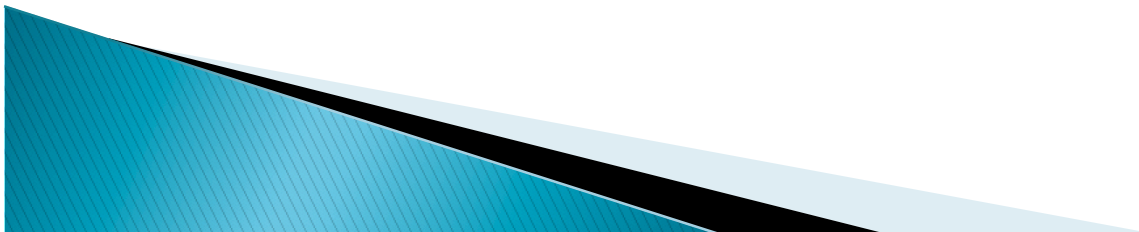


Measuring, Evaluating and Improving the Usability of Electronic Health Records



Agenda

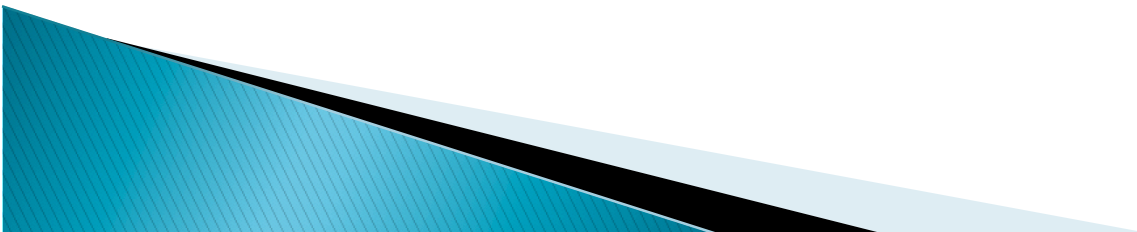
- ▶ What is Usability?
- ▶ What is the Current State?
- ▶ Role and Activities of NIST in Usability
- ▶ Reactions from Stakeholders
- ▶ What's Next?



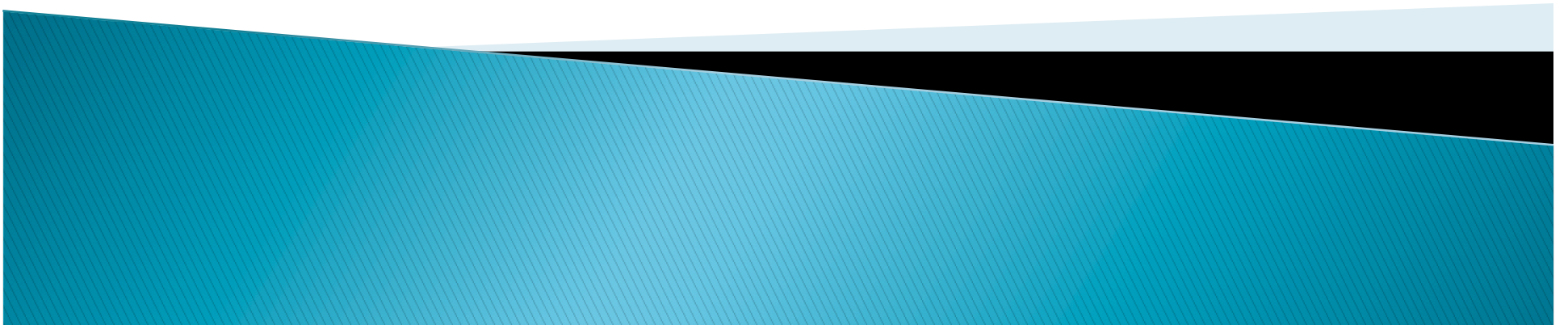
What is Usability?

Usability is "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"

– ISO9241



So where are we with
EHR Usability?

