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# HIT Policy Committee Implementation, Usability and Safety Workgroup DRAFT Report of the November 7, 2014 Virtual Meeting

## Name of ONC Staff Liaison Present: Ellen Maker

## Meeting Attendance: (see below)

Purpose of Meeting: To hear presentations about and discuss the ONC health IT certification program

Workgroup Co-chairperson Larry Wolf began by showing slides that listed the regulations for the ONC certification programs, certification criteria for user centered design (UCD), and various resources that are easily accessible. As of September 12, UCD processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1), (2), (6) through (8), (16) and (18) through (20) and (b)(3), (4), and (9).

Alicia Morton, ONC, described the processes of the ONC HIT certification program. First, ONC issues a regulation that includes certification criteria (and associated standards) for health IT products and corresponding certification program requirements. Developers design products that, at a minimum, meet the standards and certification criteria adopted by HHS in regulation. ONC-ATLs test the products based on the standards and certification criteria adopted by HHS and issue certification to tested health IT products. They conduct surveillance and submit product information to ONC for posting on the Certified Health IT Product List (CHPL). As a result, EPs and EHs have assurances that products meet specific certification criteria and associated standards. She went on to describe the seven certification criteria categories in the 2014 Edition. The ONC-AA performs surveillance and technical assessment of the ONC-ACBs according to ONC program requirements and standards governing certification bodies. The ONC-ACBs perform surveillance of certified health IT products. NIST NVLAP performs surveillance of the ONC-ATLs.

In response to a question from Paul Egerman, Morton acknowledged that she did not have information on the use of the CHPL. It was noted that different certifying bodies post different types of information on the results of their usability tests. A member reported that his organization had analyzed 62 summative testing reports. Participants in the usability studies ranged from only 2 to 24. In 25% of the reports, no physician was involved in the testing. In addition, several vendors did not attest to having used UCD. He concluded that the summative tests and evaluations were not working as intended. Another member emphasized the importance of doing surveillance in a live environment.

Lana Lowry, National Institute of Standards and Technology, gave a slide presentation entitled How Usability of EHRs and Workflow Impact Patient Safety. She said that EUP clearly distinguishes between usability aspects that pertain to user satisfaction and usability features that impact clinical safety. Limited critical usability aspects that pertain to the clinical safety must be embedded into the system and must be required as core functionality not a competition feature; a barrier to entry to the marketplace on safety is an expected outcome. Typical measures for clinical safety are adverse events (wrong patient, wrong treatment, wrong medication, delay of treatment, unintended treatment). Accepted usability and safety standards should be considered industry standard practices. Any company is free to go above and beyond the basic standard. However, the minimum standards for usability in safety enhanced design should be established and articulated to address patient safety.

According to the EHR usability protocol, only safety related usability must be evaluated. The purpose is to ensure that EHR use errors are minimized. There is technical guidance for summative usability evaluations prior to deployment or implementation of an EHR. The summative usability testing evaluation is meant to be independent from factors that engender creativity, innovation, or competitive features of the system. Examples of safety-related usability issues that have been reported by health care workers include poorly designed EHR screens that slow down the user and might sometimes endanger patients, warning and error messages that are confusing and often conflicting, and alert fatigue (both visual and audio) from too many messages, leading users to ignore potentially critical messages.

She continued. EUP is a model for understanding the relationship between usability issues and patient safety outcomes through three steps. In step I, usability application analysis is led by the development team, which identifies the characteristics of the system’s anticipated users, use environments, scenarios of use, and use related usability risks that may induce medical errors. Step II consists of expert review and analysis of the EHR application, an independent evaluation of the critical components of the user interface in the context of execution of various use case scenarios and usability principles. In step III, usability testing involves creation of a test plan and then conducting a test that will assess usability for the given EHR application including use efficiency and presence of features that may induce potential medical errors. She continued, saying that EUP is a key component of NIST’s UCD. Performance is examined by collecting user performance data that are relevant indicators of the presence of safety risks. These measures may include, but are not limited to, objective measures of successful task completion, number of errors and corrected errors, performance difficulties, and failures to complete the task successfully or in proper sequence. Performance is also evaluated by conducting post-test interviews focused on what users identify as risks based on confusion or misunderstanding when carrying out directed scenarios of use. The goal of the validation test is to make sure that critical interface design issues are not causing patient safety-related use error. As a result of its research and analysis, NIST made several recommendations to developers and providers, which were written on the presentation slides.

