

Meeting Report

HIT Standards Committee Summary of the September 15, 2009 Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC) welcomed Committee members (both those in the room and those participating via teleconference) to the fifth meeting of the HIT Standards Committee.

2. Overview of Meeting

Standards Committee Chair Jonathan Perlin acknowledged the broad participation of the public in the Committee's work, noting that Judy Sparrow assures that all correspondence is distributed to Committee members and becomes part of the record. He also thanked members of the Committee and those who participate in the Committee's Workgroups. A transmittal memo has been submitted to David Blumenthal, National Coordinator for Health Information Technology, which described what the HIT Standards Committee approved at its last meeting. Those recommendations are in the hands of ONC for its consideration.

Jonathan Perlin commented that this meeting marks a shift in the group's direction, in that the HIT Standards Committee will be forming an understanding of how it can be most effective around implementation and providing guidance based on real-world experience. One guiding question for the Committee is, how can it be collectively effective, rational, supportive, and motivating, in order to advance technologies?

HIT Standards Committee Co-Chair John Halamka also welcomed Committee members and indicated that the key theme of this meeting is implementation guidance.

ACTION ITEM #1: The Committee approved the minutes from its last meeting, held on August 20, 2009, by consensus.

3. Meaningful Use Quality Measure Grid Update

Clinical Quality Workgroup Chair Janet Corrigan presented a new measures grid to reflect the input the Workgroup received from this committee and the public. The Workgroup has been working on issues having to do with measures submission workflow. How does the data needed to calculate quality measures—whether individual level or summary level data—flow among entities? The group made some progress on this during last Thursday's conference call, and then last Friday, the Clinical Quality Workgroup and the Clinical Operations Workgroup held a joint conference call to begin to create a framework for discussion by this Committee today. Floyd Eisenberg presented a chart illustrating this framework.

Floyd Eisenberg gave credit to the Healthcare Information Technology Standards Panel (HITSP) with regard to the ISO 6 quality interoperability specification, where their comments indicated that the flow of data and the interoperable component both were unclear. He also presented a slide describing how various types of architecture are possible—sometimes the data collection assistant is included within the electronic health record (EHR) system; in other cases, the data collection assistant is a registry, an external database, or a third-party vendor.

John Halamka noted that in 2011, quality data submission is going to be part of meaningful use. What will happen if standards are not mature? He suggested that the work of the HIT Standards Committee and its Workgroups is to make sure that the path is as smooth as possible.

The discussion that followed included these points:

- Jonathan Perlin asked about the actual technologies that would be used. He said EHRs may or may not have the inherent capacity to carry out data collection. Currently, multiple pieces of technology may be needed. Do the standards this Committee is offering for this process offer a longitudinal progression?
- Floyd Eisenberg explained that the purpose of the chart he presented was to address the part of the measure that requires the ability to show some near-real time performance evaluation. This allows users to improve performance as care is delivered, rather than waiting until a reporting process that happens later. It could be that the EHR and the registry assistant are one thing in order to get that internal feedback loop. Jim Walker commented that this could be interpreted to mean that it is optional whether measures are built into the EHR, which is not a good idea. He said it should be clear that at some point, everyone will need to have an EHR that includes this reporting function. He suggested presenting it as a progression, so that people understand that the end game is to get it into the EHR.
- Janet Corrigan noted that there are some instances, like SPS registry, that have very elaborate risk adjustment measures. She said she is not clear that certain specific exceptions to the rule are ever going to be a part of the EHR, but generally she agreed with Jim Walker's comments.
- Jodi Daniel asked for guidance for a recipient organization such as the Centers for Medicare and Medicaid Services (CMS). What should they look for in certified EHR technology? And what should they make sure they develop standards for, consistent with this Committee's vision? She noted that if some part of the construct is community based, that makes it more challenging.
- Floyd Eisenberg noted that there have been discussions about advanced quality certification. This has not been discussed by the Clinical Quality Workgroup, but in his opinion, there would be a set of criteria to manage quality reporting and interplay back to the provider, whether that is a certification of the EHR itself or a certification that the EHR can and does communicate with whatever third party is playing the role of data collection assistant.

