



## Summary of [NIST Draft Guidance](#) on Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records

### **Background**

The National Institute of Standards and Technology (NIST) released a draft guidance document outlining EHR Usability Protocols and usability testing. The document was released on Monday, October 3, 2011. The goal of the guidance document is to provide usability protocols to help prevent harm done by errors of omission or errors of commission during the use of EHR systems.

### **EHR USABILITY PROTOCOL (EUP)**

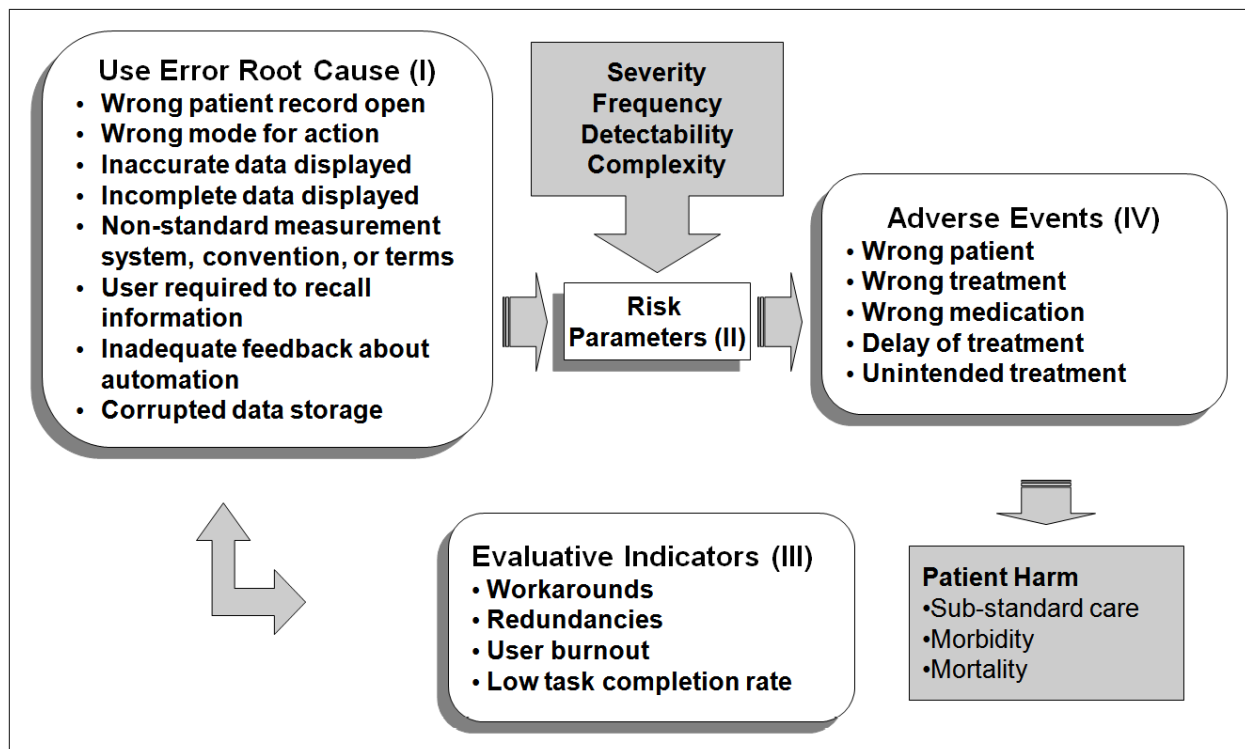
The EUP protocol includes three-steps. The three-step process incorporates both the evaluation and validation procedures for design evaluation and human user performance testing for an EHR. This process is focused on increasing safe use of the EHR and increasing ease of use of the EHR by users. The steps are as follows:

- (I) **Usability Analysis** led by the development team, which identifies the characteristics of the system's anticipated users, use environments, scenarios of use, and use related usability risks that may induce medical errors,
- (II) **Expert Review/Analysis**, an independent evaluation of the critical components of the user interface in the context of execution of various use case scenarios and usability principles, and
- (III) **User Testing**, involving creation of a test plan and then conducting a test that will assess usability for the given EHR application including use efficiency and presence of features that may induce potential medical error.

- ❖ **What the EHR Usability Protocol Is Not:** The type of usability testing protocols described in the EUP here are focused on the optimization of workflow and efficiency and safety of interactions in the EHR application or system. This evaluation, focused on user interface design evaluation, is meant to be independent from factors that engender creativity, innovation or competitive features of the system. The usability testing process documented here does not question an "innovative feature" being introduced by a designer, but could identify troublesome or unsafe implementation of the user interface for that innovative feature.
- ❖ The document states that the EUP protocol should:
  1. Provide a rationale for what user tasks are being tested, and how these test tasks relate to either (a) identifying user interaction leading to potential medical error, and/or (b) general interaction efficiency with the application.
  2. Describe the participant selection criteria for the appropriate user test population.

