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Dear Dr. Lowry:

The Electronic Health Record (EHR) Association is pleased to respond to the NIST draft proposed EHR Usability Protocol (EUP) on Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records (NISTIR 7804). The EHR Association represents not only our member companies, which employ many industry experts in healthcare information technology, but also our users, who are the vast majority of hospitals and physicians using electronic health record systems to deliver care in the United States today.

Like NIST and ONC, the EHR Association strongly supports lowering all barriers to adoption of EHR technology and improving safety and usability of EHR systems. This new national focus has the potential to accelerate our own longstanding efforts, through identification of best practices, research on the factors that could contribute to EHR design-related use errors, and better understanding of the cognitive processes that can be supported with well-designed software. We applaud the efforts in this area.

We do, however, have several concerns with both the thesis and process described in the draft EUP. In this letter, we will first describe our general comments about the draft EUP, followed by comments on specific themes within the draft EUP.

The draft EUP's thesis is that poor usability is a primary "barrier to adoption and meaningful use" of EHR systems and asserts that the proposed testing strategy will result in systems that are demonstrably more usable, safe, and efficient without compromising innovation.

Regarding the draft EUP's thesis, we believe:

1. The assertion that usability is a material barrier to adoption is unproven and not supported by the evidence cited. The draft EUP relies exclusively on anecdotal evidence and studies focused on usability alone, which are insufficient to identify the factors hindering EHR adoption in the United States.
2. The draft EUP's rigid testing and reporting structure demonstrates a fundamental misunderstanding of how EHR software is used in practice, and this misunderstanding compromises the EUP's underlying premises. The draft EUP describes detailed protocols for testing, but does not offer results that would be comparable between systems or even different configurations of the same system.
3. The reliance on 16-year-old materials in the examples of usability best practices, the failure to acknowledge the limitations of checklist-based review and the lack of any cost-benefit analysis does not align with the stated goal of encouraging and fostering innovation.

NIST, both in the draft EUP itself and through webinars and work sessions, has acknowledged that it has intentionally not addressed the proposed application of the EUP, including its role in certification. This narrow focus, however, weakens the usefulness of the EUP, since the proposed guidance does not address such issues as time and cost to implement, standardization, reproducibility, reliability, and other implementation details. Regarding the draft EUP's process, we believe:

1. The draft EUP does not take into account current industry practices for ensuring usability and patient safety. Before any approach to improving these factors in the EHR is recommended, we strongly advise that usability should be considered in the context of current and increasingly adopted practices supporting the overall goals of safety and adoption (of which usability is important, but just one component). An approach that does not take into detailed account what is already being done will almost certainly advocate duplicative processes and will not address many real opportunities to improve either usability or patient safety.
2. The strict requirements surrounding expert review are unwieldy and unproven.
3. The strict requirements surrounding summative testing are impractical and assume a single idealized system that rarely represents the numerous customized systems in practice. This assumption affects the reproducibility and generalization of the EUP's approach.

The EHR Association and software engineers from its member companies who participated in the development of these comments strongly and enthusiastically support the advancement of usability science, guidance, and research. We see great opportunities for NIST in the following areas:

1. Resources and education on usability for both the EHR developer industry and healthcare providers implementing and customizing EHR solutions. These materials should address the design, implementation, verification and maintenance of EHR systems.
2. Research on barriers to adoption and review of improvement opportunities in current industry practice, especially comparative research between areas of high and low adoption.

3. Analysis of the transition of the academic ideal to practice, and the costs, benefits, and tradeoffs involved in implementation of varied degrees of rigidity.
4. Non-normative libraries of design patterns, best practices, and case studies.

BARRIERS TO ADOPTION

In Section 2: “Background: Impact of Usability on Electronic Health Record Adoption,” the draft EUP states:

“Experts have identified shortcomings in the usability of current EHR systems as a key barrier to adoption and meaningful use of these systems.”

Our review of the available research and citations used to support this statement does not, in fact, substantiate the finding that “usability is one of the major factors – possibly the most important factor – hindering widespread adoption of EMRs.”

