MedStar Health
National Center for
Human Factors in Healthcare

Written Testimony Provided to the Joint Health Information Technology Policy and Standards Committee Certified Technology Comparison Task Force

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Raj Ratwani, PhD is the Scientific Director of MedStar Health's National Center for Human Factors in Healthcare and an Assistant Professor of Emergency Medicine at Georgetown University School of Medicine. Dr. Ratwani is an expert in health information technology (health IT) with a focus on usability and safety. His overarching goal is to improve the usability and safety of health IT for clinicians and patients. He has conducted studies to investigate the impact of health IT on frontline clinicians to examine how workflow processes change and to quantify the types of safety hazards that arise. He has studied health IT policy to understand, (1) how these policies impact consumers and vendors, (2) vendor adherence to health IT policy, and (3) how policies can be optimized to benefit stakeholders.

Dr. Ratwani holds a B.S in cognitive science from the University of California, San Diego. He earned a M.A. and PhD in psychology, focusing on human factors/applied cognition, from George Mason University and was a National Research Council post-doctoral fellow at the Naval Research Laboratory. His research has been funded by the Agency for Health Care Research and Quality (AHRQ), NIH, the Office of the National Coordinator, and several Foundations. He has published numerous articles in nationally recognized journals, has given several presentations on health information technology and human factors, and has testified to the Senate on health IT usability.

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Written Testimony

Electronic health records (EHRs) have been widely adopted and hold tremendous promise for improving patient care. Currently, the usability of EHRs remains a point of dissatisfaction for many clinicians and suboptimal usability presents safety hazards that can lead to patient harm. To optimize the usability of EHRs it will be important to develop effective comparison tools that allow stakeholders to easily understand the usability of different EHR products. With greater tools to demonstrate EHR usability, purchasers and other health information technology (health IT) stakeholders can be more informed about the usability of different products through a standardized process.

When considering comparison tools focused on the usability of EHRs the design, development, certification, and frontline use of EHRs must be examined. A better understanding of the rigor of the user centered design processes used by each vendor will give new insights into the vendors' investment in developing a product that improves the quality, efficiency, and safety of the clinical care process. However, focusing on process alone is not sufficient for providing purchasers and other stakeholders with a complete understanding of EHR usability. Formal usability assessments of EHR products should be conducted on the product that is used by frontline clinicians to provide objective data to inform purchase decisions.

Currently, formal summative usability testing is conducted by the EHR vendor, however, there are inconsistencies in how this testing is conducted and reported. Further, during the implementation process the EHR product is often customized and can be significantly different from the product tested by the vendor. Consequently, any comparison tool that is focused on products that are not yet implemented will not fully capture the usability of EHR products as experienced by frontline users.

The National Center for Human Factors in Healthcare has extensively studied health information technology (health IT) policies, reviewed existing literature, and reviewed EHR vendor certification reports to make recommendations for developing EHR comparison tools focused on improving usability transparency.[1–4] Divided into three sections, the first section describes barriers to developing effective comparison tools based on vendor usability processes and summative testing information that is reported as part of the safety enhanced design requirements. The second section describes the importance of objective assessments of the

actual usability of EHR products and describes challenges to conducting theses assessments. The third section describes other important aspects related to safety, such as implementation and surveillance, which the comparison task force may consider for comparison.

1. Barriers to Comparing the Usability Processes and Summative Testing Results of EHR Vendor Products from Safety Enhanced Design Reports

Our team conducted an extensive analysis of the safety enhanced design reports provided to the ONC by EHR vendors and found that the current safety enhanced design requirements, methods of reporting, and reporting format do not sufficiently support the development of adequate comparison tools. Our team developed and published a comparison framework based on data provided by the vendors, as part of the required safety enhanced design reports. Drs. Ratwani and Hettinger lead the development of this framework (found at www.healthITusability.org) which led to the discovery of several critical barriers. Each barrier is presented here, followed by our teams' recommendation.

1.1 *Required or necessary components are often omitted*. Current certification requirements stipulate that vendors must name or describe the user centered design (UCD) process utilized during the design and development of the EHR, with a focus on several specified functions.[5] This statement must either acknowledge that the vendor adhered to an industry recognized standard or provide a description of the vendor's own process. Our research team reviewed over 50 different statements from many of the most common vendor products and many of the statements from vendors did not provide enough detail for any meaningful comparison of the rigor by which the vendor utilized a UCD process.[6] The statement does allow one to see which process was used, but not how effectively the process was used.

Recommendation: Consider having vendors provide the byproducts of their UCD process as evidence of the process. These details might include descriptions of formative testing processes, types of subject matter experts used, number of subject matter experts as well as other details that are a by-product of a well designed UCD process. This information would facilitate comparison of the rigor of UCD processes across vendors and should not be burdensome to vendors since they are already utilizing a UCD process.

