Commentary

Increasing EHR system usability through standards: Conformance criteria in the HL7 EHR-system functional model

Rebecca A. Meehan Ph.D. a,⇑, Donald T. Mon Ph.D. b, Kandace M. Kelly DNP c, Mitra Rocca d, Gary Dickinson e, John Ritter MSc. f, Constance M. Johnson Ph.D. g

a Kent State University, Kent, OH, USA
b RTI International, Chicago, IL, USA
c UCLA Health, Los Angeles, CA, USA
d Dipl. Inform. Med., Food and Drug Administration, Silver Spring, MD, USA
e CentriHealth, Los Angeles, CA, USA
f Your Data Steward, Monroeville, PA, USA
g Duke University, Durham, NC, USA

Article history:
Received 17 May 2016
Revised 18 July 2016
Accepted 10 August 2016
Available online 11 August 2016

Keywords:
Electronic health records
Usability
Standards
Health information technology

Abstract

Though substantial work has been done on the usability of health information technology, improvements in electronic health record system (EHR) usability have been slow, creating frustration, distrust of EHRs and the use of potentially unsafe work-arounds. Usability standards could be part of the solution for improving EHR usability. EHR system functional requirements and standards have been used successfully in the past to specify system behavior, the criteria of which have been gradually implemented in EHR systems through certification programs and other national health IT strategies. Similarly, functional requirements and standards for usability can help address the multitude of sequelae associated with poor usability. This paper describes the evidence-based functional requirements for usability contained in the Health Level Seven (HL7) EHR System Functional Model, and the benefits of open and voluntary EHR system usability standards.

1. Introduction

Usability is among the highest priorities for continued use of electronic health record systems [1–5]. Usability of electronic health record (EHR) systems is critical to improving patient safety and quality of care. Poor usability impacts clinicians’ capacity to complete tasks safely, effectively, and efficiently and is associated with increased patient safety concerns [1,6]. To address these concerns, the Office of the National Coordinator for Health Information Technology (ONC) outlined criteria for usability process and testing requirements as part of its “Safety Enhanced Design” Standards and Certification Criteria [7]. Vendors seeking certification for their EHR systems must demonstrate a formal user-centered design process during development and perform summative usability testing on eight specific functionalities with their EHRs [7]. The intention is that user-centered design will produce EHR systems with greater usability. Despite these certification requirements, user-centered design criteria are not consistently met [8,9]. This gap highlights the challenges in effectively integrating usability into EHR systems. This paper presents a set of evidence-based EHR system usability requirements developed by the Health Level Seven (HL7) Electronic Health Records Usability Work Group (HL7 EHR Usability work group) through an open and consensus-driven process. These usability requirements, expressed as conformance criteria in the HL7 Electronic Health Record System Functional Model Release 2 [10] (HL7 EHR System Functional Model), provide guidance for how to achieve improvements in the usability of EHR systems. While HL7 is perhaps best known for its interoperability standards, the model discussed in this paper focuses on functional requirements. For a brief review of the various types of standards and their role in supporting health policy, see the End Note.

1.1. Structure of the EHR system functional model

Before describing the usability requirements, it is important to understand the structure of the HL7 EHR System Functional Model in which the requirements are contained. The model is comprised of 7 major sections: Overarching Criteria, Care Provision, Care
The TURF model defines usability as “how useful, usable, and satisfactory and satisfactory manner within a specific context of use” [12].

The functional requirements are specified using the structure depicted in Table 1. Each major section is comprised of one or more subsections. Each subsection contains one or more functions. Each function provides a statement and a description of the function, as well as criteria to conform to the function, and thus, to the standard. For example, the Manage User Help function in Table 1 is contained in the Care Provision Support section, and has 4 conformance criteria.

While each criterion specifies some aspect of conformance to its associated function, many of the conformance criteria specify the usability principle that can be integrated into the function. Conformance criterion 1 in Table 1, for example, specifies that user help should be configurable and customizable according to user requirements, assuming that such requirements are well-conceived and consistent with organizational policies and existing laws. In addition, conformance criterion 4 specifies that the user can set up and invoke context-sensitive help, such as for charting steps and navigation menus. This example provides a basic explanation of how usability requirements, expressed as conformance criteria, can be built into a technical standard, which can be used to help increase usability in EHR systems. Additional examples are provided in the sections below.

1.2. Usability principles: the first step in developing usability functional requirements

The HL7 EHR Usability work group based its EHR system usability requirements on evidence in published reports and the literature. Thus, as a first step, it sought to understand what usability is and how usability principles help to achieve usability overall, and specifically for EHRs. For example, from a review of the literature, the HL7 EHR Usability work group understood that usability must adhere to specific principles related to cognitive science, human factors, ergonomics, and human computer interaction [11] and attempted to structure conformance criteria accordingly. Anchoring the functional model’s conformance criteria are the definitions of usability from ISO 9241-11 [12], and the Task, User, Representation, and Function (TURF) model developed by Zhang and Wali [13]. Specifically, ISO defines usability as “the extent to which end users can achieve desired outcomes in an effective, efficient and satisfactory manner within a specific context of use” [12]. The TURF model defines usability as “how useful, usable, and satisfying a system is for the intended users to accomplish goals in the work domain by performing certain sequences of tasks” [13].