- Wes Rishel pointed out the distinction between “meaningful use” and “useful use” in an EHR. It has always been acknowledged that meaningful use points to a set of functions among those things that would be useful. It is not comprehensive, merely a set of points. It is important to recognize that the standards and workflow being identified will have the near-term importance of qualifying people for meaningful use, and the longer-term goal of having a uniform way to communicate. He suggested that it would be useful to play out the chart being presented in a subsequent series of diagrams to make this clearer.
- Wes Rishel asked, given the variety of ways that meaningful use data is collected, whether it is certain that an entity seeking incentive money can qualify on its own for meaningful use. In other words, if the entity does everything right (e.g., buy the EHR, buy the 7 components, write code, etc.), can it fail the meaningful use component because it cannot communicate with someone else in the community who did not do everything right? He noted that this could be a great way to get the community to work together, but the Committee should decide if that is what it means to do.
- John Halamka noted there is an “out” in the meaningful use definition: that is, an organization can set up its EHR, and if nobody can receive the data that is still acceptable for the organization.
- Marc Overhage noted that one cannot use the same measures to remind physicians about things as are used for quality measures. A different level of specificity is needed, and a higher level of accuracy. Quality measurement is a statistical process; it is not perfection.
- Chris Chute characterized the diagram as a superb beginning and asked about the systems that should be examined in this context. Many organizations are in a milieu that includes multiple systems (e.g., nursing systems, scores of departmental systems, feeder systems of various types such as radiology or cardiovascular, etc). All of these feed into the EHR. He recommended making this fact more explicit. In front of the EHR are layers of systems and environments, which leads to the question of what is being certified. He also strongly suggested that this be called a system, in which an EHR is at best a core or a hub. He commented that to put disproportionate focus on the hub at the expense of all of the feeder systems would be a mistake.
- It was also suggested that there is another diagram hidden in the one presented by Floyd Eisenberg—this includes all of the steps that need to be carried out, such as collection, aggregation, reporting, etc. At that level of abstraction, it is possible to determine what has to be done in order to evaluate whether a particular function is being met. This perspective views the issue in terms of function rather than technology.

ACTION ITEM #2: The quality measure grid update and the organizational chart developed by the Clinical Quality and Clinical Operations Workgroups were accepted by the Committee by consensus, with the provision that more discussion take place around implementation of this flow.

4. Report From the Privacy and Security Workgroup: Implementation Specifications Recommendations

David McCallie led this discussion for Privacy and Security Workgroup Chair Dixie Baker, who was unable to attend the meeting. He presented a series of slides showing the Privacy and Security Workgroup's latest refinements to their recommendations. John Halamka noted that the group tried to get to a "rational glide path" for security, while also recognizing cost and practicality. So in 2011, various levels of authentication are accepted, while implementation guidance tries to incorporate as granular a set of directions as possible.

A discussion followed, which included these points:

- David McCallie noted that there were a number of discussions during which Privacy and Security Workgroup members were trying to decide if a particular issue was a policy or a standards question. With privacy and security, there are a number of issues that are actually policy questions. For example, if there is a network of systems connecting to each other with differing levels of user authentication certainty, must all of the systems rise to the level of the most stringent system, or sink to the lowest common denominator? The Workgroup did not answer that question, but did specify that systems are capable of at least expressing what their level of security is as well as that of connecting systems.
- David McCallie also noted that in the area of consumer consent after 2011, there is some unclear territory in terms of how standards are written. Standards regarding consumer ability to control the flow of their data are not yet very granular.
- Wes Rishel said he is a big fan of ATNA, and that it has done more to create effective enforcement of privacy concerns than anything else so far in health care IT. However, he does not think ATNA is sufficient to meet the new Health Insurance Portability and Accountability Act (HIPAA) requirements. He asked, are we committing the industry to using ATNA at the interface of other systems, or within their own system? David McCallie said it is his understanding that the focus is on the certifiable EHR within itself, and its own audit trail—not the transfer of information.
- Jodi Daniel explained that the ONC is working through those details. The Office of Civil Rights (OCR) is looking to ONC to provide standards, so ONC is trying to figure out how to line this up so that technological requirements will support OCR's new requirements.
- Aneesh Chopra noted that from a technical standards perspective, if there was a common mechanism to harmonize data about breaches, it would create a feedback loop about the nature of these threats. Current efforts are focused on chasing a future threat and do not have the benefit of knowing who the rogue actors are going to be (e.g., foreign countries, rogue employees, mistaken code, etc.). A consistent method of reporting out would help to create an understanding of the root cause so that it can be fixed.

