

# Health Information Technology Standards Committee Summary of the July 21, 2009 Meeting

## Participants

David Blumenthal	HHS/National Coordinator for Health Information Technology
Jonathan Perlin (Committee Chair)	Hospital Corporation of America
John Halamka (Committee Vice Chair)	Harvard Medical School
Dixie Baker	Science Applications International
James Bialick (for Sharon Terry)	Genetic Alliance
Anne Castro	Blue Cross Blue Shield/South Carolina
Aneesh Chopra	Federal Chief Technology Officer
Christopher Chute	Mayo Clinic
Janet Corrigan	The National Quality Forum
John Derr	Golden Living, LLC
Jamie Ferguson	Kaiser Permanente
Steve Findlay	Consumers Union
Linda Fischetti	Veterans Health Administration
Doug Fridsma	Arizona State University/Mayo Clinic
Cita Furlani	National Institute of Standards and Technology
C. Martin Harris	Cleveland Clinic Foundation
Stanley Huff	Intermountain Healthcare
Kevin Hutchinson	Prematics/National E-Health Collaborative
Elizabeth Johnson	Tenet Healthcare Corporation
John Klimek	National Council for Prescription Drug Programs
David McCallie, Jr.	Cerner Corporation
Judy Murphy	Aurora Health Care
Nancy Orvis	Department of Defense
Marc Overhage	Regenstrief Institute/Indiana Health Information Exchange
Gina Perez	Delaware Health Information Network
Wes Rishel	Gartner, Inc.
Richard Stephens	The Boeing Company
James Walker	Geisinger Health Systems
Jodi Daniel	HHS/Office of the National Coordinator
Judy Sparrow	HHS/Office of the National Coordinator

## KEY TOPICS

### 1. Call to Order

Judy Sparrow of the Office of the National Coordinator (ONC) welcomed both those in the room and those joining via telephone to the third meeting of the HIT Standards Committee.

## **2. Comments from the National Coordinator for Health Information Technology**

David Blumenthal, National Coordinator, acknowledged that this pace of monthly meetings likely exceeds the expectations of many who have served on government committees in the past and assured the group that they are providing invaluable service to the ONC, Department of Health and Human Services (HHS), the federal government, and the American people. He acknowledged that some have the perception that this group is being asked to do too much too fast, and that a better job could be done given more time. He reminded the Committee that they are living with the deadlines that Congress created, and against those deadlines they are working toward an interim final rule that will include standards and certification criteria that will gird the implementation of Meaningful Use. The goal is to make sure that physicians, hospitals, and patients are given every chance benefit from the use of electronic health records (EHRs) and other technologies that permit improvement in care by 2011, to the maximum extent possible. The Committee's work to date represents the beginning of this process—work will continue, with the goal of addressing gaps and making improvements over the next several years.

## **3. Overview of Meeting**

Committee Chair Jon Perlin noted that there have been frequent conference calls and much triangulation among the various HIT Standards Committee Workgroups.

**ACTION ITEM #1:** The minutes from the last HIT Standards Committee meeting were accepted by consensus.

Committee Vice Chair John Halamka noted that Mark Overhage's comments at the last Committee meeting were taken very seriously, and as a result Committee leadership has been asking "what is the deployability of the standards we are creating?" Standards have been graded on a 1-4 scale, a process that involved granular thinking about how a given standard is used today, both within organizations and between them. Through this approach, the work that has been done within the industry is being used to provide a framework that will allow the creation of interim final rules that will be usable.

Each of the Committee's workgroups has created a framework that describes how to achieve Meaningful Use. The workgroups are also working to address what should be happening in 2011 and 2013, and what can be electronically reported.

## **4. Overview of Revised Definition of Meaningful Use**

John Glaser presented the revised definition of Meaningful Use to the Committee. He began by explaining that Meaningful Use is at the center of the Committee's activities (and the activities of the Committee's workgroups). In June, the Meaningful Use Workgroup offered a preliminary presentation on Meaningful Use at a previous HIT Policy Committee meeting. Following that presentation, approximately 800 comments were received during a 10-day public comment period. Last week, a revised definition of Meaningful Use was presented at the recent HIT Policy Committee meeting.

John Glaser then presented the revised definition as it was formulated by the Meaningful Use Working Group.

