

**Health Information Technology Standards Committee
Final
Summary of the December 17, 2010, Meeting**

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed members to the virtual meeting. She reminded members that it was a Federal Advisory Committee (FACA) meeting, with an opportunity for the public to make comments. She called the roll, and turned the meeting over to the Chairperson, Jonathan Perlin, Hospital Corporation of America. He reminded the members that this was the 20th meeting of the Standards Committee. He referenced findings from a recent CDC survey of adoption, which found that 50% of physician offices have at least a modest type of electronic health record (EHR), and said that the meeting agenda reflected the many on-going HIT efforts toward the adoption of an interoperable framework. He commented on the importance of reports such as that of the President's Council of Advisors in Science and Technology (PCAST). He expressed his hope that the members feel connected to the important work of the committee. Yet another level of effort is needed to help ONC achieve its goal.

2. Introductory Comments on PCAST Report

Co-Chair John Halamka noted the importance of discussing priorities for standards and interoperability, another agenda item. He said adoption of existing standards may be more of a problem than lack of standards. The discussion of NHIN Direct is also important. He opined that the role of the Standards Committee is not simply to respond to the Policy Committee and ONC but also to guide them. He referred members to his blog, which describes upcoming work of the committee and presents a review of the report.

David Blumenthal, National Coordinator for HIT, recognized the hard work of the members. He said that the President's recognition of the importance of HIT is reflected in the PCAST report (<http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>). The report reflects the importance that the administration places on achieving interoperability. The report sends a message that the administration wishes to move aggressively on HIE. It is important to pick a path that is reliable. Dr. Blumenthal said that the expression of this commitment is as important as any of the specific recommendations. ONC can move forward on data exchange with the support of the administration and congress. He went on to say that ONC intends to convene a workgroup, with members from both HIT committees as well as others, to review the report. The PCAST will also be invited to address the HIT committees. Other technical groups and privacy advocates will be asked to review the report.

3. Discussion of PCAST Report: History and Intent

Co-Chair John Halamka reported that one year ago a PCAST working group, co-chaired by Christine Cassel and Craig Mundie, met to identify challenges and key issues in standards of

information exchange. In addition to Dr. Halamka, Peter B. Bach, Basit Chaudhry, Molly Joel Coye, Eric Lander, Jonathan Levin, Louise Liang, William Press, Stephanie L. Reel, and Harold Varmus served on the group. They heard expert testimony from ONC, vendors, and representatives of standards organization. The PCAST Committee on Health conducted an independent synthesis of the information gathered from multiple sources and submitted a report to the PCAST. Dr. Halamka emphasized that the report was not necessarily endorsed by the working group; rather, it represents the synthesis of the larger body.

He asked that the members of the Standards Committee discuss how the major themes of the report can influence the future direction of its work. He acknowledged that the report contains “not precisely accurate statements” and asked that the members not focus on those statements. Instead, they should examine themes. He proceeded to speak at length on several themes and good ideas that in his view were significant for the work of the committee:

- XML concept or construct with good vocabulary controls that enable representation of data with middleware to exchange information
- Data atomic to represent specific items and the ability to separate out data elements from the document itself for exchange via middleware
- Metadata to integrate information across multiple data sources
- Search engine technology as a mechanism for ordering data
- Data pulled from XML construct for reuse for research, surveillance, and population health

He noted that privacy issues were inherent in several of these themes and then asked the other members which elements of the report should be incorporated into the work of the committee.

Members’ Comments Highlighted

Wes Rishel – The vision of a national HIE rather than merely interconnected state and local networks is important. Several of the purposes for HIE involve retrieving data as required. Some of the other use cases involve signaling an event from one entity in the health care system to another. Publish and subscribe may not be a good alternative to an event-based model. One of the strengths of the report is the emphasis on being able to extract data. Atomic or elemental data are important but they are not the entire picture. The section on demographic-based matching is not consistent with the testimony received in the recent Privacy and Security Tiger Team’s hearing on record matching. Prioritization is not a reason to avoid getting started on long term goals. It is necessary to look beyond meaningful use 2015.

Stan Huff – Universal language is the same as detailed clinical models. There are well described medical documents such as orders and lab reports, but many things are not standardized, for example, blood pressure and weight. To be useful, HIE needs to go to a much more detailed level. Interoperability will be impossible without a more specific and detailed level of modeling, for example, the expansion of problem lists to incorporate levels of severity. Huff told the members that he had been working on this issue for 10 years although he denied any financial interest. He referenced the work of the VA and DOD and suggested that the members could benefit from a tutorial. A workgroup within HL-7 is looking at the next generation of HL-7 standards, reviewing the use of the versions 2.0 and 3.0 messaging and CDA documents. The

CDA is a snapshot in time. The transactional semantics around maintaining a consistent electronic medical record are not in place.

