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**Toward a Shared Approach for Ensuring
Patient Safety with Enhanced Workflow
Design for Electronic Health Records**
Summary of the Workshop

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Executive Summary

On April 19, 2013, 47 participants met at the Johns Hopkins Armstrong Institute for Patient Safety and Quality, Baltimore, MD, for the National Institute of Standards and Technology (NIST)-sponsored full-day workshop titled *EHR Usability and Patient Safety Roundtable: Supporting Patient Safety Through EHR Design*. In addition to representatives from the host organizations, there were seventeen representatives from EHR systems developers who were invited through Electronic Health Record Association (EHRA). The remainder was clinical, human factors, information technology, and clinical safety experts. The goal of the workshop was to discuss and identify the common challenges and shared aspirations for designing EHRs that better support complex clinical workflows in order to improve usability, patient safety, and quality of care.

EHRs have great potential to improve health care quality, enhance patient safety, streamline administrative processes, and more easily support population-based quality improvement and research. However, the integration of EHR systems into clinical workflows at fast rates has also introduced some unintended consequences and adverse events. [1,2,3,4]

Clinical workflows are complex and non-linear, often involving many different professionals, paraprofessionals, and stakeholders with associated interdependencies. The EHR design is critical to support these complex interactions contained within. [5] Workflow is also a multidimensional phenomenon that can be described differently based on the perspective taken (e.g., clinician versus patient). [6,7]

At the workshop, common ground on challenges and aspirations were identified by the representatives from EHR developers, EHR users, academics and government to improve patient safety, usability and human factors regarding workflows in the use of EHRs. Achieving these objectives for common ground is necessary to enhance safe and effective care for all patients and increase the rate of adoption of electronic health records in the United States.

Common current and potential challenges in EHR usability and patient safety included: 1) high variation in EHR-related workflow at the level of institutions, units within an institution, and the individual clinicians; 2) provider (user) requests/demands involving customization and its positive and negative effects on usability and patient safety; and 3) challenges in setting user requirements and executing usability and task analyses due to a lack of consensus among developers and providers concerning primary purposes of the EHR products.

Shared aspirations among stakeholders for improving EHRs and patient safety included: 1) modeling, understanding, and reducing the sources of variability; 2) providing guidance to end users regarding best practices for customization based on their specific workflows; 3) reducing uncertainty stemming from external requirements; and 4) improving EHRs to better match the different workflows of diverse users. There was interest within the group in adapting a voluntary collaborative model from other

industries, such as, for example, the automotive industry that was successful in integrating standardized safety features into design.

The report that follows includes:

- Overview
- Structure of the workshop
- Open discussion
- Next steps
- Summary
- 2 appendices: The workshop agenda and the acronyms used throughout the report

Keywords: Electronic Health Record (EHR), patient safety, usability, workflow, electronic health record design, health information technologies, human factors, medical informatics, workarounds

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1 Overview

1.1 Introduction

On April 19, 2013, 47 participants met at the Johns Hopkins Armstrong Institute for Patient Safety and Quality, Baltimore, MD, for the National Institute of Standards and Technology (NIST)-sponsored full-day workshop titled *EHR Usability and Patient Safety Roundtable: Supporting Patient Safety Through EHR Design*. In addition to representatives from the host organizations, there were seventeen representatives from EHR systems developers who were invited through Electronic Health Record Association (EHRA). The remainder was clinical, human factors, information technology, and clinical safety experts. The goal of the workshop was to discuss and identify the common challenges and shared aspirations for designing EHRs that better support complex clinical workflows in order to improve usability, patient safety and quality of care.

1.2 Background

EHRs have great potential to facilitate clinicians' work, improve health care quality, enhance patient safety, streamline administrative processes, and more easily support population-based quality improvement and research. However, the integration of EHR systems into clinical workflows at fast rates has also introduced some potential unintended consequences. [1,2,3,4]. EHR workflows have to be designed to reflect clinical workflows and the end user needs. Not all tasks in a workflow involve electronics/computers (e.g., visual examination of patient by physician). Clinical workflows consist of a set of tasks grouped into processes and the set of people or resources needed to accomplish those tasks to achieve a specified goal. For example, there exists a link between EHR implementation and an increase in wait times for patients in an emergency department, suggesting challenges with EHR workflow integration in a dynamic clinical context. [5]