1.2 *Vendors report varying information about the methodology utilized in their summative usability tests*. The safety enhanced design requirements stipulate specific information that vendors must report about their summative usability testing. However, our team found considerable variability in the reporting of this information.[6] Many vendors do not provide complete details on the background and experience of participants, the testing conditions, and the details of the test procedures. Without this information it is difficult to make meaningful comparisons about the summative test results.

Recommendation: The reporting requirements should be clearly stipulated to ensure the certification bodies are aware of the requirements when reviewing vendor safety enhanced design reports. There should be closer oversight of the certification bodies, and require appropriate expertise among the reviewers.

1.3 *There is a lack of standard use cases to allow for direct comparisons of vendor results*. Currently, there are no standard use cases required for EHR vendors to use in their summative testing, and this has caused uncertainty among vendors during the testing process. The vendor safety enhanced design reports demonstrate inconsistent reporting: Some vendors provide no details on the use cases that were used, others provide short one sentence descriptions, and others provide detailed use cases. With tremendous variability in use cases and no standard use cases utilized by all vendors the results of the summative usability tests cannot be directly compared across vendors.

Recommendation: Standard use cases should be provided for vendors to use, in addition to their own use cases, when conducting summative usability testing. Properly designed use cases must include clinically relevant material with engaging scenarios that approximate real world use of the EHR. Cases that do not meet these standards are unlikely to show challenges in the EHR interface or discover potential safety issues.

2. Barriers to Assessing the Usability EHR Products

Currently, there are no independent comparison tools that provide detailed information on the objective usability assessment of EHR products from a performance perspective with quantitative outcome measures such as time on task and error rates. There are several different survey based comparison tools from American EHR, KLAS, and others. These tools provide an

important subjective assessment, but must be complimented by objective assessments of the products in order to provide an objective measure for comparison. Formal usability assessments of the EHR products, evaluated by usability experts, are necessary.

The current summative usability assessments that are conducted by EHR vendors are performed on products that have not yet undergone the implementation and customization process. During the implementation phase the EHR product is often extensively customized and many aspects of the product change from the certified technology that was tested by the vendor, and this creates potentially large safety hazards. Thus, it will be important to asses at least a subset of the implemented product as well as the certified products that have not yet been implemented. There are several barriers to the formal assessment of EHR products that must be overcome in order to bring this critical information to health IT stakeholders.

2.1. *There is a lack of access to EHR products*. To formally evaluate EHR products (implemented or not) requires access to the products by usability experts. Currently, there are no easy methods for researchers to access these products to perform formal evaluations. In some cases, EHR vendors may prevent the sharing of information about their product by prohibiting screenshots or publication about hazards which have been identified.

Recommendation: Reduce barriers to independent formal assessments of EHR products so that objective metrics can be used to measure usability and compliment the survey based techniques.

2.2. *There is no organizing body to coordinate the usability assessment of implemented EHR products*. Assessing a subset or all of the certified health information technology products would require an organizing body to coordinate the evaluation process and oversee the rigor of the evaluation. Currently, there is no organizing body with the means to provide this service.

Recommendation: Facilitate the formal assessment of EHR products for effective comparison.

2.3. *There is no established methodology for testing implemented EHR products*. To allow for the effective comparison of the usability of EHR products the formal evaluations must have a consistent methodology including a core set of standard use cases that are utilized during the

usability testing. A standard testing methodology would allow for more meaningful comparisons across vendor products.

Recommendation: Establish testing methodologies that can be applied consistently across vendor products when conducting usability testing.

3. Other Aspects of EHRs Important for Comparison

3.1. *Safety Surveillance Information*: Identifying safety hazards related to EHR products (and effective mitigations) and allowing consumers to compare this information across vendors would improve transparency and usability. Currently, there are no methods to support this type of comparison and as a result the same health IT facilitated errors are repeated over and over again at facilities that are forced to learn from their own errors instead of sharing knowledge across systems and EHR products.

Recommendation: Develop a method for providers to share safety related health IT events in a safe and non litigious manner.

3.2. *Implementation Support*: The implementation process significantly impacts the usability and safety of the EHR product that frontline users interact with. Otherwise well designed EHRs can be customized in ways that result in a final installed product that is suboptimal in terms of usability and safety. Most vendors provide a tremendous amount of guidance during the implementation process and some bring their historical knowledge that has accrued over hundreds of implementations while others do not. Successful implementation will be shaped by the amount of guidance provided by vendors. Currently there are few resources to compare the implementation process across EHR vendors.

Recommendation: Develop and test a method to compare the implementation support provided by different EHR vendors of certified health technology.

Conclusions

In summary, there is a tremendous need to not only compare EHR usability processes across vendors, but also usability of EHR products across implementations. The attached recommendations seek to allow for this comparison across EHR products through all phases of product development, implementation and use in the clinical environment. It is our belief that only through the tight integration of usability principles in each of these phases that EHRs will fulfill their full potential of bringing greater safety and efficiency to our healthcare system.

