MedStar Health
National Center for
Human Factors in Healthcare

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"Achieving the Promise of Health Information Technology Improving Care Through Patient Access to Their Records"
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Opening Remarks

Good morning Chairman Alexander, Ranking Member Murray and distinguished members of the committee. Thank you for the opportunity to speak with you today.

I am Raj Ratwani, Scientific Director of MedStar Health's National Center for Human Factors in Healthcare, part of the MedStar Institute for Innovation, and Assistant Professor of Emergency Medicine at Georgetown University. Our Center benefits from a unique collaboration between clinicians and human factors experts who focus on applying the science of human factors to the nation's most challenging healthcare issues. One of those issues is patient access to health information.

Patients must have easy access to their health information to improve health outcomes, facilitate patient and family engagement in care, and to reduce safety risks. Critically, this information must be presented in a manner that is both understandable and useful. The digitization of health information offers a tremendous opportunity to improve care, however, **the usability of electronic health records, patient portals, and personal health records remains subpar and is a significant challenge that we must overcome immediately**. While some have suggested that the low utilization rate of patient portals is from a lack of interest, we know that it is because in most cases the portals have not been designed using methods to optimize the system's responsiveness to patient needs. There is overwhelming evidence that usability of health IT systems impacts patient safety and that it is crucial to adoption and effective use. It takes a very deliberate and robust effort by specialized staff to develop health IT systems with good usability, and this fact is not always fully appreciated in the industry.

A more sophisticated approach to the design of this technology must be undertaken to realize the full potential of health IT. The application of **user-centered design,** in the development of health IT, uses established iterative design methods to develop an understanding of the characteristics of the people who use technology, what their information needs are, how they process this information, and how they will use the information to make decisions.

Other complex high risk industries invest heavily in this human factors approach, including aviation, defense, and nuclear energy. Healthcare has been slow to adopt the human factors

approach and slow to make advancements that would facilitate a more aggressive adoption of this approach to optimize the safety, usefulness, and efficiency of health IT.
A common misunderstanding is to think that usability is only about basic screen design such as font size, color, and layout, the more critical aspect of good usability is the degree to which the functionality and design of the system supports the decisions and actions that are critical to the typical needs of patients and clinicians. **Patients and clinicians are able to comprehend, reason, and gain insight from health information only when the systems work in concert with the way patients and clinicians think.**

Three critical factors that have a tremendous impact on patient use of health IT are: Access, Functionality, and Information Quality. All three are directly impacted by usability. Without robust user-centered design processes that are led by trained professionals, naive, clunky systems are developed that don't serve patients needs, and are therefore underutilized by the public.

The first critical factor is Access. Patients should be able to easily access all of their health information, securely, and in one place. Interoperability is crucial for patient access.

The second is Functionality. The information and capabilities of the system must be useful for the patient. The design of system capabilities, such as patient-provider communication, should be intelligently integrated with the workflow processes of the clinician so that the clinicians are able to support the patient in a timely manner.

The third is Quality of information. Information must be accurate and meaningful to the patient, presented in a manner that can be easily understood, and that will help them gain insights. This requires an in-depth understanding of how patients use their health information and recognition that a diverse population with varying levels of health literacy may use this technology.

- For example, when a patient references their medication list in today's typical patient portal, the medications are listed in clinical jargon, and this fails to effectively communicate what the patient needs to know—which medicines to take at what time and for what conditions.

These examples are a brief snapshot of the usability challenges that require our immediate attention. There are well-established methods for developing usable software systems, and as a whole the health IT industry has not yet embraced them.

It is important to note that this is not just a theory. User-centered design is an established standard in other high-risk industries, and regulatory bodies in these industries closely inspect the usability processes used in development before any technology is implemented. No technology enters the cockpit of an airplane before the usability is inspected and found to meet detailed standards. The federal government has initiated efforts to mirror this in health IT, with the implementation of what the ONC has termed Safety Enhanced Design. However, as described in studies from our Center, few vendors in the health IT industry have demonstrated evidence that they have embraced this approach. This represents a huge opportunity.

To make advancements we must (1) refocus certification requirements to promote true usability in the design, development and implementation of health IT, with an understanding of industry constraints, (2) increase transparency around usability, and (3) spur competition in the marketplace by making it easier for new vendors to develop products.

