HL7 EHRS-FM Usability Functional Profile
Increasing EHR System Usability Through Standards
As One Approach to Reducing Clinician Burden

HL7 EHR-S Usability Work Group
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Special Thanks To
Gary Dickinson, FHL7, Co-Chair HL7 EHR Work Group

12/12/2022
Electronic Health Records: Dawn of a New Age

- Better care quality
- Fewer medical errors
- Improved patient safety
- Better patient experience
- Lower per capita healthcare costs
EHRs’ Unfulfilled Promises

- Decreased efficiency: EHRs add 1-2 hours to the average MD workday
- Disconnect from patients: providers spending 50% or more of their time in the EHR
- Disruption of clinician work-life balance and an epidemic of burnout
- Modest improvement in care process metrics and guideline adherence
- **No** significant change in large scale health outcomes
- Annual US healthcare expenditures increased from $2 trillion in 2005 to over $4 trillion in 2021
Why EHRs Have Not Met Their Design Goals

- Poor usability
  - Poor support for clinical workflow
  - Poor human factors engineering
  - Exacerbate other stressors

- Poor interoperability
  - Poor information exchange
  - Much unstructured data
  - Inadequate consensus on standards
Physician Burnout

Burnout is a syndrome characterized by
- Emotional exhaustion
- Feelings of cynicism and detachment from work
- Sense of low personal accomplishment

- 54-68% of US physicians report at least one symptom of burnout (twice the rate of the general population)
- 70% of US physicians report symptoms of health IT-related stress
- 53% of self-reported physician stress and burnout is correlated with EHRs and clinical process design is highly impacted by EHRs

EHR Design and Use Factors Associated with High Clinician Stress

- Information overload (poor interface design)
- Excessive, inefficient data entry
- Slow, confusing system navigation
- Interference with patient-clinician relationship
- Lack of context specificity and situational awareness

HL7 EHR-S Usability WG: Goals

• Increase EHR system usability through standards
• Translate well established usability guidelines (heuristics) into functional conformance criteria for the HL7 EHR-system Functional Model Release 2 (EHR-S FM)
  • Well defined function statements and descriptions
  • Criteria to evaluate conformance to the function
• Develop a user-centered design companion functional profile for the EHR-S FM
Conformance Criteria

EHR-S Functional Model
What systems must do to be considered an EHR (Functions)
Measurable aspects of conformance to function (Conformance Criteria)

Usability Functional Profile
What EHR systems must do to be usable (Usability Functions)
Measurable aspects of conformance to function (Conformance Criteria)
HL7 EHR-S Usability WG: Methods

• Recruit and engage clinicians, vendors, academicians specializing in usability and human factors research, implementers, SDOs, etc.

• Collect and perform an analysis of
  • Targeted literature reviews, environmental scans, and other academic sources
  • Government publications (AHRQ, NIST) and others from non-US governments
  • Technical materials (e.g., the UK’s Common User Interface specification)
  • Work items on usability from professional associations (e.g., the HIMSS EHR Usability Task Force)
  • Work items from SDOs (HL7, ISO/TC 215, …)
  • ONC Standards and Data (e.g., SHARP-C, Strategy on Reducing Clinician Burden)

• Translate that information into standards-based guidelines that describe EHR system usability behavior in terms of specific conformance criteria
Definition of Heuristic

From Wikipedia:

A heuristic (/hjuːˈrɪstɪk/; from Ancient Greek εὑρίσκω (heurískō) 'I find, discover'), or heuristic technique, is any approach to problem solving or self-discovery that employs a practical method that is not guaranteed to be optimal, perfect, or rational, but is nevertheless sufficient for reaching an immediate, short-term goal or approximation. Where finding an optimal solution is impossible or impractical, heuristic methods can be used to speed up the process of finding a satisfactory solution. Heuristics can be mental shortcuts that ease the cognitive load of making a decision.

https://en.wikipedia.org/wiki/Heuristic
What are heuristics?