Members asked several questions, reported experiences, and shared opinions. In response to a question about how the testing differentiates users who prefer check boxes and users who prefer free text, Lowry repeated that the protocol does not take into account user preference; it is based on user performance and the elimination or prevention of errors. Members talked about the placement of responsibility—vendor or provider—in user customized systems. The SAFER Guides provide technical guidance. Implementation resources are sometimes available. There may be a need for guidance on the placement of responsibility for safety.

Responding to a question about inconsistencies, such as the use of single or double clicking and buttons, Lowry repeated that the goal is the user can perform a task without error. Certification should not prescribe consistency. Consistency and satisfaction will be driven by the market. According to one member, the publication of the summative reports is very important in that they affect those vendors with immature safety program. Mitigation details are important for surveillance as well.

Members had more questions about errors due to user modification of a system. How would a vendor be protected in that situation? Lowry talked about vendor-allowed modification compared to changes made by a user breaking into a system. Simulation testing is done first, followed by testing in the real environment. Someone suggested that placement of responsibility for guiding implementation may be a place for the workgroup’s attention. If changes are prohibited after the completion of summative testing, how can new functions be grown? Several members questioned the usefulness of summative testing given the resources required and the fact that only eight criteria, a small subset of functions, are tested.

Paul Egerman reported that Karen DeSalvo, ONC, had recently convened a call with the CEOs of major EHR vendors requesting that they incorporate screens for Ebola into their products. There was no time to test these changes. Did these changes make the products unsafe? And what about the sum total of such changes over time? Maker reported that ONC staff had a webinar last week with the Texas HIT people about the changes made to EHRs regarding Ebola, and how they were implemented and tested. She offered to share the output with the members.

Members said that it could be helpful to share best practices at the time of implementation. Also, the EHR Association’s code of conduct may be helpful. Someone reported on the effort required in implementing and testing an upgrade at Geisinger, saying that it was resource intensive and would be difficult for immature organizations. That may suggest a role for ONC. Wolf concluded that numerous incremental changes over time mean that providers must take responsibility for safety. How to incorporate that into ONC regulation is an issue.

New member Michele McGlynn, Siemens, introduced herself.

## Next Steps: The workgroup will meet December 12.

## Public Comment: None

## Flag to ONC Staff for Coordination: None

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| Meeting Attendance | | | | |
| Name | **11/07/14** | **10/24/14** | **10/10/14** | **09/22/14** |
| Alisa Ray | X |  | X | X |
| Bennett Lauber | X | X | X | X |
| Bernadette Capili |  |  | X | X |
| Betty Mims Johnson | X |  |  |  |
| David W Bates |  | X | X | X |
| Ellen Makar | X | X | X | X |
| George Hernandez | X | X | X | X |
| Janey Barnes | X | X | X | X |
| Jeanie Scott |  |  | X |  |
| Joan Ash | X | X | X | X |
| John Berneike | X | X | X | X |
| Jon White |  | X | X | X |
| Lana Lowry | X |  | X | X |
| Larry Wolf | X | X | X | X |
| Megan Sawchuk |  | X | X | X |
| Michele McGlynn | X |  |  |  |
| Michelle L. Dougherty | X | X | X | X |
| Mike Lardieri | X | X | X | X |
| Paul Egerman | X | X | X | X |
| Robert Jarrin | X | X | X | X |
| Steven Stack | X | X |  | X |
| Tejal K Gandhi | X | X | X | X |
| Terry Fairbanks | X | X | X | X |
| Total Attendees | **18** | **17** | **20** | **20** |