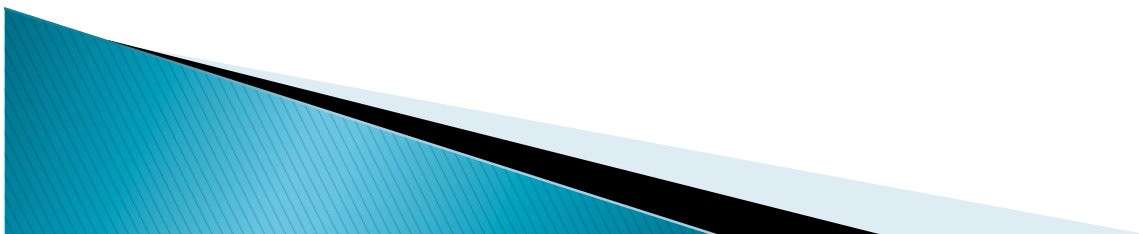


Importance of Usability

We submit that usability is one of the major factors—*possibly the most important factor—hindering widespread adoption of EMRs.* Usability has a strong, often direct relationship with clinical productivity, error rate, user fatigue and user satisfaction—critical factors for EMR adoption.

- “Defining and Testing EMR Usability: Principles and Proposed Method of EMR Usability Evaluation and Rating” HIMSS Usability Taskforce, June 2009

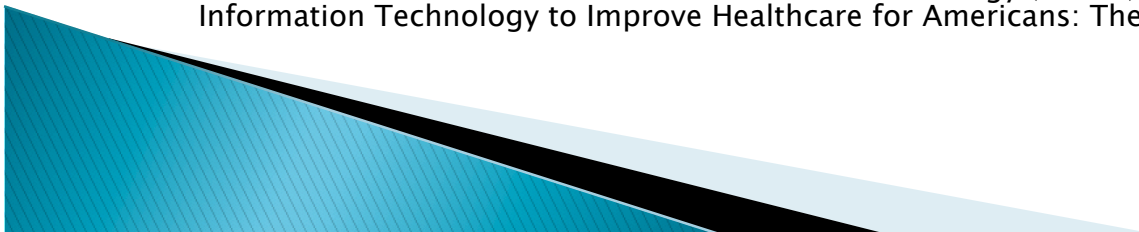
http://www.himss.org/content/files/HIMSS_DefiningandTestingEMRUsability.pdf



PCAST Report

- ▶ “...the current structure of health IT systems makes it difficult to extract the full value of the data generated in the process of healthcare...
- ▶ This means that physicians can have trouble finding the information they need, and patients often wind up with poor access to their own health data and little ability to use it for their own purposes...
- ▶ market innovation has not yet adequately addressed these challenges to the usability of electronic health records.”

– President’s Council of Advisors on Science and Technology (PCAST), “Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward,” December 2010.



IOM: Health IT and Patient Safety: Building Safer Systems for Better Care

- ▶ “The current state of safety and health IT is not acceptable”
- ▶ “The committee expressed concerns that poor usability...is one of the single greatest threats to patient safety. On the other hand, once improved, it can be an effective promoter of patient safety.”
- ▶ “Usability is a Key Driver of Safety...Health IT products are needed that promote efficiency and ease of use while minimizing the likelihood of error.”
- ▶ “Evaluation of the impact of health IT on usability and on cognitive workload is important...”
- ▶ “Usability guidelines and principles focused on improving safety need to be put into practice.”

https://download.nap.edu/catalog.php?record_id=13269



IOM: Health IT and Patient Safety: Building Safer Systems for Better Care

- ▶ “While many vendors already have some types of quality management principles and processes in place, not all vendors do and to what standard they are held is unknown.”
- ▶ Recommendation: “The Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.”



ONC → NPRM for MU Stage 2

“Safety Enhanced Design”

- ▶ A significant first step toward improving overall usability is to focus on the process of UCD
- ▶ Prioritized eight certification criteria and associated capabilities to which this proposed certification criterion would require UCD to have been applied. We chose these eight because we believe they pose the greatest risk for patient harm and, therefore, the greatest immediate opportunity for error prevention and user experience improvement.
- ▶ Use of any of several processes to apply UCD would meet this certification criterion....acknowledge and expect that EHR technology developers who have already followed UCD in past development efforts for the identified certification criteria would be performing a retrospective analysis to document for the purposes of testing and certification that UCD had been applied to the specified certification criteria. However, if UCD had not been previously applied to capabilities associated with any of the certification criteria proposed, the EHR technology would ultimately need to have such UCD processes applied before it would be able to be certified.
- ▶ EHR technology developers documenting that their UCD incorporates, in any form or format, all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742). This documentation would become a component of the publicly available testing results on which a certification is based...
- ▶ While valid and reliable usability measurements exist, including those specified in NISTIR 7804 ‘Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records,’ we are concerned that it would be inappropriate at this juncture for ONC to seek to measure EHR technology in this way...