If EHRs are to provide optimum user performance and enhance patient safety, they must be designed based on the realities of clinical workflow in which they will be used. [6,9] For these reasons, the Usability Task Force convened by the American Medical Informatics Association (AMIA) Board published a position paper in Journal of the American Medical Informatics Association (JAMIA). This position paper included recommendations for NIST, in collaboration with the Office of the National Coordinator of Health Information Technology (ONC), to "perform formal usability assessments on patient-safety sensitive EHR functionalities." [10]

The discussions at the workshop were aimed at determining issues among the stakeholders on common challenges and shared aspirations to support more usable, more efficient, and "safer and customized" EHR systems to support clinical workflows. This report summarizes the main discussion points at this meeting and the suggested necessary future steps to achieve safer and more effective care with the meaningful use of EHRs.

Clinical workflows are complex and non-linear, often involving many different professionals, paraprofessionals and stakeholders with associated interdependencies. The EHR design is critical to support the complex interactions contained within. [5] Workflow is also a multidimensional phenomenon that can be described differently based on the perspective taken (clinician vs. patient). [6,7] Moreover, well-established common workflow features to guide the developers in the design of the EHRs do not currently exist. [11]

2 Structure of the Workshop

The workshop is summarized in four main sections: welcome remarks, short talks, open discussion, and next steps. Please refer to Appendix A: Agenda for details of the workshop presentations. The presentations of the day are available at the NIST Usability website <http://www.nist.gov/healthcare/usability/ehr-usability-and-patient-safety-roundtable.cfm> The structure of the day was as follows:

2.1 Welcoming remarks by NIST

2.2 Six short presentations

As part of the morning and early afternoon sessions, there were several short presentations divided into three panels. The panel topics were:

- Patient Safety: Past, Present, and Future
- The ONC Perspective on Patient Safety and Usability
- NIST, EHRs & Patient Safety

Each panel session ended with a short question and answer session.

2.3 Open discussion

Two general discussions were held as part of the workshop for a total of approximately two and a half hours. The discussions allowed EHR developers, hosts and other experts to share opinions and information on the definition of EHR workflow, perceived and actual best practices, common challenges, shared aspirations, and potential and current solutions on making EHRs safer for patients and more usable for clinicians.

From the discussions, three themes with common challenges and shared aspirations for improving workflow design of EHRs were identified with the common consensus revolving around EHR features that may potentially impact patient safety. This is summarized in Section 4.

2.4 Next steps discussion with a short presentation

The final discussion of the day was led by the MedStar National Center for Human Factors in Healthcare representative. This section summarizes one of the examples for the best practices from the auto industry, and describes the common aspirations of the HIT community.

2.5 Review and summary

The workshop review and summary was wrapped up by NIST.

3 Open Discussion

During the discussion sessions, three important themes clearly emerged, along with several major issues and challenges.

3.1 Theme #1: Variations in workflow-related practice among developers and clinicians:

- a) Variability in design provides opportunity for innovation and enhanced efficiency. However, when core functionality is implemented inconsistently, the resulting unpredictability causes uncertainty for the user.

This can be observed in radically different user interfaces and interactivity levels (levels of text-based vs. direct input interaction, for example) for EHR applications with similar functionality, levels of training offered to users by the developers for their products, etc. As a result of these multiple factors there is inconsistency in EHR design for common clinical workflows. Frequently, developers are applying anecdotally driven or determined from non-evidence-based decisions and that may result in a fragmented approach to human factors and usability concerns taken by different companies, especially in relation to their workflow support.

One potential approach to this variation is to impose a culture of simplicity, which can be difficult to achieve due to the fact that clinical workflows are complex, non-linear, and involve many stakeholders with varying goals and skill levels. An alternative potential solution is to have discussions on variability of workflows and methods for bringing the best practices to patient safety in these dynamic and unpredictable variations in the environment. EHR designs with strong patient safety emphasis and clearly defined user requirements can help developers overcome the related design and implementation challenges.

- b) The variability among EHR developers may also occur in the context of testing. Generating and standardizing a list of EHR functionalities with explanation of terms for testing can lead to more confident and productive information exchanges.
- c) Given the complexities of clinical workflows and the amount of effort needed to identify potential variability across organizations and users, no one single organization can identify all sources of variability. Instead, each organization, including EHR developers, should work in collaboration to understand the sources and underlying factors of variability. Systematic methods and central repositories that store and update workplace-induced design requirements (so that each individual developer does not need to “reinvent the wheel” every time) and collaboration for patient safety can be part of the solution. Each EHR developer

can then use this information as a guide to produce designs with necessary flexibility and defined level of customization to compensate for these factors.