Marc Overhage – There is nothing novel in the report. The committee can ask if anything has been missed. The committee should continue to stay on task.

Linda Fischetti – This is an opportunity to develop a roadmap for moving forward. The committee needs to fully understand the privacy issues of discoverability. Resources are required for a common language.

Dixie Baker – The report confuses identity and authentication and fails to address the universal identifier issue. The variation in state privacy and security laws is not discussed. The idea of tagging individual data elements with persistent tags that reflect privacy is unworkable. Privacy preferences are context specific and the context changes over time. As medical advances are made, the sensitivity to certain types of information being exposed lessens. Privacy rules need to be attached to data at the time the data are exchanged.

David McCallie – The concept of building an indexing service of national scope is novel and positive as is the digital rights management approach to privacy and security.

4. Workgroup Updates

Implementation Workgroup January 2011 Hearing

Workgroup Co-Chair Judy Murphy invited committee members to attend the upcoming hearing. The content will focus on the experiences of early adopters and certifiers. HIEs and RECs will be represented as well.

Clinical Operations Workgroup Vocabulary Task Force on Medical Devices

Workgroup Chairperson Jamie Ferguson said that the workgroup is pursuing input on device standards including the use of remote devices for monitoring. He is planning a hearing in the first quarter of 2011 and will convene a planning committee in January. He invited Dixie Baker to participate in planning in response to her question regarding implanted devices. Members described additional use cases including acquisition of blood pressure, telehealth, management of cumulative radiation exposure, and receipt of data from diagnostic devices.

5. Standards and Interoperability Framework – Priority Recommendations Discussion

Doug Fridsma, ONC, referred to his presentation slides, which had been distributed to members in advance of the meeting. He reminded the group that the current priorities link back to the stage 1 meaningful use priorities. He said that he wanted members' input into priorities using distributed documents going forward. The priorities must be consistent with national goals. His slides summarized the following initiatives currently being considered for priority status: clinical summaries, templated clinical documents, lab interface improvement, medication reconciliation improvement, syndromic surveillance, quality measures, population health query, clinical

decision support, blue ribbon, green ribbon, and value set development. He reviewed his efforts over the past year, saying that the first contract was awarded in October 2009 and the final contract award was made in September 2010. He noted that initiatives such as the Direct project should be melded with the framework. A request for comment placed on the FACA blog resulted in only seven comments to date. Dr. Fridsma asked the members to submit their responses to the draft prioritization framework spreadsheet.

Q and A

The Co-Chair remarked on the importance of reducing the cost of a laboratory interface. A universal compendium of LOINC codes for ordering the 98% most common labs would reduce the cost. He said that the members' experiences and suggestions can potentially be very helpful to Dr. Fridsma. Carol Diamond interjected that she had the same question every time she saw the framework presentation: what is the policy direction for the process of generating standards? She emphasized the importance of policy direction at the front end in terms of the expectations for how the technical decisions are made, how standards are selected, what the implications are for those standards, and how they play out through the process. There was no response to her offer to work on the questions that she had raised.

Doug Fridsma replied that if a particular initiative is launched, the team members will include stakeholders such as vendors, providers, standards development organizations (SDO) and policy development organizations. As use cases are harmonized, there will be policy implications. Iterative and incremental development will include not only the technology, but the policy pieces as well.

Arien Malec offered information on his experience with the Direct project, saying that he had weekly meetings with key ONC staff on policy. He said that he tried to ensure that areas with policy implications were handed off to the Policy Committee and its numerous workgroups. Carol Diamond offered to convene a small group to work on the policy process.

In response to a concern that the contractors themselves are becoming the standards developers, which is a change from the open consensus development role of HL-7, NCPDP, and DICOM, Fridsma said that the framework is supported by the contractors but they are not the ones who set priorities or determine standards. Conversations with HIEs and HL-7 about how best to engage them are underway. The process will be consistent with the W3C and the ANSI requirements for openness and transparency. SDOs will be involved in harmonization. Fridsma said that he is working with open health tools and some of the model drive health tools, and work done by Dave Carlson with HL-7. Identification of a goal will help to focus on understanding which of the SDOs need to be involved. ONC is not a recognized SDO and there is no intent for it to conduct balloting.

Wes Rishel spoke about SDOs and intellectual property. Standards implementations typically occur on tight deadlines, often set by law. The time frames do not usually permit a fully consensus-based process. It is necessary to coordinate and take intellectual property from multiple SCOs and create a single source of specifications. SDOs sustain themselves by selling their standards. He said that he is concerned that the S&I framework is not using some of the

money allocated to it to support the work of the SDOs. Fridsma acknowledged that he has not yet dealt with the intellectual property issue. Resources are needed for high quality standards and appropriate business models. He is looking to the committee for discussion and direction.