Feedback from Industry (EHRA)

- ▶ Suggested an alternative approach in which vendors attest to and document current processes for incorporating UCD...but not publicly publish findings from specific tests
- ▶ If NISTIR 7742 (Common Industry Format) is required, then require only the high-level elements (Introduction, Method, Results expressed in Effectiveness, Efficiency, and Satisfaction) and leaving flexibility on the specific lower-level elements...and NOT including Major Findings and Areas for Improvement in reporting results, since those are only useful to the vendor
- ▶ Believe that summative testing (as outlined in NISTIR 7804) can catch the most basic usability errors, but is unlikely to have a significant impact on patient safety relative to cost
 - Agree wholeheartedly with the decision not to include NISTIR 7804
- ▶ Want formative UCD techniques instead of just summative testing as valid for certification
- ▶ Strong objections to the requirement for retrospective UCD analysis and application.
- ▶ *“In many cases, the core functionality and user interfaces associated with some of the specified applications and features were developed several years ago and continuously refined through user feedback over the ensuing years – feedback that has addressed usability issues, albeit not necessarily according to formal UCD protocols.”*

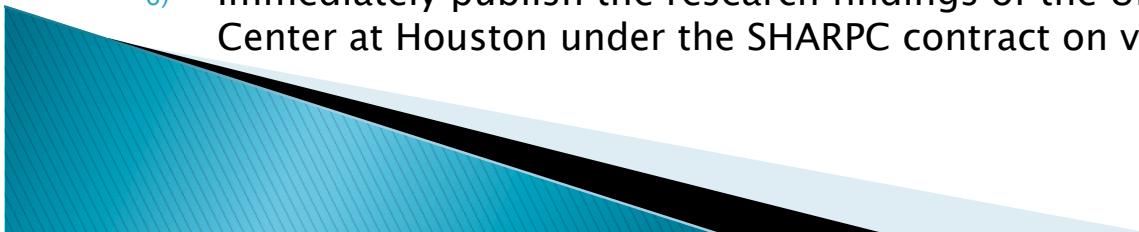


Feedback from Doctors (AMA)

“... continue to harbor significant concerns over EHR usability issues...While requiring EHR vendors to apply UCD to these priority areas is a step in the right direction, we believe it falls short of what is needed...”

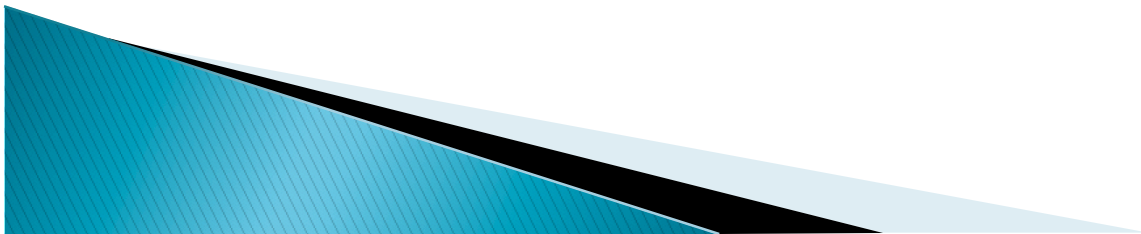
The AMA strongly urges ONC to:

- 1) Apply the principles in the NISTIR 7804 to the entire EHR certification process;
- 2) Seek industry feedback—including physician feedback—on what constitutes an appropriate level of risk as it relates to patient safety;
- 3) Ensure that the ONC Authorized Testing and Certification Bodies (ATCBs) have the expertise to address UCD issues;
- 4) Publish the results of each vendor’s performance on the eight required areas of focus for the UCD;
- 5) Name the “Customized Common Industry Format” template for EHR testing as developed by NIST to be required for use by all EHR vendors that seek certification, and publish each vendor’s results; and
- 6) Immediately publish the research findings of the University of Texas Health Science Center at Houston under the SHARPC contract on vendor usability problems