- d) A related challenge is the fact that technologies in EHR are used by diverse users, in various settings with different clinical roles and a variety of specialties. Thus, it is difficult to compensate for all of the different users' needs and expectations within one system. With many key players in clinical workflows, user needs, requirements and expectations from Health Information Technology (HIT) components can be conflicting and/or confounding. Taking workflow-related factors carefully into consideration during EHR design, as well as integrating safe customization whenever possible, are indicated as potential solutions in producing systems with the smallest number of conflicts.
- e) In relation to the items covering variability, a plan for the long run, rather than quick fixes to issues, is needed. Long-term solutions, built on evidence-based research and defined "usefulness and usability principles" have the potential to prevent harms. Also, by embracing the user experience best practices and the user-centered design process, agencies save money in the long-term and increase productivity and efficiency with usable systems. [12]
- f) There is variation in the levels of understanding of workflow among/within hospitals as well as among caregivers. Workflows can be very mature formal processes in hospitals, but they might not be well-established or formally documented across the many functions they interact with (such as writing a prescription). Even with well-established workflows, it may be difficult to translate the EHR functions properly into the workflows. Users may find out that things are missing, but only after they migrate to a new system. For example, acute care institutions can sometimes be described as having micro cultures – that is each "unit" may have a different culture and norm on their workflows and the role of EHRs within the workflows.
- g) Unlike in other industries, HIT users have a wide variety of clinical and technical backgrounds. An immediate solution to this challenge is difficult to produce, except for possibly providing safe customization in design, as indicated earlier.
- h) The next logical question is how to ensure patient safety by standardization and when to allow additional customization given the high variability in clinical workflows.

3.2 Theme #2: Standardization versus customization:

- a) Standardization can be applied to the design of EHR, implementation, employee training and many other areas. However, workflows are highly complex even within the same hospital, and sometimes within the same unit. Standardization is therefore difficult for the varying needs of clinical workflows. Customization is also a problematic issue. Providers would like to have it, as tailoring systems to

user needs can result in productivity gains and improved levels of satisfaction. Yet it is counter-to standardization, and can be excessively expensive to do for developers, with user needs varying across the board. Some developers, therefore, do not support customization of their EHR products. Safety risks could be a direct or indirect result of customization as well. EHR customization and configuration is one of the 9 high-risk areas that relate to patient safety issues that can arise from the use of the EHR and proactive assessment of risks and vulnerabilities can help address potential EHR-related safety hazards before harm occurs. [13]

- b) EHR developers indicated that it is difficult to know and decide where to standardize versus where to customize. Developers' desire to design efficient EHR products can conflict with providers' desire to have more control over EHR designs and functional elements. One suggestion is that systems can be optionally customizable, and/or customizable in some of their features. This kind of approach can be cost-effective while giving some providers what they want, and can have varying levels of feasibility based on the workflow complexity levels of the providers and other factors such as user motivations and knowledge to customize the system.
- c) Similarly, there may be a certain level of guidance necessary to be given to developers on the set of functions their EHRs should perform. The overall set of functions that an EHR should contain is just as critical as the usability of the system while performing its functions.
- d) One can argue that there is inadequate standardization in healthcare in general, and variations exist between and within hospitals, as well as between caregivers.
- e) On the other hand, customization could be potentially unsafe, and it is challenging to have a design process where both customization and safety are at very high levels. It will take a concerted effort on the part of developers and providers to determine how to balance safety factors and customization demands. It may have to be strictly defined what Graphic User Interface (GUI) components and functions can be customized by the users or providers and what customization should be restricted. Further research is necessary to determine what features should be customizable to support safe customization and flexibility.

3.3 Theme #3: The dynamic nature of clinical workflows:

- a) Clinical workflows change over time. Designing systems that can compensate for changing workflows is difficult and it can therefore be suggested that developers build long-term relationships with providers to better understand the needs and potential changes over time, designing accordingly.
- b) EHR systems should be reactive to challenges and changes rather than proactive. When workflows change, expand, or get combined, time is needed for the

corresponding designs to catch up. EHR designs take time to compensate for these changes and challenges, and in a lot of cases do not compensate at all.

