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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

Dear Mr. Gallagher:

HIMSS appreciates this opportunity to comment on the [Draft Guidance on Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records](#) (NISTIR 7804) published on October 3, 2011 by the National Institute of Standards and Technology (NIST).

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 40,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations.

HIMSS also includes over 500 corporate members and more than 150 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

In accordance with HIMSS' continued commitment to EHR adoption, we offer the following comments on the draft guidance on EHR Usability Protocols (EUP) outlined by NIST. Our comments center on the three-step process for the evaluation of human user performance:

- **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
- **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
- **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.

Usability Analysis

HIMSS appreciates NIST efforts, and recognizes that the draft guidance serves as an effective primer for EHR usability protocols (EUPs), especially with respect to use errors that are caused by user interfaces. We concur that patient safety is a critical factor in EHR use and offer the suggestion that the EUP guidance should be expanded to focus on the efficiency, effectiveness, ease of use and user satisfaction of the EHR. With this expansion, the focus of the initial draft guidance could address the usability concerns of clinicians and other users of EHRs.

In particular, user fatigue and frustration can lead to errors or process workarounds, which are also patient safety issues. Strictly focusing on errors demotes the role usability can play in developing more streamlined, effective interfaces between clinicians and EHRs. In addition, the application has to function in a manner commensurate with the workflows of the clinicians and stakeholders. The application should augment efficiencies in workflow, not hinder it. For this reason, we recommend that NIST address usability applications associated with provider efficiency, effectiveness and ease of use—in addition to patient safety—in this first stage of the EUP, rather than at the time of a future expansion of the protocols.

Expert Reviews

The draft guidance describes requirements that expert reviewers should meet, including an earned Master's Degree (or higher) in a human factors discipline or in an otherwise related field of human interaction with computing technologies. It also requires “experience and expertise in user research and in user interface design of EHRs and/or other health information technologies.”¹

HIMSS believes that a critical missing factor in the draft guidance is the inclusion of individuals with practical clinical experience. As it is laid out in the current draft guidance, the expert review exercise appears more academic in nature than clinical, even though a clinical background would help an expert reviewer bridge the gap between design and user testing. This is particularly important since the guidance suggests that during the process, this could go back into development phases during the expert review stage. One way to address errors is to improve the parameters for design/development. Including individuals with clinical backgrounds in the review process would ensure that these critical stakeholders are contributing expertise at an earlier stage of the development process, when identified issues could be revisited and improved.

In addition, the draft guidance states that “in general, each review should be a thorough review of the major elements of the user interface².” HIMSS recommends that expert reviews be based on a “loaded” or “seeded” system with a wide range of information and realistic data elements, including complexity, multiple patients, pairing of systems, versions, configuration, and clarification on test data set requirements.

¹ NIST Draft Guidance on Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records, p. 27 http://www.nist.gov/healthcare/usability/upload/Draft_EUP_09_28_11.pdf

² NIST Draft Guidance on Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records, p. 29 http://www.nist.gov/healthcare/usability/upload/Draft_EUP_09_28_11.pdf

HIMSS recommends that NIST provide guidance on selecting which system, version, and configuration to include in the evaluation. Considerable time and effort is needed for setting data in the system, and it was suggested that NIST provide a test data set for vendors and others to access/import into a test system so that usability tests could be conducted on a standard data set.

User Testing

HIMSS also offers over a decade of experience as the co-founder of Integrating the Healthcare Enterprise (IHE) International, a global non-profit organization that enables collaboration of health care providers and industry leaders to greatly improve the ability of health IT systems to safely, effectively and securely exchange patient health information. IHE publishes "integration profiles," which strictly defines how these existing standards should be applied to specific actions related to the problem. Health IT product vendors then use IHE integration profiles to ensure interoperability between health IT products including those developed by multiple manufacturers. On an annual basis, IHE provides a comprehensive testing environment for IHE Profiles and related health IT products, in an event known as "Connectathon". This event is the largest, single, ongoing health IT testing environment in the US, of which NIST has provided critical support in the development of profiles and providing oversight to testing.

As such, HIMSS suggests that testing should not be done in isolation and should represent typical care scenarios. In the draft guidance, it is suggested that the EUP protocol should "describe the environment of testing and how it is representative of real-world testing application use in terms of lighting, noise, distraction, vibration, workflow, and other conditions in the workplace." HIMSS believes that these criteria listed in the proposed testing environment can be augmented by adding more relevant adverse factors such as interruptions, medical emergencies, competing workflow and time pressures that are more typical in a practice scenario. Usability must be aligned with clinical workflow to avoid the risk for patient safety errors, and including all clinical stakeholders in the testing process is a way to align these efforts. HIMSS members also suggest incorporating unit-based testing into the user testing process.


HIMSS members want to ensure that prescribing certain methodologies for usability will not hinder vendors' ability to do the "up front" work during the formative testing process that leads to effective usability. The current NIST draft guidance provides considerable detail for the expert review process, as well as the summative testing phase. HIMSS members expressed concern that there is not enough focus in the document toward user centered design activities throughout the software design/development cycle—a sharper focus on formative testing would lay the groundwork for provider ease of use and efficiency, as well as patient safety.

Conclusion

HIMSS recognizes that the need for usability education beyond the development bench and supports NIST providing usability resources, best practices, design libraries, case studies, tools and toolkits to the industry at large. These tools and education would be not only by those that design and develop EHRs, but also by those that customize, implement and seek to optimize EHRs.

HIMSS appreciates this opportunity to offer comments on the NIST draft guidance. We look forward to continued dialogue and communication as we work toward a connected and robust health care delivery system. If you have any additional questions please contact [Thomas M. Leary](#), Senior Director, Federal Affairs, 703.562.8814 or [Stephanie Jamison](#), Director, Government Services, 804.922.3066.

Sincerely,



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