Thank you.

Written Testimony

The National Center for Human Factors in Healthcare has conducted research into both provider and vendor environments, reviewed existing literature, and analyzed current policies to make the following recommendations for improving the usability of electronic health records (EHR), patient portals and personal health records:

1. Spur innovation in EHRs, patient portals and PHRs to foster improved usability.

a. Many new vendors want to enter the marketplace of EHRs, patient portals and PHRs but are not able to because of the daunting certification requirements. This is inhibiting innovation and is limiting the ability for usability to be driven by a competitive market.

b. Poor interoperability and the lack of application program interfaces (APIs) is limiting the sharing of health information and preventing new vendors from entering the marketplace since they are not able to access existing patient health information for their products.

Recommendation: Reduce the barriers for new vendors to enter the marketplace so that vendors with better user-centered design (UCD) processes, which typically result in designs with better usability can innovative and bring new products to the market. This will shift the paradigm to a market that competes on usability.

2. Refocus Safety Enhanced Design (SED) certification requirements.

Currently the Office of the National Coordinator (ONC) has certification requirements in place to promote EHR vendor usability in eight high risk EHR capabilities. The requirements stipulate that vendors must attest to a user-centered design process and conduct formal summative usability testing on the final product. Our research and analysis suggests[1,2]:

a. Many vendors are not adhering to the certification requirements and are not following industry testing standards, yet their products are still being certified.

b. The current summative testing requirements occur at the end of development of the product and any design flaws that are identified are unlikely to be addressed since the

product has already been fully developed. Consequently, this requirement is unlikely to be effective at improving the usability of that product being released.

c. The summative testing requirement is overly burdensome for some vendors, particularly if a rigorous UCD process is employed with formative usability testing (i.e., iterative usability testing during the development phase). Over 90% of the design challenges are likely to be identified with the UCD process and formative testing before the summative testing stage. Requiring summative usability testing for vendors that have a rigorous UCD process can result in an unnecessary expenditure of limited vendor usability resources and may detract from the design of other aspects of the EHR. Our ONC-funded evaluation of a cross section of vendors and their UCD processes found that approximately 1/3 of vendors might meet this condition.[1,2]

d. EHRs undergo a customization process during implementation at each provider sight which often involves extensive changes, resulting in an EHR product that is vastly different from the product that was tested during summative usability testing. Consequently, the testing results may no longer be valid for the customized product.

Recommendation: It is our recommendation that the certification requirements be modified to provide two certification avenues: The first would require the vendor to show evidence of their UCD process and formative testing, which vendors should already be conducting given current certification standards which require vendors to attest to employing a UCD process. Vendors that are able to demonstrate a rigorous UCD process should be exempt from having to conduct summative usability testing. The second avenue would require that the final product undergo summative usability testing with no safety-critical use errors identified. For the vendors that do conduct summative usability testing, the ONC certification requirements should be more explicit about testing methodology requirements such as number of participants and background of participants.

EHR vendors should be required to demonstrate evidence of their UCD process beyond the eight capabilities that are currently stipulated by the ONC so that broader usability coverage of the EHR products can be captured.

3. Encourage more rigorous usability practices for patient portals and PHRs.

A. There is little patient involvement in the design and development of patient portals and PHRs. Patients are the intended users of this technology and without involvement during design and development it is difficult to develop a product that meets the needs of patients in a meaningful way.

B. There are currently no usability certification requirements for patient portals. In the existing health information technology literature there are studies that identify the information needs of patients and recommendations for improving usability and usefulness.[3-8]

Recommendation: Leverage our existing knowledge on how patients think about their health information to develop guidelines that can promote the usability of patient portals and personal health records. Invest in applied research to expand the knowledge base around patient health information needs to improve future products. Consider requiring vendors to demonstrate evidence of a user-centered design process in the development and optimization of their patient portal products.

4. Increase transparency of vendor usability.

a. The Safety Enhanced Design (SED) certification reports for each vendor product that is certified must be made publically available on the ONC's consumer health product list website. However, the information is difficult to access, difficult to digest, and not conducive for non-usability experts to consume. The format of the reports prevents direct comparison across different EHR products.

b. There are few, if any, formal usability evaluations of EHR products conducted by independent organizations. Consequently, purchasers cannot directly compare products based on metrics that measure the usability of the actual product.