The draft EUP quote, upon which the majority of Section 2 is based, comes from a report that cites four studies in support of this attempt to link usability to adoption. Our review, however, suggests that a reexamination of that conclusion is warranted. Smelcer et al. (2009) relies on anecdotal data; Zheng et al. (2009) evaluates a single home-grown EHR system and does not address the overall problem of adoption¹; Rose et al. (2009) examines methodologies not used in this proposed protocol in the context of another single home-grown EHR system²; and Poissant et al. (2005) presents a meta-analysis of time studies on CPOE³. Poissant comes closest to addressing usability as a barrier to adoption but focuses only on the CPOE component of EHR systems, explores time efficiency rather than usability, and addresses products in deployment between 1990 and 2003, products that are at least eight years old today.

In Section 4: “EUP Foundation: Research Findings Defining EHR Usability Issues and Their Impact on Medical Error,” sources are again cited to support conclusions that may have been overly generalized from the underlying research. Miller (2004)⁴ and Yusof (2007)⁵ both conclude that usability is but one factor of many that can affect adoption, with Miller specifically arguing that “funding agencies and policymakers should generally avoid funding initiatives that aim to directly lower technology or physician-attitude barriers to EMR use [because] vendors already have strong market incentives for developing easy-to-use EMRs.” Since Gans et al. (2005) is often cited (for example, in NIST IR 7741⁶) on this topic, we also think it’s significant to note that Gans found that concerns about usability were reduced post-implementation⁷.

Interestingly, Smelcer points to two examples of adoption rates of EHRs outside the US: the Netherlands at 98 percent and the United Kingdom at 89 percent. If the usability hypothesis truly accounts for poor US adoption, then these (and other) countries have somehow addressed usability in ways that are different from how EHRs are used in the US. A study of how these countries have addressed the usability and adoption would be extremely informative.

We welcome more research on all barriers to EHR adoption in the United States, and we suggest that AHRQ might be the appropriate organization to carry out this work. We don’t dispute that usability can be a barrier to adoption by certain users, but there are many such barriers and it would be incorrect, in our view, to conclude or report that mandating adherence to the draft EUP’s techniques is the most effective approach to improving EHR adoption rates.

USABILITY AND PATIENT SAFETY

The EHR Association is a strong advocate for patient safety. Our Patient Safety Workgroup convenes industry experts, including medical and clinical informaticists, doctors, nurses, pharmacists, and software developers,

to address widespread questions of patient safety and improving outcomes. We have strongly promoted initiatives for voluntary reporting of patient safety events.

The draft EUP addresses patient safety through a narrow focus on usability. Usability is certainly important, but it is by no means the only or even the most important factor affecting the overall safety of IT products used in healthcare. Further, the draft EUP prescribes (in great detail) two very specific methods – expert review and summative usability testing to address safety issues – and does not consider other approaches to involving safety in the design of IT systems. Of note, we would emphasize that the highly detailed approach described in the NIST draft EUP, if used as a basis for federal government policy or regulatory requirements, is at odds with the methodology used by the FDA⁸, which defines an overall process for ensuring patient safety in the development of healthcare products but leaves the specifics of implementation to the manufacturers. The draft EUP also overlooks several key issues that will affect its intent to produce applications with user interfaces that support “error-free user interactions”:

