

**HIT Standards Committee
DRAFT
Summary of the April 17, 2013 Meeting**

ATTENDANCE

The following members attended the meeting:

- Dixie Baker
- Anne Castro
- Tim Cromwell
- John Derr
- Jeremy Delinsky
- Floyd Eisenberg
- Jamie Ferguson
- Keith Figlioli
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Wes Rishel
- Eric Rose
- Andrew Wiesenthal
- Nancy Orvis
- Kamie Roberts for Charles Romine

The following members were absent:

- Lorraine Doo
- Jonathan Perlin
- Christopher Ross
- Sharon Terry

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 47th meeting of the Health Information Technology Standards Committee (HITSC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting with two opportunities for public comment and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Review of the Agenda

John Halamka, Vice Chairperson, chaired the meeting in the absence of John Perlin. He noted that the draft HITSC workplan designated tasks by quarters. Insofar as the second quarter of the year has started, recalibration of the plan is necessary. He reported that workgroup chairs recently met to coordinate their activities, resulting in a vocal reaction to the amount of work to be done. Halamka recognized that there are limits to what can be accomplished. Some things require initiatives and staff work and other can be delegated to the committee. He said that Doug Fridsma, ONC, will report on triage and how ONC staff can best support the committee. He went on to mention each of the items listed on the agenda. He clarified that Micky Tripathi's report will not include a request that the HITSC comment on standards for exchange.

Halamka inquired about objections, corrections, modifications, improvements, amendments, or additions to the meeting summary distributed with the meeting materials and, hearing none, announced the acceptance of the summary of the March 2013 meeting as distributed.

Action item #1: The summary of the March 2013 HITSC meeting was approved as circulated.

Halamka reported that the value of HIT was evident in his hospital's response to caring for injuries from the Boston marathon bombing.

Updated HITSC Workplan

Fridsma talked about looking beyond ARRA to consider the standards necessary for Stage 3 and beyond. He said that the initial work from the HIT Policy Committee (HITPC) was considered in terms of its implications for the HITSC and then used to refine and revise the workplan. He talked about triaging in terms of: coordination of the need for additional information from HITPC; the use of existing standards that can be recommended to ONC; the use of new and modified standards; and taking a pulse check for activities that have a longer time frame or multiple steps to achieve the goals. He urged members not to think in terms of what can or cannot be done. He reminded them that the FACAs are not based on ARRA funds; rather, their functions are defined in HITECH. He asked that as he reviewed the workplan they identify times for interim reports.

He showed slides for the first quarter that listed the assigned workgroups, the activities, and the next steps for each topic. Regarding the topic of additional standards to support transport of data to and from patients, Leslie Kelly Hall told him to add the Consumer Technology Workgroup. Under activities, he noted the need for several presentations. He presented the option of workgroup deliberations prior to the presentations. Dixie Baker reported that her workgroups had already considered the topic. She informed them that David McCallie had been appointed co-chair of the Privacy and Security Workgroup. Staff will work with the workgroups in May prior to a presentation to the committee in June.

Fridsma moved to the next topic, standards to support image exchange, saying that to date there is lack of clarity on the goal. The committee must specify the use case(s). He proposed doing a presentation to the HITPC in May to obtain clarification. McCallie interjected that the standard for viewing is another consideration. Liz Johnson interjected that the Implementation Workgroup will also be involved.

Halamka talked about defining the problem to be solved.

Fridsma moved on to standards which address current content gaps, saying that he wishes to involve the Clinical Operations Workgroup. Jamie Ferguson reported that that group will soon meet to delineate a plan to approach the task. He went on to suggest that possible use cases be presented to the HITPC rather than waiting for those members to define use cases.

Moving to the topic of standards for securing data at rest, especially genomic data and consumer downloads, Fridsma referred to involvement of the Privacy and Security Tiger Team. Again, thought

must be given to the use cases and purposes. Baker interjected that HIPAA says that data downloaded by the patient becomes the sole responsibility of the patient and therefore standards are not needed. She reported that the Privacy and Security Workgroup had already made recommendations to that effect. She exclaimed that she was surprised that the topic continued to be listed. Fridsma declared that additional clarification is needed. Someone referred to a frequently asked question by providers on where their responsibility ends. Baker acknowledged that additional information and education may be required. Halamka talked about an unencrypted payload.