Kevin Hutchinson asked about provider directories. If deficiencies in the directories were discovered during rollout, what process would be used for their correction? Fridsma responded that it would depend on the nature of the deficiency. Some errors might be easily corrected by contractors. But the community should be engaged in resolving errors in use cases. He referred to the Direct project in which use cases were composed in text on a wiki. A similar process might be used if different standards overlap in support of a use case. The discussion should be translated into a consistent language, such as XML or UML, and conveyed back.

Co-Chair Halamka suggested that the committee would be involved initially through the Clinical Operations Workgroup. Fridsma agreed. He said that content specifications for the clinical summary are a top priority. Other priorities are certificates, provider directories, cost of lab interfaces, and vocabularies and value sets.

Jamie Ferguson agreed to convene the Clinical Operations Workgroup to examine these issues. Halamka, acting as chairperson in the place of Jonathan Perlin, who left to attend a party, said that Fridsma should commence work on clinical summaries and templated documents, laboratory interface, certificate interoperability and provider directories with ongoing advice and guidance from the Clinical Operations Workgroup and the Privacy and Security Workgroup.

Carol Diamond repeated her concern about the framework proceeding without policy direction. Halamka responded that policy did exist for certificates and directories and several other framework efforts. Fridsma said that policy discussions need to be integrated into the initiative. Diamond spoke about the need for a parallel process pending integration.

Ferguson reported on a meeting of ONC grantees at which Fridsma was not present. Grantees indicated that the clinical summary is no longer an issue for them. Their first issue is patient identity and matching identities across entities. The Privacy and Security Tiger Team recently convened a public hearing on the topic of matching records.

Nancy Orvis said that the Radiology Society of North America has agreed to partner with the American College of Radiologists to work on linking radiology terminology, ordering terminology, and resulting terminology with actual imaging. She asked if the organizations can get a sanity check against the S&I framework. Other professional organizations may be undertaking similar work and HITSP used to offer them that venue. Fridsma responded that the goal is to have a variety of different ways that people can engage in developing standards that harmonize across the various use cases. Opportunities in addition to those already delineated will arise. Resources are an issue. Arien Malec noted that many of these efforts are dependent upon volunteers; he cautioned about volunteer fatigue.

Wes Rishel said that based on his experience with the FACAs, standards should not be mandated in regulations until they have been used. By prioritizing certain issues, bottlenecks and stifling of innovation may result. The framework should gain more experience before taking on additional work.

The Co-Chair said that he had been reminded to take action on the minutes of the November meeting. He asked if members had any objections to the minutes as distributed with the meeting materials. No objections to their approval being heard, he declared them approved.

Action item #1: Minutes of the November meeting were declared approved by the Co-Chair.

6. HIT Policy Committee Charge to HIT Standards Committee – Digital Certificates (including data fields)

Co-Chair John Halamka reported that the Standards Committee had been asked to select or specify standards for digital certificates, including data fields, to promote interoperability among health care organizations, with EHR certification to include criteria that test their capabilities to retrieve, validate, use, and revoke digital certificates that comply with standards. The request letter did not designate an expected response date. Dixie Baker recommended that the X509 digital certificates are already specified as the standard with identified fields. The committee can recommend mandatory fields and agree upon the vocabulary to use in those fields. She said that servers should be included so that organizations with more than one entry point can exchange.

Walter Suarez reported that the Policy Committee Information Exchange Workgroup, of which he is a member, recently completed a first round of recommendations regarding provider directories. Directories are one of the priorities identified for the S&I work. The Policy Committee is expected to charge the Standards Committee with a review of the recommendations on provider directories. Halamka said that the directory recommendations dovetail with the question of organization-to-organization or server-to-server certificates and are also related to the Direct specifications.

7. NHIN Direct HITSC Review

Dixie Baker referred to her presentation slides. She reminded the members that the first technical review had been completed 6 months ago. Other members of the review team were Carol Diamond, David McCallie, John Moehrke, Cris Ross, and Walter Suarez. The objective of the review was to assess the extent to which the NHIN Direct's documentation was simple, direct, scalable, and secure. They reviewed five key documents identified by Arien Malec. Each member of the team individually rated each document on the four attributes. Recommendations were generated from team discussions. They concluded that the extent to which simplicity had been achieved could not be determined. They recommended the following:

- Make it simple – SMTP transport of S/MIME-secured content objects between entities
 - Clean up the core specification
 - Remove optionality
 - Remove necessity of sender to know the capabilities of the receiver
 - Remove TLS and S/MIME wrapping from the core specification as options for protecting against information leakage (see Security recommendations)
 - Do not require DNS as the only mechanism for certificate discovery and distribution; recommend a standard for certificate discovery and distribution