1. The EUP is not grounded in the current landscape of EHRs today: systems of existing, well adopted technologies that have already been developed and deployed. It also does not address the process of developer or organization-led changes to existing user interfaces, nor does it balance usability issues against other user or government initiated requirements.
2. The EUP doesn’t take into account existing vendor and provider mechanisms to address usability and safety. Many complex patient safety issues are discovered through ongoing feedback, one of the only ways to uncover issues across broad ranges of user populations, clinical data sets, and product configurations. We believe that the processes already in use by EHR vendors at live and beta sites to uncover both patient safety and usability concerns across the spectrum identify more issues than would be found by the expert review and summative lab testing of a single, static configuration processes suggested in the draft EUP.
3. The EUP doesn’t address the reality of EHR system deployment. The EHR product is a platform upon which an organization creates an implementation supporting a wide variety of different workflows. A set of “screens” designed by one healthcare organization is rarely generalizable (or in some cases, recognizable) at another organization, or even among clinicians. This high adaptability is vital for safety and efficiency across different care settings, but it also means that test findings in one configuration and context have very little meaning outside of that singular configuration and context.
4. The EUP consistently blurs the line between factors within and outside the EHR software and the developer’s control. Many of the guidelines described in Appendix B are features of the underlying operating system or deployment platform. Some are issues of appropriate use and selection of user input hardware for the EHR users. Others address EHR implementation-specific issues. Successful partitioning of the issues into appropriate layers for expert review or user test is essential to support a scalable process.
5. The checklist provided in the expert review and the cases listed in the summative tests are obviously derived, in some cases, from single occurrence real-life events. While such findings should not be disregarded, this ad hoc approach will only lead to increasingly longer checklists instead of real reproducible systemic improvements. We encourage NIST to focus instead on techniques to improve early error detection, mitigation, and recovery.

USABILITY AND EFFICIENCY

Step 2 of the draft EUP, "Expert Review/Analysis of the EHR", is intended to, among other things, "identify areas for improved efficiency." Step 3, "Testing with Users", will "make sure that there are no critical barriers to [sic] decrease efficiency."

Any discussion of efficiency must necessarily raise questions of learnability. We've often heard the desire that an EHR be as easy to learn as a mobile tablet, or that, if a system takes more than eight hours of training time, it's not good software. Much as we reflect those sentiments as our design ideal, the fact remains that an electronic health record system is more like a high-end video editing platform than an email client: customizable, highly powerful, and highly complex, mirroring the multifaceted and cross-domain workflows it supports.

For the vast majority of users, learnability is a secondary concern to efficiency when a trade-off is required. Cooper writes

"In some specialized products, it is appropriate to optimize the user experience for experts. In particular, tools that technically minded people rely on for a significant portion of their professional responsibilities should be inflected towards a high-degree of proficiency."⁹

Many computer users are so proficient that they literally have muscle motor memory for the sequence of actions and the placement of controls on screen, a skill that is not limited to EHR systems¹⁰. As a result, the expert review process defined by the draft EUP is unlikely to yield significant efficiency gains for these existing users. This methodology is overly skewed to the novice user, and the summative testing's focus on participants with experience in a different EHR will likely introduce Frensch and Sternberg's learnability bias that the draft EUP seeks to avoid¹¹.

INNOVATION

Most of the evaluation criteria in Appendix B stem from a system checklist developed by the Xerox Corporation in 1995¹². This material is not sufficiently generalized from the conventions of the early 1990s and is overly prescriptive. It is in conflict with more current guidelines widely in use and supported by modern operating systems today.

A few examples:

- Item 5.11: "Are menu items left-justified, with the item number or mnemonic preceding the name?" Such menus were common on old terminal-based green screens but are much less applicable in current graphical interfaces.
- Item 5.15: "Do field label labels appear to the left of single fields and above list fields?" Luke Wroblewski has criticized this approach and the need to be more flexible in its application¹³. More tellingly, two years of experience led him to even stronger insights¹⁴, illustrating the need for guidelines to be able to adapt with the users themselves.
- Item 8.6: "Are long columnar fields broken up into groups of five, separated by a blank line?" This criterion could be extremely misleading for clinical findings, and is inconsistent with current conventions and best practices. For example, no applications from Amazon, Google, or Apple apply such an approach.

These examples illustrate our concern that past conventions will inhibit the innate variability and hybrid vigor that spurs truly innovative findings. And innovation is happening at a more rapid pace than ever before. For example, touch interfaces have been widely embraced by clinicians, but such interfaces break several old usability conventions. We have strong concerns that strict adherence to prescriptive standards will in fact inhibit innovation.