- Jodi Daniel said that ONC has also been working with OCR on breach notification rules. There is a requirement that those breaches be reported to HHS. Any input from Committee members would be welcome.

ACTION ITEM #3: The Committee accepted by consensus the recommendations of the Privacy and Security Workgroup.

5. Discussion on Standards Implementation Specifications

John Halamka introduced the next portion of the meeting with the observation that, if we were satisfied with name-based standards, we would have been done 10 years ago. However, the much more specific standards of today allow interoperability.

Jamie Ferguson, Chair of the Clinical Operations Workgroup, then presented a few very minor revisions to the matrix that the Clinical Operations Workgroup has created. No changes were proposed to the recommended standards. Some language clarifications were made based on input and discussion. He walked the Committee through the changes, noting in particular the issue of the Physician Quality Reporting Initiative (PQRI) standard (which is a working standard, but not ideal), versus Quality Reporting Data Architecture (QRDA) (which is a more optimal standard, but not yet usable). He noted that there is a question about what to do with regard to these two standards for 2011 and 2013.

The Committee's discussion included the following highlights:

- David McCallie questioned the reasoning around the NCPDP Scrip 10 decision, given that it is not yet supported anywhere. John Halamka noted that Kevin Hutchinson informed him that all the necessary testing will be completed with NCPDP 10.X by the end of 2009. Technologically, he said, it is not a problem. He is hopeful that policy will converge on 10.X in a timely manner. Karen Trudell noted that CMS is putting into HHS clearance an interim final rule that would adopt 10.6 with backwards compatibility to 8.1.
- Jamie Ferguson noted that a lab order compendium is likely to be needed for lab order standardization. This is not a requirement, but it is on a wish list for future topics. The Clinical Operations Workgroup anticipates setting up a series of meetings on vocabulary topics, and wants to include experts from other workgroups and other organizations to participate.
- Aneesh Chopra asked whether QRDA is easier, or more widely adopted, compared to PQRI. Floyd Eisenberg explained that, unlike PQRI, QRDA allows reporting on single or multiple patient information, using the same basic data architecture as all the other elements that the Workgroup is recommending. John Halamka noted that QRDA would be simpler for vendors to implement.

Following this discussion, HITSP Program Manager Lee Jones presented a description of how HITSP's process works, and discussed implementation guidance, because the Committee is now

at the point where it must select appropriate guidance to go along with its various recommendations.

The discussion that followed included these points:

- Aneesh Chopra asked for more information about orchestrated participation and transaction. Lee Jones explained that with regard to interoperability among different kinds of entities, various organizations are using different kinds of tools and processes. What are the rules of the transaction, and what are all the different components of the transaction?
- Linda Fischetti noted that a customer of health IT will be taking existing standards off the shelf, and others will do the same thing, using combinations of products. Knowing that what is being taken off the shelf today will not get the field through the next 6 years. She asked about what must be done to make sure that the goals of the HIT Standards Committee are being met.
- Lee Jones noted that ever since HITSP has come into being, there have been parallel efforts; and HITSP's approach has always been to try to bring everyone to the same table, to proactively solicit people to participate. Sometimes HITSP is beholden to the newer things rather than addressing the older, but he said he thinks that may change as entities begin their implementations per this Committee's work.
- Jamie Ferguson noted that for 2011, the Workgroup was able to find HITSP implementation guidance and standards that substantially support 2011 meaningful use measures. For 2013, there will be some gaps.
- One Committee member asked if there is anything that the standards development organizations (SDO) can do that would make the process more efficient and the work product more effective for non-standards experts. John Halamka suggested that everyone should agree on the same value set to pre-harmonize the work of the various SDOs. Lee Jones added that the SDOs have now had discussions about who their collective customer is, and what they want—the work of this Committee is making that clearer. He said that as he now looks at this group as HITSP's customer, he understands that they are roadmapping this standard and creating a progression of standards that must be captured. That suggests to him that maybe HITSP should also start thinking about this roadmapping activity.
- David McCallie asked if some of the levels of indirection could be removed, and if some of the intellectual property constraints could be solved so that a small, start-up IT company could get to the information it needs to enter the market. He also asked about open-source reference implementation endorsed by HITSP that would speed up the implementation of complex protocols.
- Lee Jones agreed with David McCallie's point, adding that a lot of what people perceive as the complexity and difficulty is in the presentation. He likened it to an automobile. If

a car did not have an outside—that is, if it was not recognizably a sports car or a pickup truck—it would be much more difficult to know which one to select for a particular purpose. When the “cover” is in place on an automobile, it puts things into easier perspective for the user.