David Blumenthal thanked John Glaser and ONC staff for shepherding this work forward. To put this into perspective, he explained that the HIT Policy and Standards Committees offer recommendations to the ONC; those recommendations are transmitted to the HHS Secretary and will inform the rulemaking process that will establish the definition of Meaningful Use. He noted that the rules will most likely be issued in December, he said. The Centers for Medicare and Medicaid Services (CMS) will play a part in issuing the rules because they will be administering the rules for Medicare and Medicaid.

Highlights from additional discussion include the following:

- Kevin Hutchinson offered a word of caution about requiring a certain function to take place, when the capability to receive that function is not on the other end. This will make workflow very difficult.
- John Glaser and Jodi Daniel explained that the input received during the public comment period have been categorized by type of sender and then by concern or recommendation. Hardcopies are now available for public inspection; ONC is still in the process of making them available electronically.
- One Committee member asked about the status of certification and whether there would be an associated comment period. John Glaser noted that there was a set of public hearings on July 14<sup>th</sup> and 15<sup>th</sup>, and written comments were received. The Certification Workgroup then presented some recommendations to the Policy Committee; the high-level recommendations were approved, and the specifics will be revisited in August. Jodi Daniel explained that any process that is developed will go through rulemaking. There will be opportunity for public comment at these meetings; there will also be a formal comment period at the point of rulemaking.
- Jodi Daniel noted that within both the HIT Standards and Policy Committees, there have been many questions related to process. Based on these questions, ONC will post an online high-level description of how the process works.

## **5. Presentation of Initial Set of Standards and Certification – In Support of 2011 Meaningful Use Goals**

Floyd Eisenberg presented an overview of the Clinical Quality Workgroup's efforts. The Workgroup's initial tasks were to: (1) identify a potential set of existing standardized performance measures that correspond to the HIT Policy Committee's quality measure concepts, (2) identify the "data types" that must be captured to calculate the measures, and (3) hand off this work to the Clinical Operations Workgroup to identify HIT standards. Sources of measures include those found in the National Quality Forum database as well as those used by CMS, the Hospital Quality Alliance, accrediting entities, and the Physician Consortium for Performance Improvement. The performance measure set for 2011 includes 27 performance measures along

with provisional recommendations. Significant measure “retooling” will be required—efforts are underway to ascertain measure feasibility. The Clinical Quality Workgroup is seeking HIT Standards Committee approval with the understanding that there will need to be some changes.

Floyd Eisenberg pointed out the gaps that have been revealed in codes and value sets. He also noted that both ICD-9 and SNOMED coding are being used. He also said that they acknowledge that some gaps will be handled simply with attestation in 2011. In terms of next steps, a detailed review of individual measures is ongoing to identify any necessary changes and provide guidance regarding “retooling” some measures. The Workgroup also is developing a 2-dimensional framework for classifying measures that will include the degree of readiness of a measure for 2011 implementation and the level of performance expectations.

John Halamka noted the high level of granularity in workflow, and commented that there has been a great deal of coordination and collaboration between the Clinical Quality and the Clinical Operations workgroups.

Wes Rishel commended the Workgroup, acknowledging the difficulty of moving from high-level concepts to work on actionable concepts—he noted that the Clinical Quality Workgroup’s recommendations to date seem to be very positive and potentially do-able. He noted that in determining the denominator, these measures appear similar to queries in a database, except that there seems to be some conditions missing in the queries. The bigger question is, what is the scope of the EHR? To answer these kinds of questions within many organizations, it is necessary to go not to a computerized system but to a data warehouse. If in fact this is a Meaningful Use measure which will be a factor in determining the eligibility of a hospital or practice to receive incentive payments for EHR use, will EHRs be asked to do more than what they were intended to do?

John Halamka noted that denominators are challenging. For example, diabetes could be defined as an ICD-9 code, or it could simply be defined by whether a patient is on insulin. Many EHRs have a database capability and it is becoming more and more possible to conduct queries within these systems.

One committee member commented that there are usually two reasons to have a data warehouse: (1) for additional function, and (2) because an enterprise is badly fractured. The Committee member asked whether enterprises will be expected to solve that problem in order to get incentive payments for using EHRs. Floyd Eisenberg explained that certified EHRs will be expected to have the functionality to facilitate this type of data management. Additional discussion included the following points:

- It was noted that when multiple systems are used, for the purposes of Meaningful Use, all of these systems are being looked at as a single functioning system as these rules are being formulated.
- Dixie Baker commented that the readiness of any of these measures seems to be a function of how easy it is to capture the numerator and denominator, as well as the maturity of the vocabulary used to code it. She asked how a readiness value will be

assigned to these measures. Floyd Eisenberg explained that the readiness is a function of the maturity of capture and the availability and use of the terminology.