Finally, we do not agree with the premise that such an approach will produce better outcomes than a combination of approaches that can balance and refine usability techniques based on their value to users across the range of established and innovative products, including recognition of costs and benefits.

CURRENT INDUSTRY PRACTICE

Almost all the developers represented by the EHR Association incorporate some form of formative evaluations as part of their development processes. Active user groups, focus groups, interviews, onsite observation, and discussions with customers as part of the design process are common in the industry. These are forms of the cognitive walkthrough and user observation indicated in the FDA's guidance. Most of us have employees from implementation, sales, product management, and/or clinical leadership roles, as well as usability professionals, who spend a significant amount of time embedded in the clinical care delivery processes of the healthcare organizations we serve. Their observations, coupled with these processes, also serve to understand and control risk and to ensure that new functionality is clinically safe and relevant.

The draft EUP overlooks the current industry practice of application analysis. Our current methods are not only more robust than those proposed in the EUP, they are better suited to the realities of software development. Additionally, the length of time our software has been in widespread use, coupled with our risk and usability analysis methods and mitigation strategies, yields systems in which the vast majority of "simple" risk (that is, risk confined to a single system and not inclusive of other products, services, processes, or communication patterns) has been uncovered and mitigated. While risk still exists in these systems, it is very unlikely to be uncovered by the development team performing the simplistic application analysis as defined in the draft EUP.

Patterson (2002)¹⁵ neatly dissects the numerous factors that lead us to believe that adverse events are the "black swans" of medical practice, i.e., events that have high impact, are hard to predict, and often rationalized away in hindsight. Additionally, to capture and mitigate the "complex" risk, the applications would need to be effectively instrumented, with actual usage data captured and analyzed, coupled with specific research into use environments, system integration, and process issues.

The draft EUP cites one article¹⁶ on patient safety concerns with EHRs, and that article actually focuses much of its discussion on the process changes that were a byproduct of the healthcare organization's CPOE implementation. The systems integration issues and examples of the impact on the healthcare team's dynamics illustrated in this study are, in fact, representative of the "complex" risk that is very unlikely to be uncovered using the draft EUP.

EXPERT REVIEW

Expert review is a standard process that is widely used by most vendors. We note, however, that there are several challenges in the expert review protocol as described in the draft EUP. Over a decade's worth of findings show that even expert reviewers consistently disagree substantially in their judgment of what constitutes even the most significant usability problems in a product. Most vendors that use this technique internally understand and account for its limitations.

The Evaluator Effect was first documented in usability studies by Jacobsen, Hertzum, and John in 1998. In this paper, they concluded:

“The evaluator effect revealed in this study shows that usability tests are less reliable than previously reported ... Moreover, the evaluators disagreed substantially in their judgment of what constituted the ten most severe problems.”¹⁷

It should be noted that the magnitude of this effect is substantial. Not a single “severe problem” appeared consistently across the top-ten usability problem lists determined by each of the evaluators.

Rolf Molich, the co-inventor of the Heuristic Review expert review method, who is cited by the draft EUP in the opening paragraph of Section 6, has done more than any other researcher to try to understand and document this inconsistency in a series of Comparative Usability Evaluation¹⁸ studies that stretch from 1998 to 2011. In this series of studies, he has documented that there is little agreement and consistency among experts evaluating systems much less complex than EHRs (e.g., email interfaces, and hotel and car rental interfaces).

These studies also document the surprising lack of consistency in reporting across both actual testing and expert review of systems. Some of Molich’s key findings from these studies are that “[t]here’s no measurable difference in the quality of the results produced by usability tests and expert reviews” and furthermore, “[e]ven professional usability evaluators make many mistakes in usability test task construction, problem reporting, and recommendations.”

Because usability is so critical, it is important that we are unflinching in our evaluation of the current state of our ability to measure usability of even relatively simple systems. As a country, we should take these limitations into account as we promise perfected EHR usability and consider using certification as a vehicle to address usability, an approach for which we have substantial doubts. Although we don’t discount the ability for expert review to uncover issues, we should be realistic in our expectations and our guarantees.