Fridsma referred to standards supporting digital signature. There is ongoing work with esMD. Baker said that members of the Privacy and Security Workgroup consider this to be an urgent need. Arien Malec asked that the Privacy and Security Tiger Team consider policy on proxies. McCallie asked about the use case of a tamper-proof signature and document. Fridsma said that a conversation is needed. Kelly Hall noted the importance of the topic for consumers. The patient's signature is a related issue.

Going to the second quarter, Fridsma talked about improvements to standards to facilitate unambiguous parsing, longitudinal record-sharing, and bulk record-sharing. Moving to standards to record advance directives and care preferences, Fridsma announced that the Consumer Technology Workgroup is the designated lead. He continued, talking about standards for application programming interfaces supporting modular application integration. Several ONC efforts relate to this aspirational goal. He said that a better understand of what is out there is needed. McCallie pointed out that standards are very use case specific and said that Fridsma was being vague. Fridsma acknowledged the need for a broader conversation before proceeding. Fridsma referred the topic to Baker and McCallie. Wes Rishel expressed concern about aspirational goals: What is the path from aspirational to something that improves health care in the United States? The right standard to adopt is the one in use. He advocated paying attention to use beyond the United States. Fridsma wondered about vendors moving in the direction of open exposure and being opportunistic and sharing approaches to APIs. Rishel said that the more common approach is to collaborate because of the complexity. He agreed that many vendors are promoting APIs and there may be consensus. Someone agreed. Fridsma indicated that these thoughts may be expanded upon.

Next, Fridsma noted standards which support flexible platforms for measuring and reporting quality (QueryHealth, QRDA/HQMF). He acknowledged that it is difficult to know what the HITPC has in mind. ONC staff is working on various projects in these areas. These standards will be considered in conjunction with standards for clinical decision support; both knowledge representation and APIs for query/response to knowledge resources is another topic.

Standards which support defect reporting to PSOs will be considered in conjunction with AHRQ efforts. Finally, he referred to standards needed for registry support, including structured data capture and transmission to third party repositories. A member reported that eSOS standards are being developed for all E.U. registries. Floyd Eisenberg noted that several of the topics could be referred to the Clinical Quality Measures Workgroup. He said that roadmaps are needed. Fridsma agreed and said that quality measurement and quality improvement can be combined. Both tools and standards are needed.

Discussion

Halamka observed that the workplan accurately reflected the discussion with the workgroup chairs. Regarding additional topics, Kelly Hall talked about harmonization of standards for patient engagement. Halamka reported that Johnson offered to have the Implementation Workgroup consider the feasibility of standards implementation. Fridsma said that both implementation and testing should be considered up front. Halamka reported that vendors perceive a disconnect between standards and certification. He asked Johnson whether the Implementation Workgroup plans to have hearings on Stage 2 certification. She relied that plans were underway.

John Derr asked about long term care. He reported that he is a member of three workgroups, all of which focus exclusively on EEs and EPs. He acknowledged that the legislation does not include long term care. Nevertheless, harmonization with long term care is necessary.

McCallie mentioned a presentation at a previous meeting about standards for transitions of care, which does not appear on the workplan. Fridsma suggested that the C-CDA may be an opportunity for inclusion of long-term care. He assigned the activity to Ferguson for an analysis of gaps. Derr declared that he wanted solutions rather than the identification of gaps. Baker suggested that the activity be added to longitudinal care.

Rishel asked two questions: What about studies of the cost of not coordinating with long term care? Where is the HITPC on the issue? Halamka declared that Tripathi's presentation will deal with the latter question. Fridsma said that transition of care is a priority and considerable effort has been applied to it. Although long-term care providers are not eligible for incentive payments, the FACAs are not restricted to meaningful use.