Recommendation: The SED certification reports should be adjusted to present information in a standard format that can be easily consumed by all audiences to allow more informed purchasing decisions. Methods should be developed to foster independent usability evaluations of EHR products so that purchasers have more usability insight prior to purchase.

5. Improve the vendor access to usability resources.

A good UCD process includes detailed data on the cognitive tasks, environments, and information needs of all potential user groups in different environments. Studies to generate this knowledge are resource intensive. Our analysis has demonstrated that many vendors do not have the necessary resources to employ a sophisticated UCD process and to conduct appropriate formative and summative usability testing.[1,2] This includes access to rigorous clinical use cases, clinician participants, and knowledge of how to conduct UCD given rigorous software development timelines.

Recommendation: Develop standard testing use cases for all vendors to utilize. Incentives may need to be developed for clinicians to engage with EHR vendors during the UCD process. In addition, detailed best practices around UCD and usability testing should be widely disseminated to all EHR vendors.

MedStar Researchers Find Large Number of EHRs Do Not Meet Usability Standards

A report by MedStar Health's National Center for Human Factors in Healthcare finds that a significant percentage of electronic health record (EHR) vendors failed to meet federally mandated user-centered design requirements and did not conform to usability testing standards for their EHRs, yet their products were certified as having met all the requirements of the government's meaningful use program for EHRs. The findings, reported in the September 8, 2015, issue of the *Journal of the American Medical Association*, are based on publicly available information supplied by the EHR vendors to the Office of the National Coordinator for Health Information Technology (ONC) between April 2013 and November 2014.

The investigators studied official reports submitted by the EHR vendors to the federal government attesting to the user-centered design (UCD) process they had followed to develop their products and providing results of usability testing they had conducted. Specifically, the study focuses on the computerized order entry function, since it is primarily used by clinicians and presents significant safety hazards when not designed well. The authors conclude that enforcement of existing standards and oversight of usability processes are necessary to meet usability and safety goals for the next generation of EHRs.

The MedStar Health study found that among the problems were failure to adequately test the usability of an EHR and failure to document that an EHR was developed with a UCD process. Among the specific findings:

- 63 percent of the vendors whose reported results were analyzed failed to enroll the recommended number of users—at least 15— in tests on their EHRs.
- 17 percent used no physician participants in testing systems intended for physician use.
- 12 percent of reports lacked enough detail to determine whether physicians participated.
- 34 percent of the vendors did not state, as required, the UCD process they had followed.

Researchers compiled their study by examining available reports from the top 50 EHR vendors, as measured by the number of meaningful use attestations made between April 1, 2013, and November 30, 2014.

Ratwani RM, Benda NC, Hettinger A, Fairbanks RJ. Electronic Health Record Vendor Adherence to Usability Certification Requirements and Testing Standards. *JAMA.*2015;314(10):1070-1071. doi:10.1001/jama.2015.8372.

MedStar Researchers Show Tremendous Variability in EHR Vendor Usability Practices

A report by MedStar Health's National Center for Human Factors in Healthcare finds that many EHR vendors do not have a rigorous user-centered design process in place. The findings, reported in the June, 2015 issue of the *Journal of the American Medical Informatics Association*, are based the research team visiting 11 different EHR vendors to better understand their usability processes and barriers to usability.

The MedStar study found that one third of vendors have a misunderstanding of usability and user-centered design, one third of vendors have a basic user centered design process in place and only one third of the vendors have a sophisticated process. Among the specific findings:

- Some of the largest EHR vendors (total revenue over $1b) do not employ usability staff and do not have rigorous user-centered design processes in place.
- Many vendors only have a basic user-centered design process in place and require additional knowledge and resources to improve their process.
- The vendors that do have a rigorous process in place have developed methods to integrate user-centered design with their aggressive software development timelines.

The research identifies targeted ways to improve the usability processes of EHR vendors including: sharing of best practices, improving vendor access to clinicians to better inform their products, and developing standard use cases for testing.

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. 2015 Jun 6. doi: 10.1093/jamia/ocv050. PMID: 26049532

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.

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