The TURF model’s definition of usability differs from the ISO definition in two distinct ways. First, instead of using ‘effectiveness’ as defined in ISO as the ability of users to complete tasks and goals, the TURF model uses the term, ‘useful,’ which refers to “how well the system supports the work domain where the users accomplish the goals for their work” [13]. Second, instead of using the term ‘efficiency’ as defined in ISO as ‘effort’, as in time to complete their tasks, the TURF model uses the term, ‘usable,’ which is defined by learnability, efficiency, and error prevention. The TURF model also provides a more “work-centric” view of usability that captures the importance of minimizing functions that are non-essential to the work domain and developing intuitive and efficient systems that protect users from error [13]. In summary, regardless of the cited definitions, usability is an attribute that determines how easy it is for users to accomplish their goals within a system.

Significant work has generated system usability design principles and strategies to guide system development [4,6,14–21]. Three widely accepted sets of principles are, the “Nielsen 10” [14], Shneiderman’s eight ‘golden’ rules of interface design [15], and Zhang’s fourteen principles for the health domain [13,16]. Collectively, these well-supported design principles include guidelines related to the system status, workflow compatibility, human-computer interface, cognitive demand, consistency and standards, error prevention, and ease of use. Building upon this work a number of expert stakeholder groups have integrated, revised and expanded the above mentioned heuristics to a list of heuristics related to a healthcare context [4,16,18,19]. The National Institute of Standards and Technology Technical Report (NISTIR) 7804 [18] Appendix B, proposed a standard EHR usability evaluation protocol including EHR system heuristics which aimed to minimize user errors with EHR systems by providing usability guidelines focused on patient safety related elements. Specifically, the report details design considerations for 17 safety related use errors that include patient identification errors, mode errors, data accuracy errors, interpretation errors, recall errors, feedback errors, data integrity errors, visibility of system status, match between real world and system status, user freedom and control, consistency and standards, error recognition, diagnosis, and recovery, error prevention, recognition rather than recall, aesthetic and minimalist design, help and documentation, pleasurable and respectful interaction

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Examples of usability-oriented conformance criteria in the HL-7 EHR system functional model.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section/ID#:</strong></td>
<td>Care provision support</td>
</tr>
<tr>
<td><strong>Type:</strong></td>
<td>Function</td>
</tr>
<tr>
<td><strong>Name:</strong></td>
<td>Manage user help</td>
</tr>
<tr>
<td><strong>Statement:</strong></td>
<td>Support the ability to manage the configuration and/or customization of appropriate user help that is context-sensitive and may include the exchange of live online chat</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>Throughout the system it is necessary to provide configurable, context-sensitive and/or searchable user help to assist in the use of the system. User help levels should be configurable based on user requirements, scope of practice, organizational policy and/or jurisdictional law. User Help may include the live online chat support</td>
</tr>
<tr>
<td><strong>Conformance criteria:</strong></td>
<td>1. The system <strong>SHOULD</strong> provide the ability to manage the configuration and customization of User Help in accordance with user requirements, and according to scope of practice, organizational policy and/or jurisdictional law. 2. The system <strong>SHOULD</strong> receive queries and render responses for data entry and system navigation assistance (User Help). 3. The system <strong>MAY</strong> Exchange User Help queries and responses via live online chat. 4. The system <strong>SHOULD</strong> render context-sensitive invocable help to guide users through activities in the system (e.g. charting steps, menu navigation).</td>
</tr>
</tbody>
</table>
with the user, and privacy. In order to implement these recommended improvements and to make significant progress in improving EHR system usability, the HL7 EHR Usability work group applied these design recommendations from NISTIR 7804 as conformance criteria in the EHR System Functional Model.

1.3. Rationale

In the same way that technical standards have facilitated interoperability, data capture, and quality measurement in health IT, usability standards provide an opportunity for addressing the multitude of sequelae associated with poor usability. Functional requirements and standards are not only useful for EHR system development, but also for specifying objective conformance criteria, and enabling system selection, testing, and evaluation [22]. Similarly, usability standards may prove effective at catalyzing large-scale usability improvements. The sections below describe the process of creating standards to improve EHR system usability.

