

NIST Response to Comments Received on Draft EHR Usability Protocol

In response to our request for public input on the Draft EHR Usability Protocol (EUP) released on October 7, 2011, NIST received many informative comments from a broad spectrum of stakeholders. We would like to thank reviewers for their constructive feedback. The comments we received covered a range of Health IT usability concerns and their potential impact on patient safety.

This document is a summary of the input we have received. The technical comments were very insightful and will be useful as we revise the EUP. Comments were submitted from a wide range of perspectives, including clinicians, Health IT vendors, and usability/human factors experts. Feedback from these stakeholders fell into several categories:

- Nearly all respondents commended NIST for providing a structured protocol for usability validation.
- Many respondents commended the use of clinically-relevant use case scenarios.
- Several respondents questioned the audience and purpose of the NISTIR 7804 guidance and whether the focus on safety/ critical usability error (vs. efficiency or other dimensions of usability) was most pressing and appropriate for validation testing.
- Several respondents discussed the skill level, educational requirements and other aspects of the expert reviewer requirements.
- Some respondents raised methodological issues with expert review as an objective approach.
- Some respondents requested more specificity regarding risk assessment techniques and use of failure mode and effects analysis (FMEA).
- Some respondents questioned the applicability and usefulness of summative usability testing and use of the protocol in agile (vs. waterfall) development environments.
- Some respondents questioned the use of labs instead of actual healthcare environments for validation testing.
- Some respondents questioned the selection criteria for test subjects outlined in the protocol.
- Some respondents suggested that additional discussion would be helpful for the usability assessment.

Those areas that fell outside the intention of the document (e.g., policy) were not addressed in this technical document and will not be addressed in the revision.

The focus of the EUP revision will be to (1) sharpen the framing of the introductory sections including the patient safety framework and role of summative testing (vs. formative testing), (2) better explain the procedures and rationale for the expert evaluation protocol, (3) address specific comments about use cases, procedures, and testers involved in the summative testing, (4) make many of detailed constructive changes suggested by reviewers, and (5) tie each of the pieces together into a tighter summary.