- Jim Walker noted that as the group gets through the first few years of this, during which the work is clear and there is a great deal of it, the group will get to a point at which it needs to re-imagine health care if it is going to make fundamental improvements in quality and efficiency. He suggested the Committee start to consider what transformed health care would look like, and what kinds of standards would be required for its support.
- There was a plea for the group to think about this from the context of a UNIX-based approach.
- Chris Chute noted the importance of having a national terminology resource that would house, manage, and maintain vocabulary so that they can be referenced transparently.

ACTION ITEM #4: The revised Clinical Operations Workgroup matrix was approved by consensus.

6. Implementation Workgroup Introduction

Jonathan Perlin invited Aneesh Chopra to chair a newly formed Implementation Workgroup. Aneesh Chopra thanked Jonathan Perlin and explained that he has three basic principles about this work:

1. He would like to see some measurements about where the field is regarding standards today. Are most providers at one level? If this is not possible through formal channels, is there a way of listening to where the baseline is?
2. He wants to start listening to those who have to make the “tough” calls. He suggested that they knock on the collective doors of the CEOs of the big health care organizations, CIOs, group practice administrators, and extension centers. He would like to ask, how are you thinking about this? What might the barriers be?
3. He noted that there is now a beautiful map of 2011, 2013, and 2015, but that does not mean people should not start sharing now. His presumption is, people are hungry to start now. For example, 70 percent of the Department of Defense’s care at this moment is external to their health system. They want that data now. So, how does this group take the lessons learned from those who want to start consuming now? The success this group has had over the last 120 days gives great hope for the future.

ACTION ITEM #5: Aneesh Chopra will chair the new Implementation Workgroup.

7. Next Steps—Upcoming HIT Standards Committee Agendas

The group discussed the direction that future HIT Standards Committee work should take. In discussion, the following points were made:

- Jonathan Perlin noted that there is a degree of specificity that can occur in the regulatory process, but it is unproductive to specify every last detail. The Committee must address how to support meaningful use with enough specificity to be helpful, but not so much that it will be cumbersome to modify over time.
- Wes Rishel pointed out that the economic impact of cooperating and interoperating has not been mentioned. The American Recovery and Reinvestment Act (ARRA) has created an economic benefit in the civilian community investing in interoperability that is, in government terms, a “flash in the pan.” There is at least one other significant economic opportunity that should be used to achieve interoperability—civilian health care organizations doing business with the VA and DoD. If the policy problems are solved, it should create pressure from Kaiser-like organizations that stand to profit more based on improved work with the VA and DoD, and there should be a rapid push toward interoperability among those organizations.
- Janet Corrigan suggested that perhaps this Committee could provide focus on how to get information regarding the 30-day hospital readmission standard available sooner rather than later. She noted that this would be a beneficial economic move in that if hospitals receive lower payment for readmissions, it would free up dollars.
- Chris Chute noted that value sets and terminologies are simply not available in common consumable access methods. The requirement to make these things available in formats and structures that are readily usable cannot be overemphasized. Historically, this is a huge practical sticking point to many of these standards.
- David McCallie said that he is struck, as a vendor, with the fact that unanswered architectural questions of organizing interchange are not well addressed in the existing standards. He suggested that in line with solving some of the granular consent management questions, the group ought to look at the broader architectural issues that still remain.
- Wes Rishel said that the feedback loop has not yet been achieved. The Implementation Workgroup will need to find ways to facilitate and promote the feedback loops, and must begin to talk seriously about a “connect-a-thon.” He said it is remarkable to see competitors help one another, because if any single one of them does not work, none of them works.