2. Methods

The HL7 EHR Usability work group, consisting of health care providers, EHR system vendors, government organizations, non-government organizations, standards organizations, and academic usability experts, is using evidenced-based usability principles in EHR system usability [18] to create conformance criteria within the EHR System Functional Model. Preliminary work for creating the appropriate conformance criteria for EHR system usability included an environmental scan and targeted literature review based on standard usability principles. The HL7 EHR Usability work group developed a comprehensive list of the usability principles developed by Nielsen [14], Shneiderman [15], and Zhang [16], and coded each of these principles using the ones published in the NISTIR 7804 report [18] to determine if there were any major gaps in the NISTIR 7804 principles. The HL7 EHR Usability work group was able to match the overall major principles of Nielsen, Shneiderman and Zhang to those outlined in the NISTIR 7804 Appendix B. As the usability principles in Appendix B of NISTIR 7804 are solely focused on patient safety, and were comprehensive and aligned with other expert sources [13–16] these usability principles were used to guide the initial development of usability conformance criteria and were selected as the primary resource to apply to the EHR System Functional Model. A gap analysis was then conducted between the report’s usability principles and the EHR System Functional Model. Where the usability principles were absent in the model, new conformance criteria were developed.

3. Results

The NISTIR 7804 Appendix B was used as a foundation for generating conformance criteria in the HL7 EHR System Functional Model. Before this was done, however, the NISTIR 7804 usability principles were compared to other usability design principles [13–16]. For example, where the NISTIR 7804 and Nielsen’s principles identified “Consistency and Standards”, Zhang listed these as “Consistency” and Shneiderman described them as “Strive for Consistency.” Likewise, the NISTIR 7804 describes a design principle as “Recognition rather than recall;” whereas, Zhang described the principle as “Memory,” and Shneiderman described that issue as “reduce short-term memory load.” Overall, the usability principles were compatible, but were labelled differently than the other expert resources, yet were consistent with the NISTIR 7804 Appendix B, which focused solely focused on patient safety.

The HL7 EHR Usability work group developed conformance criteria for issues identified in a gap analysis where existing conformance criteria in the HL7 EHR Functional Model did not address usability issues outlined in the NISTIR 7804 Appendix B [18]. While the gap analysis and conformance criteria development remained ongoing, Table 2 illustrates usability principle categories from NISTIR 7804 Appendix B, and violations of those usability principles that would necessitate an improvement, along with the corresponding conformance criteria developed by the HL7 EHR Usability work group that addressed the violations.

The value of the functional requirements in the EHR System Functional Model is that they provide an efficient and effective means of communicating conformance criteria to EHR system

<table>
<thead>
<tr>
<th>Usability principle categories [18]</th>
<th>Violation of a usability principle [18]</th>
<th>Usability conformance criteria developed by HL7 EHR usability work group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient identification error</td>
<td>Actions are performed for one patient (or are documented in one patient's record) that were intended for another patient</td>
<td>The system SHALL render an indication to the user when a PATIENT-CONTEXT changes</td>
</tr>
<tr>
<td>Patient identification error</td>
<td>Actions are performed for one patient (or are documented in one patient's record) that were intended for another patient</td>
<td>The system SHALL render patient identifying information (e.g., the patient name, identification number, and age or date of birth) on all screens according to scope of practice, organizational policy, and/or jurisdictional law</td>
</tr>
<tr>
<td>Mode error</td>
<td>Actions are performed in one mode that were intended for another mode</td>
<td>The system SHOULD provide the ability to capture an indication that certain data might be “bad” or “questionable” (e.g., data has been corrupted or altered due to a system mode error)</td>
</tr>
<tr>
<td>Data accuracy error</td>
<td>Displayed data are not accurate. For example, a physician ordered the wrong dose of a medication because the amount of the medication dose was truncated in the pick list menu display</td>
<td>The system SHALL provide the ability to manage data accuracy errors. For example, sets of business rules engines can be employed to identify various types of data accuracy errors</td>
</tr>
<tr>
<td>Data accuracy error</td>
<td>Displayed data are not accurate. For example, a physician ordered the wrong dose of a medication because the amount of the medication dose was truncated in the pick list menu display</td>
<td>The system SHOULD provide the ability to capture an indication that a given notification, reminder, and/or alert is inappropriate (e.g., so that redundant notifications, reminders, and/or alerts are not presented to the user regarding a given patient)</td>
</tr>
<tr>
<td>Data integrity error</td>
<td>Decisions are based on stored data that are corrupted or deleted</td>
<td>The system SHOULD provide the ability to render an indication that control-access protocols have been invoked for certain data (e.g., blocking multiple users from updating the same data simultaneously)</td>
</tr>
<tr>
<td>Visibility of system status</td>
<td>The interface provides no indication of the status of an action initiated</td>
<td>The system SHALL provide an indication of the status or progress of an action initiated</td>
</tr>
<tr>
<td>Match between system and the real world</td>
<td>The interface uses system oriented terms for processes, rather than terms consistent with clinical practice</td>
<td>The system SHOULD conform to provide the ability to present standard terminology terms in a language which is appropriate for the user</td>
</tr>
</tbody>
</table>
developers to meet usability standards. The HL7 EHR System Functional Model clearly illustrates how usability improvements can be incorporated into EHR systems, and provides a way to measure and test usability enhancements made to an existing system.