Summary of Recommendations to Facilitate EHR Comparison

1. **Design/Development Phase**
   - 1.1. Consider having vendors provide evidence of their UCD processes to facilitate the comparison UCD rigor across vendors.
   - 1.2. Clearer safety enhanced design certification requirements are needed with oversight of the accrediting bodies to ensure appropriate expertise.
   - 1.3. Standard and appropriate use cases should be provided for vendors.
2. **Implementation Phase**
   - 2.1. Reduce barriers to independent formal assessments of EHR products so that objective metrics can be used to measure usability and compliment the survey based techniques.
   - 2.2. Facilitate the formal assessment of EHR products for effective comparison.
   - 2.3. Establish a testing methodology that can be applied consistently across vendor products when conducting usability testing.
3. **Surveillance Phase**
   - 3.1. Develop a method for providers to share safety related health IT events in a safe and non litigious manner.
   - 3.2. Develop and test a method to compare the implementation support provided by different EHR vendors of certified health technology.

About MedStar Health

MedStar Health is an academic health system which includes 10-hospitals, 20 diversified healthcare organizations, 250 outpatient sites, an air and ground EMS provider, and a population health insurance provider. MedStar Health is the largest healthcare provider in the Baltimore and Washington, DC region, and is a microcosm of the American healthcare system, representing the broadest possible spectrum of hospitals and patient populations. The ten hospitals include large tertiary care/academic medical center hospitals, small community hospitals, and a university hospital (MedStar Georgetown University Hospital); inner city, suburban, and rural hospitals; teaching hospitals and hospitals staffed only by private attending physicians; and large, medium, and small-sized hospitals. MedStar Health has $5 billion annual net operating revenues, and our resources total 3,300 licensed beds, 5,600 affiliated physicians, 166,000 annual inpatient admissions, and 2 million annual outpatient visits. MedStar's six teaching hospitals, including MedStar Georgetown University Hospital, have a total of 1100 resident physicians (the 11th largest GME organization in the US).

National Center for Human Factors in Healthcare's mission is to apply human factors research methods and concepts to the medical domain, with a focus on information technology, device design, and systems design. The Center is involved in patient safety, risk management, and systems engineering research sponsored by National Institutes for Health / National Institute of Biomedical Imaging and Bioengineering, *Agency for Healthcare Research and Quality* , Latham Foundation, Robert Wood Johnson Foundation, Emergency Medicine Foundation, American Diabetes Association, American Society for Healthcare Risk Management, Office of the National Coordinator, and other sources. With 20 people including PhD human factors scientists, clinical researchers, usability specialists, physicians, nurses, and support staff, the Center is the largest hospital based human factors engineering center in the US. The National Center for Human Factors in Healthcare is part of the MedStar Institute for Innovation.

The MedStar Institute for Innovation is a system-wide initiative to foster and catalyze innovation at MedStar Health, and is lead by MedStar Health's Chief Innovation Officer Mark Smith, MD, who also serves as Professor and Chair of Emergency Medicine at the Georgetown University School of Medicine. Dr. Smith is the co-creator of MedStar Health's innovative Azzyxi clinical information system which is considered to be a highly innovative health IT application, as evidenced by its purchase by Microsoft, Inc.

MedStar Health Research Institute (MHRI) is the research center of MedStar Health, and provides a robust research support infrastructure, including a centralized IRB, grants management, biostatisticians, and other research support services. MHRI is in the top 20% of all U.S. institutions in total funding received from the National Institutes of Health, with over $35M in sponsored work per year. There currently are over 500 externally funded projects, from 175 principal investigators, and 325 MHRI employees in support roles.

References

1. Benda NC, Meadors ML, Hettinger AZ, Ratwani RM. Emergency Physician Task Switching Increases With the Introduction of a Commercial Electronic Health Record. *Ann Emerg Med*. September 2015. http://www.sciencedirect.com/science/article/pii/S019606441501104X. Accessed October 13, 2015.

2. Ratwani R, Fairbanks R, Hettinger A, Benda N. EHR Vendor Usability Practices. In: Zhang J, Walji M, eds. *Health Better EHR: Usability, Workflow & Cognitive Support in Electronic Health Records*. Vol ; 2014.

3. Meadors M, Benda N, Hettinger A, Ratwani R. Going Live:Implementing an Electronic Health Record System in the Emergency Department. In: *Proceedings of the International Symposium of Human Factors and Ergonomics in Healthcare*. Vol ; 2014:44-49.

4. Ratwani RM, Fairbanks RJ, Hettinger AZ, Benda N. Electronic Health Record Usability: Analysis of the User Centered Design Processes of Eleven Electronic Health Record Vendors. *J Am Med Informatics Assoc*. 2015;(In Press).

5. Department of Health and Human Services. *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition*. Vol 77. 2012.

6. RM R, NC B, Hettinger A, RJ F. ELectronic health record vendor adherence to usability certification requirements and testing standards. *JAMA*. 2015;314(10):1070-1071. http://dx.doi.org/10.1001/jama.2015.8372.