Remarks

Farzad Mostashari, National Coordinator, arrived and reported on the administration's budget. When ONC was established in 2006, less than 1 percent of U.S. physicians used electronic prescription. Now over 50 percent of physicians use e-prescription. During this time, ONC's appropriations have not changed from 61 million. Its current funding will expire in September 2013. The administration has proposed an increase in funding to 78 million, a tiny amount compared to expenditures for health care. He said that ONC uses its funds to leverage community participation. Most of the requested increase is to replace HITECH funding. Included in the budget proposal is a user fee associated with the certification process totaling \$1 million. If certification is not well designed, problems will result for everyone. He requested industry support for this concept of vendor fees.

Rishel asked about an extra value. Mostashari indicated that the value is in maintaining the certification process. Institution of a fee would give vendors a stake in the program and its improvement.

Halamka asked about the effect of the proposal on self-certification. Mostashari said that if the proposal is enacted, the regulation process would deal with such issues.

ONC Updates

Jodi Daniel reported. The 2014 Edition test procedures have been updated to align with the Cypress tool. The CMS and ONC RFI on advancing interoperability and health information exchange will close later this month. Staff has been holding listening sessions on interoperability and exchange. A brief on LTPAC was recently published. PlanningRoom.org was launched with Cornell University to use social media to test tools and to obtain input on select topics. Public comment closes on May 9. Comments will be used to revise the consumer health strategy. Mostashari commented on the value of social media tools to open government. Daniel continued. Interoperability training courses are available on several topics— interoperability basics, interoperability and transitions of care, and interoperability and lab exchange— with more to come. Resources for critical access and small rural hospitals are now available, including implementation support tools and information about funding. A new video for the PBS *My Health Counts* series was produced. It describes how patients can leverage technology to track their health and wellness. Health Datapalooza IV will be held June 3rd and 4th, 2013, in Washington, D.C. Registration is now open.

Fridsma reported again, showing slides on S&I Framework activities. In terms of outputs, 34 pilots involving 42 vendors are underway or completed. Eleven ballots have been conducted, with 3,128 HL7 ballot comments received and 2,415 comments resolved. He emphasized that staff is looking at the sustainability of the portfolio. They are working with HL7. Active initiatives include Query Health, electronic submission of medical documentation, public health reporting, longitudinal coordination of

care, lab orders interface, Health eDecisions, Blue Button automation, and structured data capture. He talked about development of a standards implementation testing framework to ensure the testability and implementability of standards. The C-CDA implementation and testing platform will have the following capabilities:

- Provide and maintain a knowledge base curated by HL7 Structured Documents Work Group Community where implementers can search for information and answers to questions and moderators can post answers and example code from experts in the community
- Provide a moderated mechanism for implementers seeking answers to questions from HL7 Structured Documents Work Group Community where implementers can post questions, experts in the community can respond to questions, and moderators will monitor the forum, create issue tracking tickets for unanswered questions, or questions that require input from experts in the community, and post answers back to the forum and tag them to facilitate future searches by others in the community
- Provide a mechanism to triage, route and track issues that are posted on the forum to assure that they are handled in a timely fashion, and answered by the appropriate experts in the community following the appropriate processes, and publish the vetted responses back to the knowledge base to benefit other implementers in the community

In the second phase of platform development, a sandbox will be added to allow implementers to test standards live, ask questions about the results, and receive feedback from the community.

Q&A

Rishel asked about the forums: Is there a way to identify when a definite answer is necessary and to schedule the forum to generate that answer? Fridsma talked about working with SDOs, NIST, and others. The community does not necessarily come to consensus. The purpose of a forum is to get feedback on what is working. Rishel went on to say that due to the uneven participation in forums, their output can be unreliable. He recommended use of a moderator to identify issues that appear to be critical and to move the discussion forward.

Eric Rose reported on his use of the issue tracking site with his vendor. This phenomenal step forward is an example of why ONC must be funded.