Regarding the attribute of direct, they could not agree on a determination. They recommended:

- Make it direct
 - Keep the NHIN Direct scope as intended – secure exchange of content objects from organization A to organization B
 - Keep content-agnostic
 - Sender should be able to send, and receiver should be able to accept, a variety of unstructured, semi-structured, and structured content
 - Content standards are generally controlled by national requirements such as HIPAA, Meaningful Use, and others
 - Default is human-readable content package

Although they agreed that it was scalable, they recommended:

- Clarify intended purpose and usage
 - Not well suited for workflows involving high-transactional-volume, point-to-point exchanges that require mechanisms to deal with complex discovery, addressing, and routing issues
 - We consider these workflow issues outside the control of basic NHIN Direct technology
 - Local policy may limit bandwidth requirements of attachments (e.g., large images) – again, outside the control of basic NHIN Direct technology

They determined it was secure but went on to recommend the following:

- Specify SMIME as standard for securing NHIN Direct content end-to-end
 - Remove TLS and message wrapping as security options in core specification – consider as potential security enhancements to be addressed in future implementation specifications
 - Address residual risk through policy direction regarding suitable content for subject fields

They observed several discontinuities and made an overall recommendation:

- Support Postel’s Law: “Be conservative in what you send; be liberal in what you receive” (a.k.a. Robustness Principle)
 - Enable senders to send the minimum information necessary, with high confidence of the identity of the receiver and with end-to-end security protection
 - Enable receivers to receive a content object without constraints on the format or coding of the information contained therein, other than assurance of its provenience and safety
 - Optionality among Standards should be limited, but services should have maximum flexibility (Fridsma’s corollary)
- Recommend that the HITSC adopt both Postel’s Law and Fridsma’s corollary as principles in the development of standards moving forward

Discussion

Members commented on SMIME, SMTP, and forcing TLS from HISP-to-HISP. TLS and SMIME are not different. They both need the certificates of the sender and the receiver. TLS is implemented as a machine-to-machine trust, not person-to-person trust. If one wants to control

the trust framework at a more granular level than machine-to-machine, the SMIME certificates, which can be allocated at the individual level, are used.

Wes Rishel asked for clarification on the recommendation. Dr. Baker said that the NHIN Direct focuses on exchanges between organizations, not individuals. The e-mail server has to find the digital certificates in either case. The Direct documents currently recommend that TLS be used even if the content is SMIME encrypted in server-to-server communication. The team recommended a change.

Rishel went on to suggest that both structured and unstructured versions of the data be sent so that the sender does not need to know the capabilities of the receiver. Arien Malec said that the recommendation would be used to make the specifications tighter and better aligned with the directions of the Policy Committee and the Standards Committee. He said that organizations should be encouraged to receive a wide variety of content. But it is also important to error if information is not received as expected. He used CLIA requirements as an example. Baker indicated that the recommendations do not preclude that response. The specifications say that the sender is to be so informed. There are acceptable and unacceptable reasons for rejecting a message. Messages should not be rejected because they are not structured. To do so would inhibit exchange from small providers.

Jamie Ferguson interjected that this is the clearest case of a standard overriding policy that the committee has encountered. The reasons for rejecting information belong in the policy domain; yet here the policy is being determined by setting standards. Halamaka agreed, saying if a message is rejected for a policy reason, an error should be sent.

Carol Diamond pointed out that it is not appropriate to reject the content because the sender does not know what applications or capabilities the receiver has. To do so could break the system. SMTP SMIME cannot be rejected simply because the receiver is running a more complex system than is the physician in a small practice.

Halamka said that the removal of the requirements to use DNS as a means of certificate exchange and for the core specification inclusion of XDR provides a transport mechanism that can be used for a variety of information. What that information is is within the policy domain rather than in the technical domain. He declared consensus, saying that Rishel's concerns can be followed up on via e-mail.

Walter Suarez pointed out that although everyone agrees that the sender can send and the receiver can receive any kind of messaging, unstructured to structured, there are some external forces that might require those senders and receivers to use a particular structure.

Members continued to debate the boundary between policy and standards. The Co-Chair said that the committee has not imposed policy guidance in the context of its technical discussion, and that through NHIN Direct, different kinds of exchanges of structured, unstructured, semi-structured data, and restrictions on the nature of the data should be enabled.

8. HIT Standards Committee Discussion and Next Steps

The next meeting is scheduled for January 12, 2011.

9. Public Comment

There were no comments from the public.

SUMMARY OF ACTION ITEMS

Action Item #1: Action item #1: Minutes of the November meeting were declared approved by the Co-Chair.

Meeting materials:

Agenda

<http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>

Summary of November 30, 2010 meeting

HITPC letter November 29, 2010

Presentations slides