

Good afternoon, my name is Lana Lowry, and I am the Health IT Usability Project Lead at the National Institute of Standards and Technology (NIST). I have devoted my career to practicing the scientific discipline of Human Factors to improve the usability and accessibility of many complex systems.

I would like to express my appreciation for the fact that we are actually discussing usability and human factors at this important public forum today and would like to present an overview of the work that NIST is conducting - in close collaboration with other Government Agencies, with academia and most importantly with Industry - to establish a framework that defines and assesses HIT usability and accessibility.

Usability is a key factor in Meaningful Use because at the end of the day, no one can be satisfied with a system in which the system itself is a contributing factor to an error in patient treatment. It is essential that "meaningful users" (doctors, medical technicians, nurses, administrative staff and others) be able to successfully access, retrieve, process, and act on data easily, without error, and without excessive time burden.

A recent HIMSS Usability Task Force publication prioritized usability as one of the major factors—*possibly the most important factor*—hindering widespread adoption of EMRs and identified that usability has a strong, often direct relationship with clinical productivity, error rates, user fatigue and user satisfaction—critical factors for EMR adoption.

We know from science that humans have many capabilities but also many limitations – limitations in the ability to perceive, process and act on the information presented to us. We also do know from Human Factors science that if we design our systems in a way that exceed these limitations, we produce use errors. The challenge therefore is to develop systems that enable human performance; not undermine it.

In response to this challenge, NIST is developing an EHR Usability Protocol or EUP that provides the detailed specification of an objective, repeatable procedure for measuring and evaluating the usability of HIT systems. The goal is to establish formal technical methods for measuring usability that will uncover critical usability issues that may impact performance and errors in EHR use based upon known human factors principles, processes and best practices. Simply put, applications should be designed to eliminate the causes of error – including human error. On a practical level, this means that we deliver a *process* that describes guidelines on usability factors associated with critical safety issues, and *technical evaluation protocols* for ensuring EHR developers have a framework to understand how usability affects critical safety issues in patient care. This protocol will be presented and discussed in a workshop setting at NIST on June 7, 2011.

In developing our guidance to measure the usability of EHR systems, we are adopting existing best practices, such as the FDA human factors evaluation process; the Army MANPRINT process; Navy Human-System Integration; FAA flight deck certification process; and potentially others, adopted by federal agencies with oversight on system usability. We are thoroughly customizing these best practices and methods to the specifics of EHRs.

We are working closely with diverse experts from government, industry and academia in the fields of:

- Human factors
- Clinical practice
- Informatics
- Safety/Risk
- Accessibility

The intent of our EHR usability program is to validate that an application's user interface is not leading users to make critical usability, and potential safety-related, errors.

Key components of the protocol include:

Identification and reduction of use errors through thorough analysis of all user groups, use environments, and use cases
Demonstration of evidence for formative user research, such as iterative usability testing and cognitive walkthroughs, and changes made as a result of this research
Validation studies conducted by qualified professionals with a truly representative range of real users under realistic conditions; all use errors documented with discussion of remediation
Establishing Best Practice: Educating industry that some qualitative methods, such as focus groups and surveys, are insufficient for the identification and mitigation of risks associated with use errors

The goal is to help EHR developers generate and submit their formal usability reports in the Common Industry Format (standard for reporting the results of summative usability testing that was released by NIST in November 2010; Customized Common Industry Format Template for Electronic Health Record Usability Testing http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312)

Let me be clear: the usability evaluation program (EUP) is focused on helping developers of systems assess and demonstrate that their software is free from design-induced user-error and will not dictate particular user interface designs. Providing these tools and guidance will empower the vendor community to innovate while being sensitive to the impact and importance of user interface design decisions on medical staff and patients.

NIST has worked in close collaboration with the HIMSS EHR Usability Task Force, the EHR Vendor Association, the ONC SHARPC team, the US Access Board and other public and private stakeholders. In order to ensure maximum transparency and opportunity for constructive technical input, NIST is hosting a Technical Workshop on June 7 of this year at our agency in Gaithersburg, MD. This workshop will build off of the one that we hosted last year. We hope to see you there.

Thank you for the opportunity to share our work and I look forward to your questions.