McCallie talked about failure due to the lack of standards. He urged finding a way to speed up the development cycle and to avoid the overhead cost of going through the SDO process. Fridsma responded that issues raised in forums will identify gaps that can be used to drive use case development and harmonization. They will use pilots to create scalable national approaches. Halamka asked about the implications of consensus on a wrong answer and the need for revisions. Fridsma replied that the forums will not make recommendations directly; recommendations will come through the HITSC. Johnson asked about the exclusive use of platform and trackers for quality measures. Fridsma said that the use will eventually be expanded. Johnson suggested that the platform be used for testing implementation overall. Fridsma suggested that the testing group make a presentation to the Implement Workgroup.

Baker noted the interdependency between policy and technology. The forums may raise policy issues. Rishel talked again. He said that the unique role of implementers, who are expected to get it done even if it is not done right, must be recognized. Clarification has two values: queuing up an issue to get it right and queuing up an interim solution.

Structured Data Capture (SDC) Presentation

Fridsma reported that the project was launched on January 23, 2013, in partnership with NIH, NLM, and AHRQ. The focus is on enabling the collection of structured data within EHRs to supplement data

collected for other purposes specific to clinical research and patient safety event reporting. More than 280 individuals participated in the initiative launch webinar. Other federal partners are FDA (CDER/CDHR), CMS (esMD), CDC, and SAMSHA. He talked about several reasons for a focus on structured data capture. There has been an exponential growth in the volume and detail of information captured by health care organizations and payers. There is strong public and private interest in leveraging clinical data captured in the health record during episodes of care and using these data to supplement data collected for other purposes, including research, patient safety event reporting, and public health reporting. Eventually, such data could be used to enhance EHR data. Enhanced data would be valuable for quality and performance improvement and determination of coverage. Aggregated and analyzed EHR data can be used to identify trends, predict outcomes, and influence patient care, drug development and therapy choices. EHRs are the data source with the highest potential to provide timely and relevant data in a form that is quickly usable for quality and safety improvement, population health, and research. Linking EHR data with other data in a uniform and structured way could accelerate the utility of EHR data for supplemental purposes.

Fridsma continued, talking about the scope of work, which is to develop and validate a standards-based data architecture so that a structured set of data can be accessed from EHRs and be stored for merger with comparable data for other relevant purposes. The set will include: electronic Case Report Form (eCRF) used for clinical research including PCOR; Incident Report used for patient safety reporting leveraging AHRQ 'Common Formats' and FDA form 3500/3500a; Surveillance Case Report Form used for public health reporting of infectious diseases; and collection of patient information used for determination of coverage. SDC will identify, evaluate and harmonize four new standards to enable EHRs to capture and store structured data: a standard for the structure of the CDEs that will be used to fill the specified forms or templates; a standard for the structure or design of the form or template (container); a standard for how EHRs interact with the form or template; and a standard to auto-populate form or template. The idea is to first get consensus on syntax and, then, on semantics.

Q&A

Andy Wiesenthal expressed concern about the absence of a defined data model: Without that, how can one proceed? Fridsma talked about the various definitions available for meaningful use. Wiesenthal noted that in a clinical setting data collectors do not pay sufficient attention to definitional details. Fridsma said that the intended use of the data may determine the required precision in collection.

A member opined that what may appear simple is often difficult. Ferguson suggested consideration of requirements management as an additional step. All requirements should be managed as common data.

Kelly Hall said that the patient can participate in SDC. The patient's role should be added. Collection burden also applies to the patient.

Rishel talked about the importance of separating the effort into standards for process and for syntax. One can never assume that semantics problems are solved. For instance, there may be four genders for administrative purposes, but the number will vary for clinical purposes. The new EHR roles for the researcher and the consumer must be recognized. Data collected for care and data collected for research are different. A smooth process from clinical data to research data is needed. When asked whether he agreed or disagreed with SDC, Rishel acknowledged confusion. Halamka called for the record to show that Rishel agreed.

Eisenberg observed that based on his experience with quality measures, significant importance should be placed on the data model and semantics. The same model used in quality measures should be used. Provenance of the data, including the patient's information, needs to be included.