- General principles of human-computer interaction design
- Arise from validated studies of human computer interaction
- More broad rules of thumb than specific design specifications

Sets of heuristics

- Jiajie Zhang’s General Design Principles for EHRs: [https://sbmi.uth.edu/nccd/ehrusability/design/guidelines/Principles/index.htm](https://sbmi.uth.edu/nccd/ehrusability/design/guidelines/Principles/index.htm)
- Nielsen’s 10 Heuristics for User Interface Design: [https://www.nngroup.com/articles/ten-usability-heuristics/](https://www.nngroup.com/articles/ten-usability-heuristics/)
Nielsen’s Heuristics

1. Visibility of the system status
   – What’s going on…
2. Match between the system and the real world
   – Natural, logical, clear
3. User control and freedom
   – Cancel, undo, redo
4. Consistency and standards
   – Words, actions, locations
5. Error prevention
   – Avoid errors, confirm before committing
6. Recognition, not recall
   – Objects, actions visible
7. Flexibility and efficiency of use
   – Accelerators, personalization
8. Aesthetic and minimalist design
   – Only relevant, commonly needed information
9. Help users recognize, diagnose, recover from errors
   – Clear error messages with constructive solutions
10. System help and documentation
    – Easy to search, concise, context sensitive, step-by-step

## 2. Visibility of System Status

The system should always keep the user informed about what is going on, through appropriate feedback within reasonable time.

<table>
<thead>
<tr>
<th>#</th>
<th>Review Checklist</th>
<th>Severity Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Does every display begin with a title or header that describes screen contents?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Is there a consistent icon design scheme and stylistic treatment across the system?</td>
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<td>2.3</td>
<td>In multipage data entry screens, is each page labeled to show its relation to others?</td>
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<td>2.4</td>
<td>If pop-up windows are used to display error messages, do they allow the user to see the field in error?</td>
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<tr>
<td>2.5</td>
<td>Is there some form of system feedback for every operator action?</td>
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<tr>
<td>2.6</td>
<td>After the user completes an action (or group of actions), does the feedback indicate that the next group of actions can be started?</td>
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<tr>
<td>2.7</td>
<td>Is there visual feedback in menus or dialog boxes about which choices are selectable?</td>
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<td></td>
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<tr>
<td>2.8</td>
<td>Is there visual feedback in menus or dialog boxes about which choice the cursor is on now?</td>
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<tr>
<td>2.9</td>
<td>If multiple options can be selected in a menu or dialog box, is there visual feedback about which options are already selected?</td>
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<tr>
<td>2.10</td>
<td>Is there visual feedback when objects are selected or moved?</td>
<td></td>
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<tr>
<td>2.11</td>
<td>Is the current status of an icon clearly indicated?</td>
<td></td>
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<tr>
<td>2.12</td>
<td>Do Graphic User Interface (GUI) menus make obvious which item has been selected?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.13</td>
<td>Do GUI menus make obvious whether deselection is possible?</td>
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<tr>
<td>2.14</td>
<td>If users must navigate between multiple screens, does the system use context labels, menu maps, and place markers as navigational aids?</td>
<td></td>
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</tbody>
</table>
### NISTIR 7804 Category Descriptions

<table>
<thead>
<tr>
<th>NISTIR 7804 Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visibility of System Status</td>
<td>The system should always keep the user informed about what is going on, through appropriate feedback within reasonable time.</td>
</tr>
<tr>
<td>Match Between System and the Real World</td>
<td>The system should follow the user’s language, with words, phrases and concepts familiar to the user, rather than system-oriented terms.</td>
</tr>
<tr>
<td>User Control and Freedom</td>
<td>Users should be free to select and sequence tasks (when appropriate), rather than having the system do this for them.</td>
</tr>
<tr>
<td>Consistency and Standards</td>
<td>Users should not have to wonder whether different words, situations or actions mean the same thing.</td>
</tr>
</tbody>
</table>
## Usability Functional Profile Conformance Criteria