4. Discussion

There is value for all stakeholders in improving EHR system usability, the most critical value among them being safer patient care. User-centered design guidelines are not being consistently implemented in the formative stages of building EHR systems, constraining robust usability in the final EHR product. Standards for EHR usability provide a uniform resource that have been developed by usability experts and translated by standards developers. Further, the HL7 EHR System Functional Model offers a tool for developers to more easily consume and build in usability standards into their EHR systems. Standardized system usability guidelines within the HL7 EHR System Functional Model provide an opportunity to make these improvements in early stages of product development, reducing the likelihood of compromising patient safety and costly, post-implementation product enhancements. These standards do not aim to dictate the "look and feel" of a system; nor, do the standards aim to solve "how" the usability requirements are folded into the EHR system. Instead, the standards allow developers to have an efficient means to access and apply evidence based usability principles to improve EHR system.

EHR system usability standards offer benefits to clinical and vendor stakeholders, as well as to supplemental or secondary users for comparative effectiveness research, quality improvement, and post-market surveillance. Vendors and developers of EHR systems can use these standards to test their products, and clearly demonstrate to their clients and accredited certification bodies, specific examples of how their EHR system achieves usability, and how it enables delivery of safe patient care. For example, vendors can show to clients how they are following the standard by displaying a title on each page to remind the user of the content and context of each page (see Table 2). Further, they can link that feature to the best practices by indicating how the interface should keep the user informed about what is going on, with appropriate feedback, in a reasonable amount of time, and thereby address the expert endorsed "visibility of system status" usability principle. In a similar manner, clinicians, healthcare administrators, and IT staff can use the conformance criteria to evaluate EHR systems and to inform purchase decisions. For example, they can determine whether a vendor product can help ensure that treatment intended for one patient is not delivered to another patient by seeing if the product renders patient identifying information on each page, thereby complying with the patient identification error principle in Table 2, line 2.

5. Conclusion

The activities of the HL7 EHR Usability work group are one of the many professional efforts being made to improve patient safety and overall end user experience with the EHR. The development of the conformance criteria for the HL7 EHR System Functional Model can help to improve EHR usability by creating an opportunity to apply best practices in usability in the formative stages of EHR development, and to evaluate usability of products in the summative stages. In addition, these standards allow clinicians, healthcare administrators, and IT staff to identify and evaluate usability requirements for their EHR systems, and facilitate communication of specific requirements to their EHR vendor partners. Providers and policy makers continue to struggle with how to effectively improve EHR system usability for the wide array of EHRs and components. Usability standards within the HL7 EHR System Functional Model provide an efficient and effective way for stakeholders to apply evidence-based criteria to improve EHR system usability.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

End note

HL7 is perhaps best known for its interoperability standards. However, HL7 also develops, and collaborates with other standards organizations to develop guides to implement, a variety of standards needed to express clinical logic, unambiguously define data elements, specify actions and behaviors of electronic systems, and exchange data between systems. For example, HL7 produces:

- Rules and references for medical logic (HL7 Arden Syntax, HL7 Decision Support Service), and a common expression language.
- Codes and values sets used in exchanging messages or documents, or in resources to support data exchange (see FHIR below).
- Health information models for data elements (e.g., HL7 detailed clinical models [DCMs], and those produced by the HL7 Clinical Information Modeling Initiative [CIMI]), as well as for interoperability (e.g., ISO/H7 reference information model [RIM]).
- Functional requirements for electronic health record and personal health record systems (e.g., ISO/H7 EHR and PHR System Functional Models).

The above standards are applied to certain use cases, the product of which is called a Profile. For example, the HL7 Consolidated Clinical Document Architecture (C-CDA), which specifies the patient summary record as a use case, is a profile of CDA. While C-CDA is a profile for interoperability, there are a variety of use cases, and hence profiles, for EHR systems. For example, profiles have been developed for ambulatory care, behavioral health, child health, public health, and records management/evidentiary support. Ultimately, usability requirements contained in the current EHR System Functional Model, Release 2 may be culled out to form a system usability profile.

Profiles are often vetted by policy makers and selected for nation-wide implementation. For example, for the Meaningful Use of EHR systems in the US, the Health IT Policy Committee identified the need for a consistent implementation of a patient record summary. In conjunction with these efforts, the Health IT Standards Committee selected C-CDA as the standard for patient record summaries. The US and other countries have similarly adopted the EHR System Functional Model and its various profiles for their national purposes [23].

Conflict of interest

No conflict of interest.

References