Rebecca Kush mentioned previous work that could inform the effort, such as international standards for a minimal data set for research that also satisfy regulatory agencies' requirements. Data are collected in a form to enable analysis. AHRQ event reporting standards could perhaps be harmonized across agencies.

McCallie referred to side effects of semantic granularity mismatch. At Cerner, he worked on the development of trees of granularity. But users were dissatisfied with the complexity. Mostashari clarified that no pre-population of EHRs is planned. Fridsma reiterated that the focus is on syntax, not semantics. It is an incremental process to tolerate heterogeneity of syntax. The first step is to identify a common way to define syntax.

Public Comment

Tom Bizzaro commented that pharmacy providers, including community pharmacies, play a key role in providing pharmaceutical care in long-term care facilities, in the home, at transitions of care, and in acute and chronic care situations. Pharmacists have a significant role to play with patients' management of their own care. Pharmacy should be included in meaningful use.

HITPC Comments on Joint CMS and ONC RFI on Interoperability and Exchange

Halamka introduced this as an informational item only. Micky Tripathi, Chairperson, HITPC Information Exchange Workgroup, explained that ONC staff had asked the workgroup to comment on the RFI. Working within an abbreviated time frame, workgroup members selected these areas for their focus: payment policy, providers ineligible for meaningful use, and state-level program and policy variation. Next, they examined these levers: regulation, payment, certification, state action, reporting and public reporting, and convening authority. The workgroup's recommendations were recently presented to the HITPC, which resulted in a few additions. The recommendations are based on the framework set out in the RFI. Tripathi went through his slides, which gave background for each of the high-level recommendations. He told them that the appendix contains more specific and detailed recommendations. The general recommendations are:

- HHS should work to simplify and harmonize requirements across advanced payment models for public and private payors. This will help providers focus on the desired outcomes rather than the often complex mechanics of the current programs.
- Since there is still a lag in adoption of HIE capabilities through advanced payment models, highly focused supplemental payments to capitated and fee-for-service models to motivate HIE-enabled activities (e.g., higher E&M coding for "cognitive activities" using HIE, such as information reconciliation) should be considered.
- Voluntary certification program for HIE functions that enhance enablement of value-based purchasing activities
- HHS should harmonize required documentation and reporting across programs and with the MU framework, including: harmonization of CMS-required documentation with C-CDA; incentives to Part D providers to motivate HIE-enabled and HIE-enabling activities; and advance administrative simplification where it intersects with clinical standardization, such as prior authorization documentation requirements.
- For laboratories, provide safe harbor from certain CLIA requirements if providers are compliant with MU and using certified technology and increase aggressiveness of Stage 3 eligible hospital laboratory results delivery requirements to move the market faster.
- Require (if possible) or facilitate (if not) voluntary certification of technology used by providers ineligible for meaningful use, in alignment with MU requirements.
- CMS should include HIE requirements in all programs including state waivers and future advanced payment demonstrations, and require coordination as much as possible with the State HIT Coordinators.

- CDC should continue and increase its work to harmonize the variability across states in the standards utilized for public health reporting to enhance use of HIE.
- CDC should establish a single standard for the exchange of immunization information.
- HHS should create model language available for inclusion in state-level programs (e.g., Medicaid MCO contracts, state employee health plans, etc) to encourage HIE activities.
- HHS should identify and encourage any opportunities for reducing state-level variation in privacy and liability policies related to HIE activities.
- CMS should repurpose existing data and business infrastructure to facilitate market development of HIE capabilities; apply open data principles to provider databases (NPES, MU, NPI) to make data available to market for provider directory creation; build on credentialing of patients and providers to support validation needs for HIE activities (e.g., provisioning patients with Direct addresses); and build on the development of health insurance exchanges to support HIE activities.
- As feasible, enable patient access to immunization information contained in public health immunization registries.
- Align of FDA programs with MU framework, such as device interoperability (facility and home), structured product labeling standards, and event reporting standards.