- John Halamka noted that the HIE Workgroup is looking at enterprise-to-enterprise communication. Although they have necessarily discussed architecture issues within an organization mandating specific codesets within the organization, etc., encouraging groups to “get their own houses in order” to communicate with the outside world is a valuable activity.
- Kevin Hutchinson commented that in large enterprises, there will be multi-vendor environments. He asked whether it will be necessary to recognize this rather than asking these enterprises which system they are using. He also asked about the Medicare-based incentive funding and whether the percentages just tied to Medicare percentages or tied to all patients that they receive? Jodi Daniel said that the ONC will be looking for advice on this issue and will examine legal possibilities.
- Doug Fridsma noted that the goal is to measure evidence-based practice and determine the best care. By 2015, the field should be driving towards continuous improvement. He indicated that if activities such as the potential need to build in the ability to conduct clinical research and comparisons is considered now, it may be much easier to continue this process in 2015.
- Nancy Orvis suggested that it will need to be made very clear that users will require the ability to pull data across several different platforms as necessary. Vendors will need to have standards among themselves, and a commonality within that information exchange. Clinicians will need to answer questions about their clinical decision support that will require these systems to communicate with each other. Vendors will need to address the concept of standardizing their interchanges.
- Aneesh Chopra asked whether there is starting to be some consistency in the business analytics set of activities and whether users are looking at mechanisms for quality improvements and using analytics to improve care. Floyd Eisenberg responded that it varies by practice—he believes that large practices are starting to engage in this type of activity.
- Gina Perez noted that this discussion emphasizes the need for HIE; hospitals and physician practices using EHRs are not capable, and will not be capable any time soon of using SNOMED. Therefore, it is important that the Policy Committee knows keeps this in mind and understands the role that HIE can have in emphasizing the importance of data in a unified view.
- John Halamka noted that standards will be measured by calendar year, while measures will be viewed according to adoption year.

**ACTION ITEM #2:** The Clinical Quality Workgroup report was accepted by consensus as a work-in-progress.

## 6. Clinical Operations Workgroup Update

Jamie Ferguson, Chair of the Clinical Operations Workgroup, updated the Standards Committee on the progress of the Clinical Operations Workgroup. A two-phased process was used first to identify EHR standards, then to assess feasibility for widespread implementation—almost all of the current 2011 Meaningful Use measures were addressed. Applicable HHS-adopted, recognized, or accepted standards are recommended for 2013 and 2011, and gaps were identified that may affect the 2011 Meaningful Use measures. Jamie Ferguson noted that unstructured documents, local and proprietary codes generally are recommended as allowable alternatives for 2011, but not for 2013 reporting of Meaningful Use measures. In terms of process, the Clinical Operations Workgroup: (1) reviews proposed Meaningful Use objectives and measures (with an initial focus on proposed Meaningful Use Quality measures), identifies existing EHR standards for Meaningful Use measures, and (3) identifies the feasibility of widespread implementation of the identified national EHR standards by 2011, 2013, or beyond.

A number of concerns arose during Clinical Operations Workgroup discussions. For example, there is concern that those who have not yet implemented, as well as those who have implemented legacy alternatives to HHS-adopted standards for Meaningful Use. The longer legacy systems are in place, the more is built up around them and the greater the upgrade cost. Workgroup members agreed not to let these concerns impede progress and identified interim solutions to facilitate implementing or upgrading to the standards.

The Workgroup requested HIT Standards Committee approval of its detailed recommendations for 2011 measures of Meaningful Use and that they be forwarded to the ONC. The Workgroup also requested HIT Standards Committee approval to proceed and to recommend to the ONC if adopted standards may apply to the 2011 Meaningful Use measures not yet addressed. The group also recommended that the ONC determine how to address gaps in standards via the Healthcare Information Technology Standards Panel (HITSP), direct requests to standards organizations, or other means.