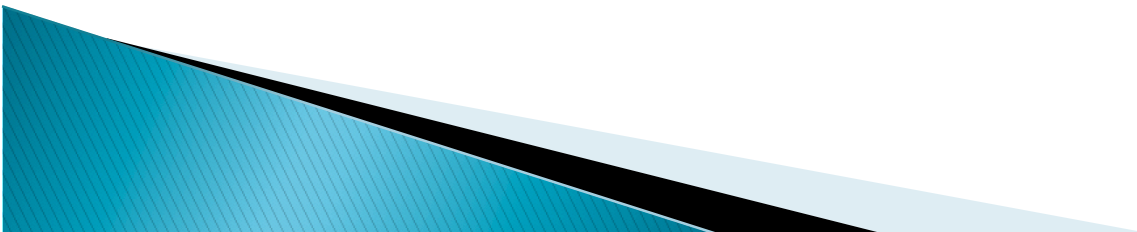
Mission and Role of NIST

- ▶ NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life
- ▶ NIST Laboratories conduct research that advances the nation's technology infrastructure and is needed by U.S. industry to continually improve products and services



Standards Development at NIST

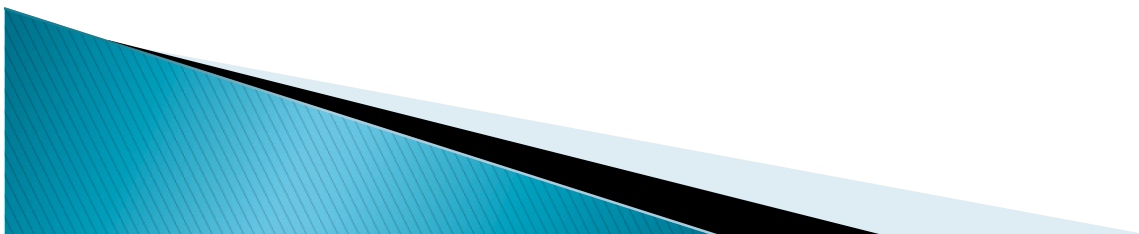
- ▶ Developing standards is a consensus based process
- ▶ NIST traditionally works with all stakeholders to develop standards, and then to ensure that the standards are harmonized and industry is able to implement them



NIST Technical Guidance

- ▶ NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741)
- ▶ Customized Common Industry Format Template for Electronic Health Record Usability Testing (NISTIR 7742)
- ▶ Human Factors Guidance to Prevent Healthcare Disparities with the Adoption of EHRs (NISTIR 7769)
- ▶ “Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records” (NISTIR 7804)

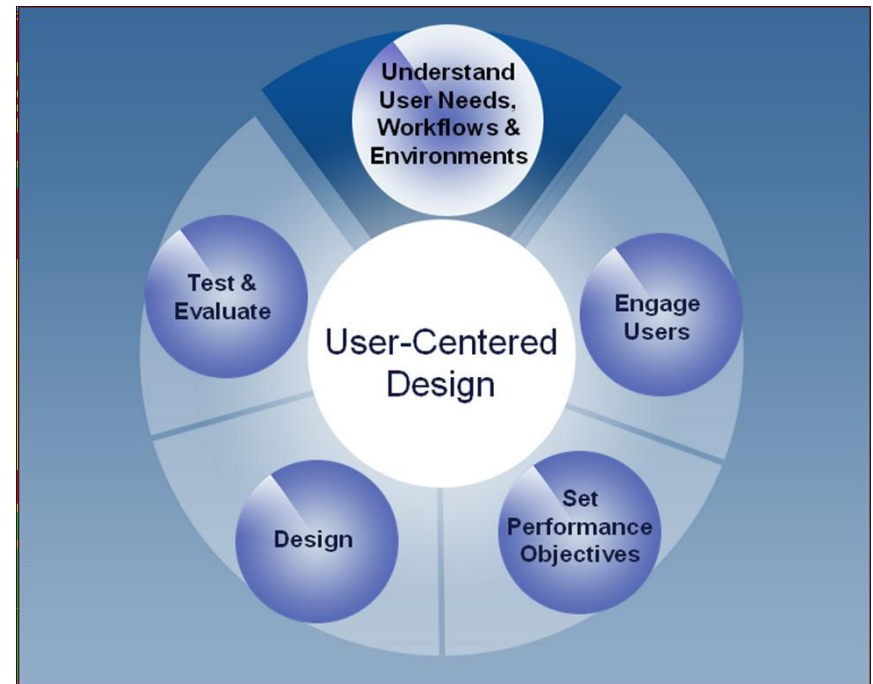
www.nist.gov/healthcare/usability



NIST Health IT Usability Activities Applying the Science

- ▶ NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741)
- ▶ Customized Common Industry Format Template for Electronic Health Record Usability Testing (NISTIR 7742)