3. Describe the environment of testing and how it is representative of real-world application use in terms of lighting, noise, distraction, vibration, and other conditions in the workplace.
4. Describe the facility and equipment required to represent final or near-final design of the user interface including use of the appropriate application platform(s) that will be used (e.g., desktop computer, smart phone, touch screen, tablet PC, etc.) Where appropriate, multiple platforms of application delivery should be tested. An EHR can have different appearances on different platforms. That is, one EHR is available on a desktop PC and is also on a tablet PC. These instantiations might be considered to be separate and distinct software products even though they are distributed from the same company.
5. Provide a checklist of steps for testers (i.e., qualified usability/human factors professionals) of EHR applications to follow.

## **MODEL: ANALYSIS AND UNDERSTANDING OF USE RELATED RISKS OF EHR SYSTEMS<sup>1</sup>**



<sup>1</sup> Source: NIST. (2011). *Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records*. Retrieved from [http://www.nist.gov/healthcare/usability/upload/Draft\\_EUP\\_09\\_28\\_11.pdf](http://www.nist.gov/healthcare/usability/upload/Draft_EUP_09_28_11.pdf).

- ❖ **Use Error Root Causes (I)** can be defined as attributes of the interface that produce an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator. Examples include:
  - Patient identification error
  - Mode error (i.e. direct dose vs. weight dose, test mode vs. production mode)
  - Data accuracy error ( i.e. a physician ordered the wrong dose of a medication because the amount of the medication dose was truncated in the pick list menu display)
  - Data availability error (i.e. a patient received four times the intended dose of a medication because the comments field was not visible without being opened that explained that there were progressive dose reductions (taper dose) over several days to wean the patient off the medication)
  - Interpretation error (i.e. a patient received a larger dose of a medication than was intended because most displays used the English system but the pediatric dose calculation feature used the metric system)
  - Recall error - Decisions are based on incorrect assumptions because appropriate actions require users to remember information rather than recognize it
  - Feedback error - Decisions are based on insufficient information because lack of system feedback about automated actions makes it difficult to identify when the actions are not appropriate for the context
  - Data integrity error - Decisions are based on stored data that are corrupted or deleted
- ❖ **Risk Parameters (II)**, defined as controllable or uncontrollable factors that affect variation in the magnitude of the potential risk due to a use error.
- ❖ **Evaluative Indicators (III)**, defined as recurring themes in reports of system use that can serve as early indicators about systems issues in general, some of which might stem from usability problems. By gathering data through interviews, focus groups, ethnographic research, and observations of the system in use, gaps in optimizing user interaction design needs can be identified. In addition, use cases and scenarios for usability evaluations can be developed that are more likely to detect system flaws that create use error hazards or traps proactively.
- ❖ **Adverse Events (IV)**, defined as sentinel events attributable wholly or partially to an EHR's user interface design defects. These defects create error traps that make it easy for use errors to be committed. These event outcomes are similar to the patient safety checklist items for EHRs developed by HIMSS.

## **DEFINITIONS INCLUDED IN GUIDANCE DOCUMENT**

**Patient Safety:** a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.

**Usability:** The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. These terms are further defined as:



- **Effectiveness:** the accuracy and completeness with which users achieve specified goals,
- **Efficiency:** the resources expended in relation to the accuracy and completeness with which users achieve goals,
- **Satisfaction:** freedom from discomfort, and positive attitude to the use of the product, and
- **Context of use:** characteristics of the users, tasks and the organizational and physical environments.

**Use Error:** an act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator.

- ❖ Error of Omission vs. Error of Commission: For example, in a patient room, a caregiver not seeing or hearing vital information conveyed by an EHR that requires immediate intervention with a patient, would be an error of omission, while selecting the wrong drug from a formulary due to ambiguous or confusing abbreviations would be an error of commission.

## **ADDITIONAL GUIDANCE**

- ❖ Criteria and best practices for selecting expert reviewers
- ❖ Protocol for conducting a review
  - Uses a process similar to that used in the SHARPC program
- ❖ Overview of protocol steps
  - sets out the major steps of the protocol in a temporal sequence so that testers can follow them sequentially
  - Includes: recruiting participants, determining a sample size, setting up testing environment, setting up the EHR system being tested, developing a tester's guide, orienting and instructing participants, conducting the test, and analyzing data and reporting results.

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