3.4 Other Issues:

- a) Trust issues and cultural resistance to change are other major factors that may make EHR design and implementation difficult and cumbersome. User trust can be gained over long periods of time, and cultural changes can happen with long-term developer-user relationships and collaborations.
- b) The HIT community should work more closely with medical representatives, such as doctors and nurses, to better define user requirements and to help developers in achieving positive end user experience. However, what metrics can be used for success concerning these types of collaborations may need to be discussed and clarified more.
- c) The Web component opens the use of EHR onto a larger platform. It can include home access of medical records by physicians and nurses. Access, security, usability and other issues need to be considered for such large-base environments, which is difficult for the broad variety of medical information and varying goals behind accessing the information.

Table 1 summarizes the challenges identified in the discussion with specific examples and shared aspirations for moving forward. The challenges identified in the discussion, in general, include: 1) high variation in workflow at the level of institutions, units within an institution, and the individual clinicians; 2) demands for customization by providers that have the potential to negatively impact usability and patient safety; and 3) complications in setting user requirements and executing task analyses due to a lack of consensus among developers and providers concerning the primary objectives of EHRs.

The shared aspirations were 1) modeling and reducing the sources of variability; 2) providing guidance to end users regarding best practices for customization to local workflows; and 3) reducing uncertainty regarding external requirements.

Table 1. Major issues and challenges discussed in the workshop and the corresponding shared aspirations

Challenges	Examples of potential negative impact on workflow and patient safety	Shared Aspirations
Variations in workflow-related practice among developers and clinicians	Inconsistent use of applications; Reduced levels of efficiency and effectiveness of processes; Financial, and sometimes life-related losses; Anecdotal, non-evidence- based solutions resulting in negative user experience; Lack of unity in understanding the different user groups; and Lack of trust in the system.	Understanding the sources of variability; Standardized functions; Plans aimed at long-term usage of EHRs; Sharing responsibility and accountability
Standardization vs. customization	Lack of safety assurance in customization; Complex workflows not being compatible with standardization techniques; Customization being counter-standardization and resulting in trade-offs; Inadequate standardization in health IT;	Presenting customizations that do not negatively impact safety and achieve optimal efficiency and effectiveness; Collaboration between developers and providers for more tailored designs
The dynamic nature of workflows	One-size-does-not-fit-all phenomenon; Highly variable users and demographics; Web-based workflows changing rapidly and often being not well understood.	Better understanding of end-user needs by defining specific user requirements and accommodating changes in workflows over time;

4 Next Steps: Borrowing from Examples of Other Industries That Successfully Integrated Safety into Design

In 1965 and 1966, public pressure grew in the United States to increase vehicle safety. In 1966, Congress created the United States (US) Department of Transportation. The National Highway Traffic Safety Administration (NHTSA) was officially established in 1970. The mission of NHTSA is to “save lives, prevent injuries and reduce economic costs due to road traffic crashes...” Some examples of its involvement in safety are noted in the use of the center high mounted safety lamp, electronic stability control on vehicles and the new car assessment program. In the early 1990's, in an era of exploding technological capability during which the potential for collision avoidance technology was changing the landscape for vehicle safety, the thought was that a consortium of auto manufacturers could be formed to conduct collaborative research to determine the appropriate metrics and measures for evaluating the safety and efficacy of collision avoidance technology. The manufacturers later thought they could leverage their data in a way that they not only believed in, but were prepared to support so that they could get vehicles to the market faster. The Crash Avoidance Metrics Partnership (CAMP) was formed in 1995 to accelerate the implementation of crash avoidance countermeasures in passenger cars to improve traffic safety. [14]

Once the consortium came into place, both CAMP and NHTSA recognized the potential of working together. By forming collaborations that included academic and independent evaluators, NHTSA and CAMP could drive the science that determined the metrics and measures for vehicle safety. Recognizing this cooperation as the fastest and most cost-effective approach to improving safety with initiatives like connected vehicle research. Today NHTSA funds as much as 65 percent of research to support new safety technologies. For auto manufacturers, they gain the non-automotive partners they need to develop cutting-edge technology. NHTSA and the Federal Highway Administration support the infrastructure requirements of collision avoidance technology that is required for new technologies such as intersection collision avoidance, once they know that the critical mass of automotive manufacturers are on target for a new safety technology release. With immense safety consequences of poor design, the safety technology would take many more years to get introduced, resulting in lost lives and lost economic benefit. CAMP is merely one example of consortia in the automotive industry. Other industries, such as aviation, have an even longer and richer history of federal/industry cooperation to satisfy common and independent motivations.