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
<th>CONFORMANCE CRITERIA (Class)</th>
<th>CONFORMANCE CRITERIA (Evaluated)</th>
<th>Usability Identification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
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<tr>
<td>3</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
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<tr>
<td>5</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
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<tr>
<td>6</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
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<tr>
<td>7</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
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<tr>
<td>8</td>
<td>- The system SHOULD provide the ability to manage error information in an error dialog.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
## UFP Function List Descriptions

<table>
<thead>
<tr>
<th>Section/Id#:</th>
<th>Type:</th>
<th>Header/Function Name</th>
<th>Reference</th>
<th>Chg Ind</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.1</td>
<td>Header</td>
<td>Manage the User's Situational Awareness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Statement:</strong> Enable the user to understand their current context within the system's environment.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>Description:</strong> Usability is improved when the user knows where in the system they are and what they can do.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.1.1</td>
<td>Function</td>
<td>Manage Aspects of the User's Situational Awareness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Statement:</strong> Enable the user to remain oriented to their location and what actions they can take.</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>Description:</strong> Usability is improved when the system offers indications: (1) of the user's location within the system's information architecture (IA), (2) of the actions that can be taken from a certain IA location, (3) of the locations that can be navigate to from an IA location, and (4) regarding the origin, provenance, or trustworthiness of certain data (e.g., indications that certain data are partial, estimated, or summarized; indications that certain data were translated from another language; or indications that the system is in the process of recovering from certain errors).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.1.2</td>
<td>Function</td>
<td>Manage the Visibility of the System Status</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Statement:</strong> Enable the user to understand the system status.</td>
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</tr>
<tr>
<td></td>
<td></td>
<td><strong>Description:</strong> Usability is improved when a system keeps the user informed about what is going on in the background, through appropriate feedback within reasonable time. For example, the system could inform the user that it is temporarily experiencing a slowdown in communications and that normal communications speed is likely to resume within fifteen minutes.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Possible Next Steps (1)

- Perform socialization/education to motivate developers, researchers, regulators, etc. to use the UFP in system design/testing
- Consider creating a means of automatically collecting Usability metrics (and reporting them to appropriate stakeholders)
- Consider creating a “Patient Safety Reporting” FP
- Collect stories/experiences of UFP users
- Continue to align the UFP with elements of the “Reducing Clinician Burden” project
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National Burden Reduction Collaborative Meeting
Day 1: Tuesday 11.8.22

Sponsored by

Pacesetters
Problem Statement

Healthcare information technology software developers (developers) almost universally state that their development processes include and emphasize user-centered design (UCD). In addition, Federal certification programs established by the ONC require a design process that promotes usability and requires usability testing. Yet developers vary greatly in both their maturity in implementing UCD processes and their adherence to certification requirements. A substantial majority of the clinicians required to use enterprise level electronic health records (EHRs) express dissatisfaction with the usability of these products, citing decreased efficiency and clinical productivity, frustration, fatigue, difficulty keeping focus on the patient, and even increased errors and safety risks. The healthcare system’s difficulties in addressing the scope and complexity of EHR usability challenges is a significant (though far from the only) factor underlying the epidemic of clinician burnout, with up to 50% of physicians reporting one or more symptoms of burnout and 117,000 physicians leaving the profession in 2021 due to retirement, burnout, and pandemic-related stressors.

Interventions

While there is a large body of knowledge regarding healthcare information-system usability in the scientific and technical literature, no one has yet translated that information into standards-based guidelines that describe EHR system usability behavior in terms of specific conformance criteria (by which conforming systems may be certified). The HL7 Usability Functional Profile (UFP) was generated by a diverse all-volunteer workgroup including physicians, nurses, clinical informaticians, healthcare IT software developers, standards development experts, EHR implementers, and other experts based on an extensive survey of existing literature regarding usability and human factors engineering as applied to information systems.