www.nist.gov/healthcare/usability

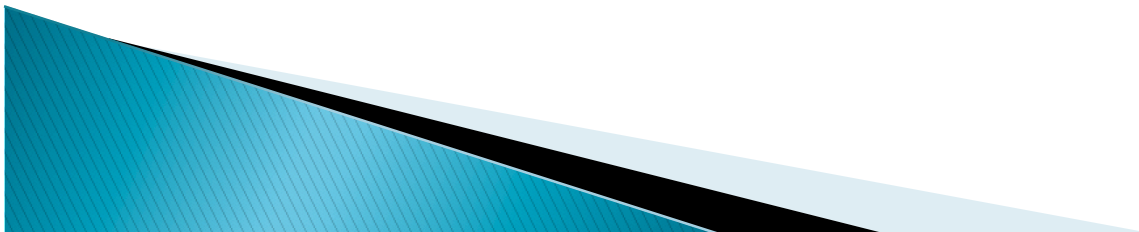


NIST Health IT Usability Activities

Establishing the Metrology

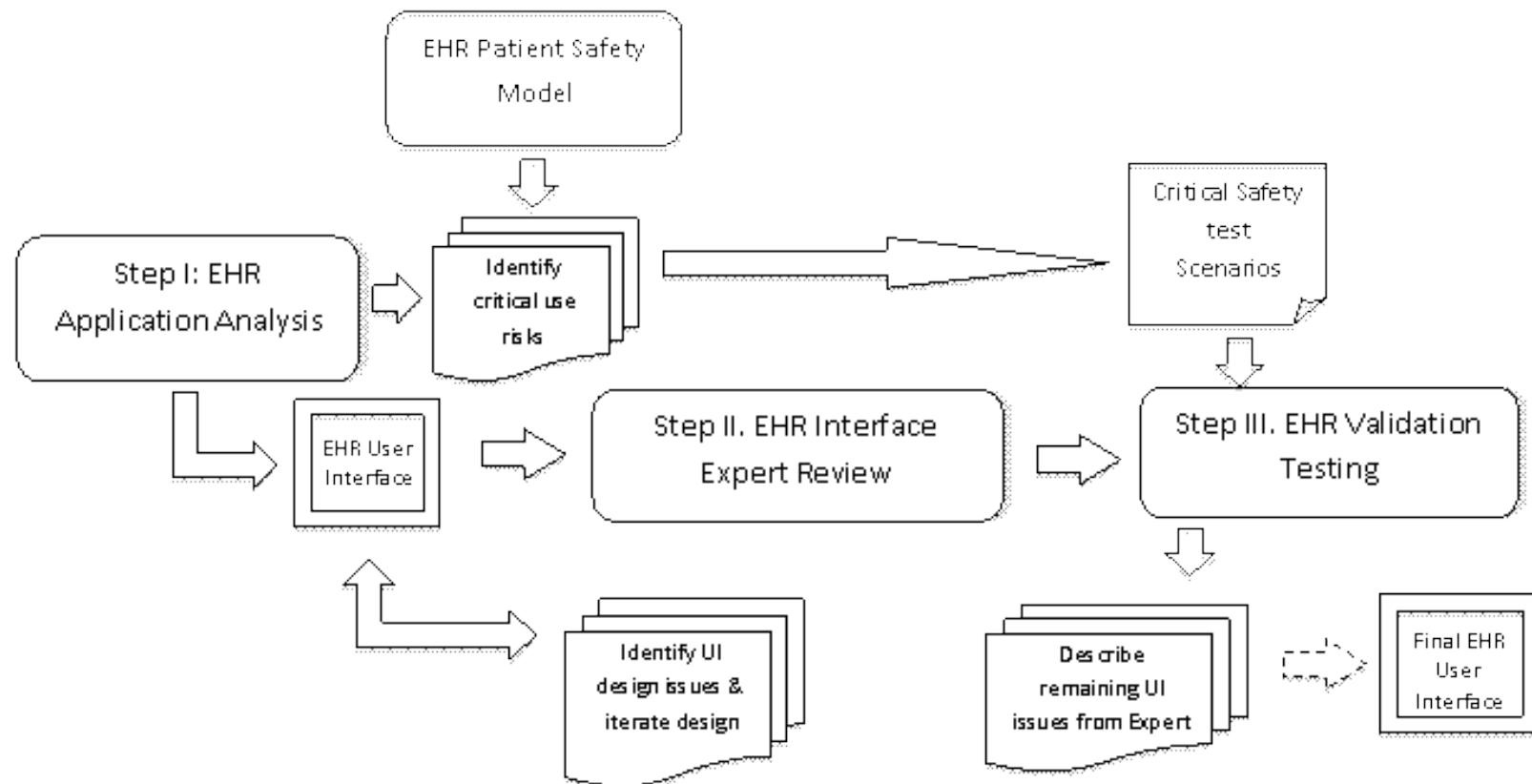
NISTIR 7804: “Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records”

