emergency situations should fulfill three main requirements: availability, opportunity and information integrity, in order to allow decision making by medical staff. Otherwise, patient's safety may be jeopardized. Availability refers to possibility of access to patient medical records. Opportunity is related to the ease of a just-on-time access to medical records. Integrity refers to a complete patient information required for care, diagnosis, and diseases treatment.

In a business devoted to patient care in emergency situation, organizational goals are oriented to provide an appropriate and timely service, according to considered quality standards. In this way, risks related to human factors should be diminished. Moreover, in most of cases, the developed e-Health system should interoperate with a logistics system.

The identification of needs for a UCD can be addressed by considering usability characteristics. In one hand, an EHR designed for medical emergencies, the operability is a fundamental characteristic. The EHR should be easy to use and control, since the time window for querying and recording may be narrow. In practice, a low operability may produce a poor quality of medical records. Thus, an EHR should be protected against unintentional errors introduced by users. On the other hand, characteristics such as aesthetics, intelligibility, and learnability, should also be taken into account. The aesthetics of user interfaces will facilitate the use and improve user experience. According to Intelligibility, the EHR content should be tailored to the information requirements, indispensable in an emergency care. Finally, a proper learnability will reduce the learning curve required by users.

2) Design

The three components involved in the EHR usable design can be tackled by prioritizing usability characteristics. A proposed prioritization is shown in Table V, involving the following categories: HIGH, MEDIUM, LOW, and NONE.

3) Evaluate

UCD testing should be applied to validate compliance with the requirements of EHR. If organization and user needs are not satisfied, it is necessary go back to step 1 and start all over the cycle again. In the context of patients' care in an emergency situation, evaluation methods based on user participation, (e.g. technical consultations and interviews) are suited to be used, since physicians have a high level knowledge about how to use clinical records. Thus, in practice, such type of users are capable of perform an expert analysis.

TABLE V: PRIORITIZATION OF USABILITY CHARACTERISTICS FOR EHR DESIGN

Characteristic / Design Component	User Centered Design	Principles of Quality Management	Patients Safety Events
Learnability	LOW	NONE	LOW
Operability	HIGH	MEDIUM	MEDIUM
Protection against user errors	HIGH	HIGH	HIGH
Aesthetics of the user interface	MEDIUM	NONE	NONE
Intelligibility	LOW	HIGH	HIGH
Accessibility	MEDIUM	NONE	LOW

VI. CONCLUSIONS

A usable EHR allows a proper decision making by medical staff regarding patients' care. In this paper, an interpretation of the ISO 9241-210 UCD standard is proposed. Proposed interpretation involves three iterative steps: understanding, design and evaluation. It aims to continuously guide developers in order to achieve and improve an EHR usable design, by relating high-level guidelines, with low-level design activities. Proposed interpretation has been discussed in the context of patients care in an emergency situation, from a UCD perspective, considering as well principles of quality management and patient safety events. The adoption of proposed interpretation may improve acceptance rates of e-Health systems by physicians, as well as to reduce adverse events caused by human error due to lack of information about patients.

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