Following Jamie Ferguson's remarks, the following points were made in discussion:

- John Halamka noted that all HITSP work is now available at [wiki.hitsp.org](http://wiki.hitsp.org) in fully searchable HTML format. It was noted that the Workgroup is emphasizing that in 2011, structured reporting is preferred, but unstructured reporting is acceptable as well. In 2013, structured reporting is much more important.
- Marc Overhage noted that clarification is needed for transmitting a measure at a patient level to a quality registry. David McCallie agreed, noting that ICD is extremely confusing because it is about moving data from place to place and does not represent the state of a patient—it is not a data structure, only a transmission vehicle. Chris Chute, Chair of the ICD revision process for the World Health Organization acknowledged ICD's limitations and noted that SNOMED has shortcomings as well (e.g., it does not adequately deal with pediatrics). Recently, a new and different version of the SNOMED listing was published. Chris Chute voiced concern about moving forward because SNOMED is a core product of these recommendations and the maintenance of SNOMED

is “fuzzy at best.” Jamie Ferguson acknowledged that there will have to be a maintenance process for not just SNOMED, but also for the list of labs, prescription drugs, and so on. Those activities are out of the scope of the Clinical Operations Workgroup.

- In discussing the issue of local codes, Floyd Eisenberg said that his assumption was that someone locally will be expected to use some analysis to map the local codes to the value sets provided. The Workgroup is not expecting that it will be able to address all local codes.
- Jamie Ferguson noted that where the Clinical Operations Workgroup specified ICD-9 as an alternative to SNOMED, it hoped that the Operations Workgroup would do that mapping rather than leaving it to local organizations. It was noted that there would be value in taking one or two examples of these and driving them through the process. This would inform the rest of the work as it moves forward.
- Anne Castro emphasized that standard, officially recognized coding with regularly scheduled maintenance, and no proprietary coding is needed. She indicated that her feelings on this are strong enough to the point where she would not approve of the wording of these recommendations without it. It was suggested that to the extent that the recommendations do allow flexibility for proprietary coding, it is a reflection of the reality that standardization may not be achievable by 2011. Anne Castro disagreed and suggested that if the requirement cannot be met, then the group should “back off” the quality standard that is being upheld.

**ACTION ITEM #3:** The Committee adopted by consensus the recommendations of the Clinical Operations Workgroup as they stand, with the understanding that the Workgroup will review the application of these standards as they articulate with quality measures and return at the next Standards Committee meeting for further discussion.

## **7. Privacy and Security Workgroup Update**

Steve Findlay began the Privacy and Security Workgroup update with a series of data slides indicating that most Americans rate the health care system as “fair” or “poor,” and that most consumers have little confidence that EHRs will remain confidential. He explained that the American Recovery and Reinvestment Act (ARRA) addresses these concerns by stimulating the adoption of HIT. The current paper- and faxed-based system is inefficient and costly; moving to electronic records and exchanges will reduce inefficiencies and cost, while improving patient safety and the quality of care. However, the use of computers and networks introduces new risks to personal privacy—as providers become more dependent on EHRs, the potential impacts of data corruption and service interruption will increase. Privacy and security mechanisms (both those currently in place as well as those under development) are designed to help protect patients’ personal privacy and to assure quality care.

Steve Findlay explained that to encourage broad adoption of EHRs, ARRA offers reimbursement to eligible providers who meet the following two requirements: (1) they acquire a certified HER product or service, and (2) they demonstrate that they are using that product/service “meaningfully.” The HIT Standards Committee therefore needs to recommend both criteria for certifying products as well as criteria for demonstrating that an applicant is using that product meaningfully. For privacy and security, certification that a defined function or service has been implemented in a product is not sufficient to demonstrate “meaningful use” of that function or service. The Privacy and Security Workgroup has adopted an approach that addresses both the certification of products and the demonstration that a user is using the certified product “meaningfully.”

Dixie Baker continued with the presentation, describing the process of mapping the “ARRA 8” areas to product certification criteria and meaningful use criteria as well as the “ARRA 8” requirements and standards. She presented the Privacy and Security Workgroup’s recommendations as follows:

- Certification criteria should not dictate policy beyond what is specified in ARRA and the Health Insurance Portability and Accountability Act (HIPAA) security and privacy rules.
- Product certification should address both functional requirements and assurance levels.
- For greater openness and broader interoperability, standards developed by international standards development organizations are preferred.
- Certification criteria and standards should enable design possibilities that leverage fundamental principles and open standards.
- Product certification criteria should build towards full interoperability with both health care partners and consumers.
- “Meaningful Use” criteria should be rules-based and should specify what certified features must be used and how, within the context of defined, operational use cases.
- “Meaningful Use” should include at least: (1) required certified features and their configuration within applicable use cases, (2) secure IT infrastructure, (3) current HIPAA risk analysis and risk management plan, (4) current HIPAA contingency plan.