SUMMATIVE TESTING

Like expert review, summative testing is a practice that is widely used by many of our organizations. Also like expert review, however, we are aware of the limitations of our tests and we do not rely on them more heavily than is warranted. As we mentioned above, EHRs are highly adaptable and configurable based on provider policy and practice. They support a wide variety of user roles and levels of training, and they are often only components in complex workflows across numerous other systems. These factors pose significant challenges deriving valid, standard, and generalizable usability findings for a particular EHR.

The draft EUP, on the other hand, describes a process for summative user evaluation in great detail, going so far in the body of the EUP to call out “escorting the participant to the parking area”, but fails to describe a summative evaluation process that can be generalized to produce comparable usability findings for different EHRs. We see nothing in this draft EUP that would support applying the work in the report to develop valid and reliable inter-EHR usability comparisons. Significant environmental factors, including frequent interruptions, are also important considerations and difficult to replicate in the lab environment proposed in the current draft EUP.

Returning again to Molich, he found extreme variability in his summative test measuring how many seconds it would take users to rent a car (a task far more simple and straightforward, and with far less data variability than most clinical workflows). Expert teams reported their summative findings of time on task ranging from 108 to 451 seconds, depending on the team doing the measurement, the test methodology used, and how the data was analyzed.

Nor is Molich the only investigator to document the dramatic effect of protocol and analysis technique on the reported results. A seminal study¹⁹ by Gray and Salzman reviewed the data in five prominent usability experiments and concluded,

“Unfortunately, our examination shows that small problems in the way these experiments were designed and conducted call into serious question what we thought we knew regarding the efficacy of various usability evaluation methods. If the influence of these experiments were trivial, then such small problems could be safely ignored. Unfortunately, the outcomes of these experiments have been used to justify advice to practitioners regarding their choice of usability evaluation methods.”

In one of the usability tests reviewed by Gray and Salzman, R. W. Bailey and associates performed two independent experiments on a given system: a redesign based on nine rounds of testing and a separate redesign based on heuristic review. Surprisingly, both studies measured an improvement in usability between the original system and a redesign where only two critical usability problems were corrected, but no further improvement was demonstrated between this redesign and any subsequent design based on further testing or expert review. They concluded:

“The study’s predominantly negative conclusions suggest that Heuristic Evaluation may name many more false alarms than hits.”

Given the lack of demonstrated improvement even after significant usability improvements, we recommend additional research focused on the overall goals of safety and adoption (including, but not limited to, usability) in order to advance these common goals.

CONCLUSION

On behalf of the 43 electronic health record companies represented by the EHR Association, we absolutely agree with and reflect in our practices the importance of EHR software usability. We also wholeheartedly agree that patient safety is an issue of vital importance to the EHR development community and to the health care professionals and patients who use and depend on our products. We applaud NIST for its attention to these concerns.

We have identified several significant areas of concern with regards to the NIST proposal:

1. Implementation of the draft EUP is unlikely to provide substantial improvements over current vendor practices in evaluating and enhancing EHR safety and usability.
2. Mandated and prescriptive standards for EHR functionality and aesthetics based on this EUP or similar approaches will impair the innovation of future enhancements.
3. The draft EUP methods will not accurately capture the complexity of experienced health care professional users employing adaptable EHR systems in a dynamic clinical environment. In particular, the strategies of expert review and summative evaluation have documented weaknesses.

We recommend that NIST take the following steps to enhance its strategy for evaluating electronic health record safety and usability:

1. Undertake a thorough reassessment of the proposed evaluation methodologies and include a discussion of cost-benefit analyses in future strategies.

2. Engage all stakeholders in ongoing dialogue to provide education and guidance on understanding and improving patient outcomes and system adoption.

We thank NIST and the ONC for this opportunity to comment.

Sincerely,



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Epic



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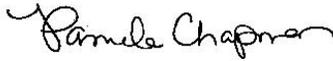
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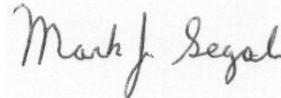
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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himssehra.org>.

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