Technology
- EHR: human factors and safety engineering
- EHR: integration into clinical workflow
- EHR software development: usability testing systems and processes
- EHR certification processes and tools
- Communication tools: more rapid and robust communication of usability issues from users to developers and more rapid response

Policy/Regulatory
- Work with regulatory agencies to improve EHR usability certification:
  - Utilize more granular and specific usability conformance criteria
  - Establish standard measures of subjective clinician user experience
  - Develop objective usability measures based on plausible use case scenarios tested by qualified, experienced real world practitioners
  - Publish usability testing results so markets can react
  - Establish a national public usability/safety best practice database
- Work with EHR software developers to improve user-centered design processes
  - Robust UCD departments which include both experienced clinicians and experts with specific training in user experience design and measurement
  - More influence of UCD recommendations on development pathways and checkpoints

People
- Physicians
- Nurses
- Health system administrators
- IT professionals
- EHR software developers
- Policy makers
- Regulators

Process
- Technology
- EHR software development
- User centered design
- EHR implementation and customization
- EHR certification
- Clinical workflow
- Workforce wellness management

Roles impacted
- Physicians
- Nurses
- Health system administrators
- IT professionals
- EHR software developers
- Policy makers
- Regulators

Success Metrics
- Adoption of UFP, a subset of UFP, or other conformance criteria as part of EHR certification
- Adoption of a standard set of requirements and metrics for developer UCD processes and staff and publication of results as part of EHR certification
- Construction of a library of standard specialty-specific plausible scenario based usability testing cases and procedures to serve as objective measures
- Transparent communication of standard measurements of clinician user experience during interaction with Healthcare IT products to identify problems and serve as a basis of comparison
- Establishment of a national usability and safety best practices database

Organization Alignment Opportunities
- Work with EHRA to develop more robust, transparent, verifiable UCD processes supported by staff with appropriate clinical and user experience training
- Work with Federal partners (e.g., ONC, CMS) to develop new usability-related EHR certification processes and criteria
- Work with AMIA, AMDIS, and academic research partners to develop the scenario-based use cases and standard UX measurement procedures referenced above
- Work with health system administrators to arrange protected time for experienced clinicians to participate in usability testing

Organization: HL7 International

Title: Usability Functional Profile, Release 1, of the Electronic Health Record System Functional Model, Release 2.0.1
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<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician Burden (the current situation)*</td>
<td>Recommendations</td>
<td></td>
</tr>
<tr>
<td>Light Green (Column A): Findings, strategies and recommendations from US Office of National Coordinator for Health Information Technology (ONC), DRAFT Strategy on Reducing Regulatory and Organized by Burden Topic --- (Ix.Sx.Rx) designates ONC Initiative[I], Strategy[S], Recommendation[R]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light Orange (Column A): RCB Success Stories of Note</td>
<td></td>
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</tbody>
</table>

**Project Focus** - Our current analysis is focused on Root Causes, broken down by RCB topic. See Topics (10th Tab) and Root Causes (5th Tab) below. Please review and offer your comments. We are also seeking “Reducing Clinician Burden” Success Stories. If you have one (or more) to share, please use this template: [http://wiki.hl7.org/images/0/0a/Reducing_Clinician_Burden-Success_Story_Template-01.jpg](http://wiki.hl7.org/images/0/0a/Reducing_Clinician_Burden-Success_Story_Template-01.jpg)