- ▶ 3 Step protocol for demonstrating that EHRs are free from critical “use error”
- ▶ Use of CIF (Common Industry Format) for Reporting Results of Validation Testing
- ▶ www.nist.gov/healthcare/usability



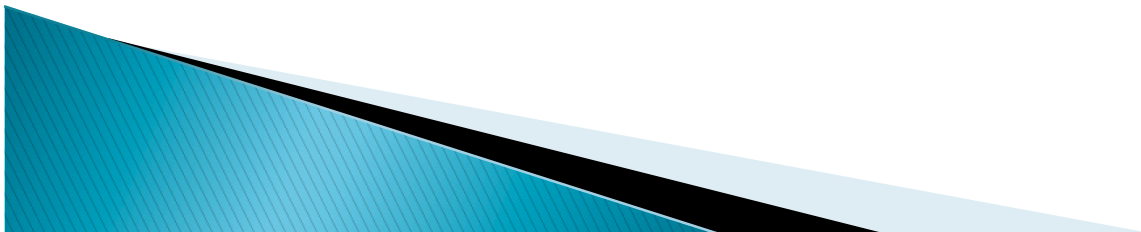
NISTIR 7804 – EUP Process

Figure 1. EUP Three-Step Process



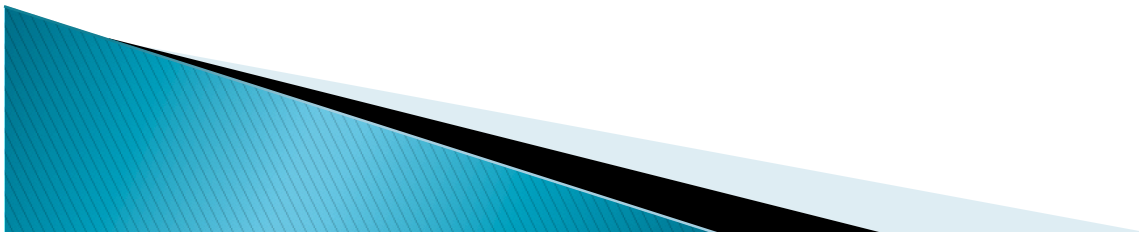
Perspective from Industry

- ▶ “My first impression of the report is that it was developed by the right people – usability experts....
- ▶ My second impression of the report is that it is, in itself, usable. It’s an easy-to-read overview of what software usability is. It’s not an opinion piece, an academic literature review, or government boilerplate.”
 - Mr. Histalk, Health IT industry blogger / thought leader



Perspective from Industry

- ▶ “amazing job on the NISTIR 7804 on evaluating usability of EHRs. The second half reads like a primer for teaching people how to conduct valid studies! You guys did an awesome job pulling this together!!”
 - Director of Usability for major EHR vendor



Back to the IOM Report

- ▶ “The National Institute of Standards and Technology (NIST) has been developing guidelines and standards for usability design and evaluation ...Usability guidelines and principles focused on improving safety need to be put into practice.”
 - ▶ – *Institute of Medicine, “Health IT and Patient Safety: Building Safer Systems for Better Care”, 2012*



Where Do We Go From Here?

- ▶ Read MU2 Certification NPRM
 - “Safety-enhanced design” – pp.11–12
 - <http://www.gpo.gov/fdsys/pkg/FR-2012-03-07/pdf/2012-4430.pdf>
- ▶ Integrate usability / HF into development and implementation processes
- ▶ Validate designs using NIST guidance
- ▶ Look for: “A Human Factors Guide For Usability Of Critical User Interactions For The Pediatric EHR”



www.nist.gov/healthcare/usability

- ▶ NIST EHR Usability Wiki
 - Available from the above address

Matt Quinn

National Institute of Standards and Technology

matt.quinn@nist.gov

phone: 301-975-5936