Discussion included the following points:

- Wes Rishel questioned whether by endorsing these criteria, the Committee would be endorsing a certain level of EAL certification. Dixie Baker said that there are six levels of EAL certification. The Privacy and Security Workgroup recommends that the ONC designate specific certification levels based on use cases.

- In response to a question about consent beyond the consent levels associated with HIPAA, Dixie Baker said that the Privacy and Security Workgroup is recommending that when consent is captured, that the approach used be able to capture not only the privacy authorizations (as per HIPAA) but also other informed consent for delivery of care. Nothing specific is said about the granularity of consent going beyond HIPAA standards.
- John Halamka noted that this work is all completely based in HITSP standards.

**ACTION ITEM #4:** The Committee accepted by consensus the Privacy and Security Workgroup report and the standards as named (per last three slides).

## 8. Public Comment

- Mike Kappel of the McKesson Corporation commended the Committee’s Workgroups, and asked that both the Clinical Quality and Clinical Operations Workgroups clarify what is design-necessary for Meaningful Use versus what is suggested as certification criteria. He said that without this discrimination, he is not sure that the ONC can move forward with clear guidance, and he does not believe that any stakeholder can move forward without this clarity.
- Kathleen Connor, an analyst with Microsoft Health Solution Group, thanked the Committee for its rapid progress, and said that Microsoft supports a limited and flexible certification process focused squarely on validating that there are security, privacy, and data use capabilities. Timely adoption must leverage the infrastructure already in place. It is imperative that the Meaningful Use standards be technology neutral, platform independent, and platform agnostic. She noted the widespread use of all kinds of modular components as HIT solutions, and urged that they should be a part of the landscape of Meaningful Use. Microsoft supports the many affordable, easy-to-adopt, low-tech technologies, and said that these innovative modules are a great help to low-tech practices.
- John New from the Maryland Institute for Emergency Medical Services informed the Committee that the pre-hospital care data set has an international data dictionary. This set of terminology represents a consensus for many partners, and is well on the way to being implemented.
- Deborah Peel, speaking on behalf of a patient privacy rights coalition, suggested that even though the Committee accepted the report from the Privacy and Security Workgroup, there should be a public comment period. The health privacy advocacy community—including her group, which represents 10 million Americans—has not seen this before. This information needs some study and comments, she said, and part of the purpose of this Committee was to ensure adequate public input. Passing on the recommendations does not provide adequate time for public comment. She recommends that a process be developed to take in public comments and require that they be addressed. Secondly, she noted that the most significant of the “ARRA 8” in terms of

consumer privacy protection is the sale of protected health information (PHI) without consent. That particular requirement of ARRA does not seem to be on the timetable. She asked when this would be addressed and how the privacy community and the public can interface more effectively with this Committee for the development of key privacy standards.

- Jodi Daniel responded regarding the sale of data. She said that the ONC is discussing this issue with the Office for Civil Rights. She said this is something that would be incorporated into HIPAA regulation modifications. It is not necessarily a Standards Committee issue, because it will be a legal requirement rather than a standard.
- Robin Raiford noted that there are layers of complexity with consent for certain populations such as children, especially those in foster care, as well as disabled adults.
- Jodi Daniel briefly discussed the public comment process. All of the activities in the area of standards and certification, all CMS activities in terms of developing the incentive program and defining Meaningful Use, all of the provisions regarding modifications to HIPAA privacy rules will go through the normal rulemaking process. This process is designed to be a two-phased process. The agency comes out with its best proposal, and then looks to the public for comment and informs the public about how it has addressed (or not addressed) each comment. The Federal Advisory Committee Act (FACA) process is also an intentionally open and transparent process. In some ways the process was confused by having a public comment period on Meaningful Use. The ONC supported the Committee in doing that, but it was not required and will not be a part of every deliberation.

## **SUMMARY OF DECISIONS AND ACTION ITEMS:**

**ACTION ITEM #1:** The minutes from the last HIT Standards Committee meeting were accepted by consensus.

**ACTION ITEM #2:** The Clinical Quality Workgroup report was accepted by consensus as a work-in-progress.

**ACTION ITEM #3:** The Committee adopted by consensus the recommendations of the Clinical Operations Workgroup as they stand, with the understanding that the Workgroup will review the application of these standards as they articulate with quality measures and return at the next Standards Committee meeting for further discussion.

**ACTION ITEM #4:** The committee accepted by consensus the Privacy and Security Workgroup report and the standards as named (per last three slides).

The HIT Standards Committee will reconvene on August 20, 2009.