**Clinician Burden - In General [1:1]**

- "3 out of 4 physicians believe that EHRs increase practice costs, outweighing any efficiency savings." (26)
- "7 out of 10 physicians think that EHRs reduce their productivity." (28)
- "Four in 10 primary care physicians (40%) believe there are more challenges with EHRs than benefits (30).
- "Seven out of 10 physicians (71%) agree that EHRs greatly contribute to physician burnout (30)."
- "Six out of 10 physicians (59%) think EHRs need a complete overhaul (30)."
- "Only 8% say the primary value of their EHR is clinically related (30)."
- "Physicians express that EHR systems detracted from professional satisfaction (54%) as well as from their clinical effectiveness (49%)." (60)
- "Poll results... showed that few physicians and nurses were involved in the decision-making process of EHR to implement in their workplace. Of participating physicians, 66 percent said they had no input, 28 percent had input and 7 percent did not use an EHR. Of nurse and APRN participants, 80 percent said they had no input, 18 percent had input and 2 percent did not use an EHR." (63)
- "Of the physician and nurse/APRN participants who had input in choosing their workplace's EHR system, just 2 percent said the system they wanted was chosen." (63)
- "A recent... report revealed that almost 40 percent of surveyed outpatient providers are looking to replace their EHR and other IT tools with solutions that offer better ease of use, more functionality and increased interoperability with other IT systems."

**Recommendations**

- "Nearly three out of four primary care physicians (72%) think that improving EHRs' user interfaces could best address EHR challenges in the immediate future." (30)
- "Seven out of 10 primary care physicians (67%) think solving interoperability deficiencies should be the top priority for EHRs in the next decade—and 43% want improved predictive analytics to support disease diagnosis, prevention, and population health management." (30)
- "One out of four primary care physicians (27%) think 'developing Artificial Intelligence (AI) assistants to support physicians with patient care' should be a priority." (30)
- "Many doctors do recognize the value in the technology: 60% of patients... said EHRs had led to improved patient care." (60)
- "When asked what changes they would like to see be made to the EHR, 44 percent of physicians participants said to make the systems more intuitive or user-friendly and 30 percent said enhancing interoperability and record sharing." (63)
- "The primary goal of EHR-generated documentation should be concise, history-rich notes that reflect the information gathered and are used to develop an impression, a diagnostic and/or treatment plan, and a recommended follow-up. Technology should facilitate attainment of these goals in the most efficient manner possible without losing the humanistic elements of the record that support ongoing relationships between patients and their physicians." (3)
### RCB Project Burden Statement

Cell B 69

- "**Improve presentation of clinical data within EHRs.** EHRs contain vast quantities of clinical data and are capable of sending and receiving incredible amounts of patient information with a keystroke. This can present a challenge for the end user trying to locate one critical piece of information; a needle in the proverbial haystack. Various modes of information storage also complicate finding desired data—some information is stored as structured data, while other data are contained in scanned images files." (50, I2.S1.R4)

NISTIR 7804 Heuristic:
Aesthetic and Minimalist Design

### Usability FP Conformance Criterion

ID U.1, CC 2

The system SHOULd provide the ability to manage the configuration of the representation of data (e.g., by configuring the user interface screen/window layout to promote clean, efficient, uncluttered human-computer interfaces, with minimal expression of a screen's title, identification fields, logos, banners, dialog boxes, prompts, alerts, reminders, pictures, graphics, and/or icons; offering differing representational modes for conveying raw-data information (e.g., pain scale of 1-10 versus frown/smile face)) according to user preference, scope of practice, organizational policy, and/or jurisdictional law and according to User-Centered Design Heuristics that support Aesthetic and Minimalist Design.
Possible Next Steps (2)

- Work with EHRA to develop more robust, transparent, verifiable UCD processes supported by staff with appropriate clinical and user experience training
- Work with Federal partners (e.g., ONC, CMS) to develop new usability-related EHR certification processes and criteria
- Work with AMIA, AMDIS, and academic research partners to develop the scenario-based use cases and standard UX measurement procedures referenced above
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Discussion

- What do you think?
  - Is the UFP, by itself, adequate to drive significant improvement?
  - Will a (loose, ad-hoc) market-driven approach ever be effective in producing demonstrably (certifiable/conformant) usable systems?

- Two (possible) types of "Usability Measurement"
  - Manual: Feedback from the user
  - Automated (transparent): Metrics collected by the system in the background that help managers and developers measure and improve usability
Comments And Questions