



November 10, 2011

Patrick D. Gallagher  
Under Secretary for Standards and Technology and Director  
National Institute of Standards of Technology  
U.S. Department of Commerce  
1401 Constitution Ave NW  
Washington, DC 20230

Sent via email to: [EHRUsability@nist.gov](mailto:EHRUsability@nist.gov)

Re: Guidance on Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records (NISTIR 7804)

Dear Mr. Gallagher:

The Alliance for Nursing Informatics (ANI) advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and health care through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 5,000 nurse informaticists and brings together 28 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 3 million nurses in practice today. Nurses constitute the largest single group of healthcare workers, including experts that serve on national committees and interoperability initiatives focused on standards and terminology development, standards harmonization, and electronic health record (EHR) adoption, as well as certification of EHR systems. Further, nurses are active in the research, education, implementation, integration and optimization of information systems throughout the healthcare system. In that spirit we offer the following comments regarding the *NIST Draft Guidance on Technical Evaluation, Testing and Validation of EHR Usability Protocols*.

The Technical Evaluation, Testing and Validation of Usability of Electronic Health Records (EHRs) draft guidance issued by the National Institute of Standards and Technology serves as a good primer for EHR usability, especially as it pertains to use errors that are related to the user interfaces. ANI requests consideration of the following comments:

- ANI believes that the guidance should acknowledge that there is a narrow focus related to patient safety outcomes and medical errors, since it is not clear how the correlates for usefulness, learnability, and satisfaction are included in the models proposed.
- ANI recommends that the list of expert reviewers should be broader and reflect experts with more diverse backgrounds. Informatics professionals also are exposed to these same methodologies, and, as such should be included as potential reviewers. Although most clinicians are not necessarily trained in heuristic evaluation, clinicians with an informatics




background would have knowledge of how to conduct these procedures. Furthermore, clinicians provide much needed experience and knowledge about how these systems should be used in the clinical setting. They should be included in the selection of expert reviewers.

- ANI is concerned that human factors tools are not referenced in the current NIST protocol, yet there are important elements in human factors to consider including environmental variables. The environment is also an important variable to include because of the different setting scenarios being introduced in the appendix.
- ANI questions if the traditional heuristics described in the DRAFT Guidance are appropriate and still applicable given the newer technologies being imbedded into our healthcare system. For example, consider the use of sensors to detect activity levels and to monitor functional activities. The scope of these heuristics does not adequately cover all forms of technologies which are becoming integrated into our electronic health records systems today.
- ANI suggests that the evaluation case scenarios should include the clinical reasoning and thinking processes for decision making which involves extensive use of any captured information within electronic health records. The mechanism of care where patient information is used requires a complex patient case scenario that reflects the holistic approach to patient care. ANI is concerned that these diagnostic and evaluation processes are not exposed within limited scenarios. Thus, ANI recommends that the presentation and use of information for decision making should be accounted for within the model.

ANI believes that the Draft Guidance Document should include at least one component of testing beyond the “sterile” environment and in a more realistic scenario. Testing should not be done in isolation and should represent typical care scenarios. It is understandable that testing in a laboratory simulation of a clinical environment would be important to conduct; however, most clinicians do not use EHRs or other technologies in distraction-free environments void of exogenous factors. Simulated testing is not sufficient as a stand-alone method to explore usability in the clinical setting. Certainly costs are prohibitive for these types of analyses, but medical errors are costly as well. For example lab testing often includes using specific cases studies with the use of think aloud techniques or eye trackers. However, actual data used and processed in a busy ICU or home care environment are actually much more complex than data from use cases processed in a lab. Without adequate testing in these environments, errors can occur

Focusing on patient safety alone is not sufficient, particularly with much of the nation moving toward meaningful use (MU) and in the process of implementation of practices to meet MU requirements and improve patient outcomes. To that end, usability and efficiency are highly important and should be considered during this first phase of usability testing and evaluation in order to sufficiently address clinician concerns. Thus, ANI recommends that NIST incorporate usability testing associated with provider efficiency and effectiveness. Finally, ANI requests that additional clarification be provided regarding the extent to which NIST’s usability protocols may be incorporated into any future standards and/or certification criteria for Meaningful Use Stages.



ANI is grateful for the opportunity to submit these comments. Again, we thank NIST for soliciting public input to help inform the DRAFT Guidance. Please let us know if we can provide any clarification or additional information regarding our comments.

Thank you for your consideration.



Judy Murphy, RN, FACMI, FHIMSS  
ANI Co-chair (HIMSS representative)  
33 W. Monroe, Suite 1700  
Chicago, IL  
Email: [judy.murphy@aurora.org](mailto:judy.murphy@aurora.org)



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Bonnie Westra, PhD, RN, FAAN  
ANI Co-chair (AMIA representative)  
4915 St. Elmo Avenue, Suite 401  
Bethesda, MD 20814  
E-mail: [westr006@umn.edu](mailto:westr006@umn.edu)



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