7. Public Comment

Alison Viola, American Health Information Management Association (AHIMA), explained that AHIMA is a proponent of uniform standards. They are working with the health care industry for

ICD-10 classifications and SNOMED. This is just a sample of the classifications and terminologies they deal with; they and the American Medical Informatics Association have raised concerns about coordination and appropriate use of all the terminologies. She said the Association stands ready to help.

Beth Feldpush of the American Hospital Association (AHA) suggested that meaningful use should be defined as the ability to provide better care. It should focus on metrics that measure whether hospitals are using HIT to have a direct, meaningful affect on patient care. Unfortunately, many of the meaningful use measures do not meet this criterion. Using criteria not related to better patient care will be distracting and unnecessary. She said this Committee is supportive of the use of National Quality Forum measures, and is using physician-level measures, but it has not mentioned the lack of hospital-level measures. A large reduction of readmission rates (10%) in 1 year is irrelevant to meaningful use, and is unrealistic.

Laura Choose, AHA, addressed privacy and security standards. She said the AHA supports the requirement that the meaningful use definition take into account privacy and security issues covered under HIPAA. The statute includes a warning that cautions that the work of this Committee should not alter the authority of the Secretary. However, some of the standards will, in fact, change the nature of what it means to comply with the privacy and security standards. For example, both required and addressable specifications have been developed. They changed the addressable specifications into mandatory items. She urged the Committee to be careful about going beyond the current privacy and security rules, and changing the nature of what it means to comply.

Charles Haslinger, Electronic Health Records Association, welcomed the establishment of a consensus of clear standards. The exceptions listed need to have a better linkage to the specific capability. He noted that there is a sense of complexity that could be quite simply corrected or clarified, and offered to provide examples showing ambiguities. Regarding quality reporting, he noted that there is still work ongoing by HITSP to charter new territories. The standards selected are not all complete, in terms of transport and security. The ongoing work of HITSP in this area is making tremendous process, and the HIT Standards Committee should continue to support this work.

David Tau, Siemens, commented that the mapping to HITSP capabilities is very helpful. He recommended that there be a helpdesk, helpline, a Web site with FAQs, or something similar. Also, he noted that on the glide path to SNOMED, the ICD-9 alternative is allowed, and then ICD-10. But the ARRA year 2013 actually starts in 2012. Therefore, it seems more logical to allow ICD-9 alternative to stand until ICD-10 starts. Also, IHE is selected for 2011, and then disallowed in 2013. This could cause a lot of expense for organizations migrating to this only to see that it is a short-term investment.

Tim McNamar, a technology vendor, emphasized that there should be some type of collaborative Web site. His organization is now in the process of creating a tracking system for federal financial information. He is hoping that they can use this information and apply it to other areas of government, including health care.

Clint Laird, Universada, noted that there is a revenue model for HIT, and it is the release of information. This is not sophisticated technology, but it is a technology.

Lindsey Hagel, a registered dietician with the American Dietetic Association (ADA), told the Committee that ADA provides evidence-based nutrition guidelines and standardized terminology (the International Dietetics and Nutrition Terminology). She hopes this terminology will be included as languages and definitions are considered.

Corinne ?, American Academy of Ophthalmology, noted that with regard to computerized physician order entry (CPOE). Ophthalmologists are in an ambulatory setting, and may not order standard tests as those in hospital settings can. But there are several mandatory measures for ambulatory care that are not relevant to ophthalmologists, and will make it impossible for them to be able to qualify. If it is not possible to make quality measures electronically compatible for all specialties, then measure should be pushed back and full compensation still offered.

SUMMARY OF DECISIONS AND ACTION ITEMS:

ACTION ITEM #1: The Committee approved the minutes from its last meeting, held on August 20, 2009, by consensus.

ACTION ITEM #2: The quality measure grid update and the organizational chart developed by the Clinical Quality and Clinical Operations Workgroups were accepted by the Committee by consensus, with the provision that more discussion take place around implementation of this flow.

ACTION ITEM #3: The Committee accepted by consensus the recommendations of the Privacy and Security Workgroup.

ACTION ITEM #4: The revised Clinical Operations Workgroup matrix was approved by consensus.

ACTION ITEM #5: Aneesh Chopra will chair the new Implementation Workgroup.

The next HIT Standards Committee meeting is scheduled for October 14th.