The usability and usefulness of HIT are important and necessary measures to move the potential and safety of Health IT forward. The lessons from other industries would indicate that more opportunity exists to create sweeping innovations in Health IT through consortia between Health IT vendors, federal agencies, and healthcare entities. The history of consortia in other industries indicates that even greater potential exists by widening the net to include federal and healthcare partners. One may look at consortia developed in other industries as a model for collaboration that benefits all parties involved.

Attendees expressed interest in adapting a voluntary collaborative model from other industries, such as the automotive industry, to prioritize and address patient safety concerns with developers and academic representatives. The common desire for the participants is to have common consensus on safety features, and to do this by holding voluntary meetings to harmonize the EHR industry in making a positive and lasting impact on patient safety.

5 Summary

Usability and human factors approaches in supporting EHR clinical workflows have been identified as critical factors for patient safety and other quality of care metrics.

Application of the EHR workflows and their use by multiple users and teams with varying technologies has had mixed results to date. Clinical workflows are unique due to the high stakes they involve, the high diversity of users, the specific processes and technologies, and the number of stakeholders involved (e.g., multiple EHR developers or decision makers on purchasing). In this meeting, EHR developers, government representatives, users and academicians identified common ground on challenges and aspirations to improve patient safety, usability, human factors, and customized workflows with the use of electronic health records. Achieving these objectives is necessary to provide safe and effective care to all patients and increase the rate of meaningful adoption of EHRs in the United States.

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Appendix A: Final Agenda

EHR Usability & Patient Safety Roundtable “Supporting Patient Safety through EHR Design”

April 19, 2013 - 8:30am – 4:30pm

The Johns Hopkins Armstrong Institute for Patient Safety and Quality
Room A, 4th Floor, Constellation Building, 750 E. Pratt Street,
Baltimore, MD

Agenda

- 7:30- 8:30 **Breakfast**
- 8:30 – 8:45 **Welcome and Objectives for the Day**
Lana Lowry, PhD - National Institute of Standards and Technology
- 8:45 – 9:30 **Patient Safety Past, Present and Future**
Peter Pronovost, MD, PhD – Armstrong Institute
- 9:30 – 10:00 **The ONC Perspective on Patient Safety and Usability**
Jacob Reider, MD - Director, Office of the Chief Medical Officer, ONC
David Hunt, MD, FACS - Medical Director, Health IT Adoption and Patient Safety, ONC
- 10:00-10:15 **Break**
- 10:15-11:15 **NIST, EHRs & Patient Safety**
Provider Challenges – David Brick, MD - Village Cardiology
Patient Safety – EHR Usability Framework and EUP – Emily Patterson, PhD OSU
Clinical Perspective and NIST Research – Dean Calcagni, MD – NIST
- 11:15 – 12:00 **Discussion**
Emily Patterson, PhD – Ohio State University Medical Center
- 12:00 – 1:00 **Working Lunch**
- 12:30 – 1:30 **NIST, EHRs & Patient Safety**
Emerging Provider Challenges, EHR Workflows – David Brick, MD – Village Cardiology
EHR-Workflow Integration- Ayse Gurses, PhD – Armstrong Institute
Gaining Deeper Insight into EHR Usability to Support a National Standard – Michael Wiklund, PhD - UL, LLC

1:30 – 2:30

Discussion

Emily Patterson, PhD – OSU, Ayse Gurses, PhD – Armstrong Institute

2:30 -2:45

Break

2:45 – 3:45

Next Steps Discussion

Vicki Lewis, PhD – National Center for Human Factors Engineering in Healthcare “How one industry has driven best practice and the potential for healthcare”

3:45-4:15

Meeting Review & Summary

Lana Lowry, PhD - National Institute of Standards and Technology

4:15-4:30

Closing Remarks

Armstrong Institute, ONC

Appendix B: Acronyms Used in the Report

AMIA	American Medical Informatics Association
CAMP	Crash Avoidance Metrics Partnership
EHR	Electronic Health Records
GUI	Graphic User Interface
HIT	Health Information Technology
IT	Information Technology
NHTSA	The National Highway Traffic Safety Administration
NIST	The National Institute of Standards and Technology
ONC	Office of the National Coordinator of Health Information Technology
US	United States