Discussion

Halamka asked about image exchange. Tripathi said they did not discuss images. In response to a question about approach, Tripathi agreed that they had considered HIE within the context of other programs. Nancy Orvis spoke about the need for financial incentives. Her agency is interested in creating incentives for vendors and others and is working with the FDA on international device standards. She asked about credentialing and verification of providers. Tripathi indicated that the workgroup did not consider credentialing. He offered to take the issue to the HITPC and to get back to her. Halamka asked about DoD and incentives for commercial labs. Mostashari reminded the members that the RFI was jointly issued with CMS. The levers are not limited to meaningful use. He gave a hypothetical example of CMS payment policy affecting labs: CMS could pay more for lab results delivered electronically rather than by fax. The idea is to make it profitable to share information.

Rishel talked about a change in attitudes of hospital CIOs leading to privately funded HIEs. HIE is not confined within state boundaries and state HIEs. What about a less state-oriented approach to HIE? Tripathi responded that the question had not been asked in the policy discussions. Exchange can be done in multiple ways.

Governance Update

Mary Jo Deering, ONC, described the launch of the National HIE Forum and the Exemplar HIE Governance Program (cooperative agreements) Awards. She reminded the members that they had requested the update. HIE governance refers to the establishment and oversight of a common set of behaviors, policies, and standards that enable trusted electronic HIE among a set of participants. It is not based on regulation. The National eHealth Collaborative and ONC established a forum for HIE governing entities in order to identify high-impact issues on HIE governance that will support the movement of information across exchange organizations and geographic boundaries and to identify and share emerging best practice approaches to common governance challenges. The launch occurred by teleconference April 12th. Participants were asked to vote on priorities. Fifty-two percent of participants voted for handling patient consent and process to accurately associate patients with their data. The next meeting is scheduled for May 3rd. All meetings are public.

Kory Mertz, ONC, reported on the two cooperative agreements awarded in response to the FOA released December 2012. The awardees are DirectTrust.org, Inc and New York eHealth Collaborative Inc. DirectTrust will continue and expand its work to establish security and trust rules of the road for Directed

exchange and advance adoption of these rules through the trusted agent accreditation program. DirectTrust's critical work will facilitate and enable vendor-to-vendor and provider-to-provider exchange for Stage 2. The EHR|HIE Interoperability Workgroup will address some of the stickiest implementation challenges facing the exchange of health information including patient matching, querying provider directories, and applying good governance principles for both query-based and directed exchange.

Q&A

Lisa Gallagher asked about mechanisms for obtaining input from other stakeholders. Mertz responded that both awardees work with a wide variety of groups. He offered to talk with her about her organization's work with matching.

The cooperative agreements are for one year with a potential one-year extension. The activities and output will be reported through the Forum and the ONC Website.

Derr commended Mertz for his work with LTPAC.

A member asked about state level exchange: What is the governance structure for HIEs? Does the ONC project cover "my state"? Mostashari explained the earlier effort to develop a regulatory model, which was abandoned in favor of the current approach. He talked about rules of the road and how HIEs relate to each other. The Forum is a way to collect information on HIE structures and processes. The member suggested that different types of payors be represented in the Forum. Payment innovation is essential to successful HIE. Deering offered to follow up with her on her participation.

Baker asked about compatible exchange between the two exchange models. Mertz said that the two awardees will coordinate. Deering said that the various exchange models will be considered at the May meeting of the Forum. The goal is to find the common as well as the unique elements.

Public Comment

Robertson announced the three-minute limit on comments.

Darrell Roberts, American Nurses Association, reflected on his master's thesis on HIPAA. HIPAA set a floor and although it was a weak law, it started a conversation among states on how to strengthen privacy and confidentiality. The accreditation bodies, particularly the Joint Commission, became involved in enforcement. But HIPAA became overly prescriptive in some elements, which have yet to be truly implemented. He advocated that the experience with HIPAA be taken into account in current policy development around governance.

Gary Dickerson commented on Mostashari's remarks on the value of certification. He co-chairs a HL7 committee. He made a technical recommendation for the use of an international standard to develop a functional profile for certification. Use of an international standard would have market advantages.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the March 2013 HITSC meeting was approved as circulated.

Meeting Materials

Agenda
Summary of March 2013 meeting
Presentations and reports slides