HIT Standards Committee
Final Summary
Summary of the March 24, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to this meeting of the HIT Standards Committee, and conducted roll call.

2. Opening Remarks From the National Coordinator

David Blumenthal, National Coordinator for Health Information Technology, was present on the day before this meeting at the President's announcement about the passage of the health care bill. This bill has some indirect implications for the HITSC. It makes assumptions about the group's ability to empower many aspects of the health system, including accountable care, quality, measurement of quality, and the coordination of care. All of these will be impossible to realize without the success of this Committee, and it lends even more impetus to HITSC activities, creates more expectations, and moves the group forward with added momentum.

3. Overview of the Meeting

John Halamka, HITSC Vice Chair, noted that the meeting would include the usual workgroup reports and would focus on the remarks by Doug Fridsma on the Nationwide Health Information Network (NHIN) Direct interoperability framework.

4. Priority Setting and Synchronization with the HIT Policy Committee

John Halamka noted that the HITSC workgroup Chairs presented reports at the most recent meeting of the HIT Policy Committee (HITPC). The Clinical Operations Workgroup is working on vocabulary starter sets, and wants to make sure that code sets and value sets will be free and downloadable. The recommendation for broad families of standards with a floor of very detailed implementation guidelines was well received by the HITPC. The Clinical Quality Workgroup reported that it is focusing on retooling and stressed the importance of giving early indications of any retooling that will be necessary to ensure that the results are EHR-friendly. The Privacy and Security Workgroup reported on its efforts related to handling the timing of disclosure. Meaningful use does not require disclosure until 2013, but the Workgroup thought it would be important that the HITSC and HITPC align on the accounting of disclosures.

John Halamka reported that HITSC members have been seated within HITPC workgroups to discuss about privacy and security issues.

5. Implementation Workgroup Report on Implementation Starter Kit Hearing

Liz Johnson reported on the recent Starter Kit Hearing, and noted that the Implementation Workgroup received specific direction and several requests. The purpose of the meeting was not to solicit feedback on the Interim Final Rule (IFR), but to gather information. During the hearing, three main themes emerged:

1. Clear interoperability standards are needed. It is evident that there is not an identifiable set of standards for how to move information from one entity to another. A source of data is needed to understand how to tag data (i.e., how to know what is coming in and out of an organization). Specific comments from the panel were included in the information packet given to Committee members.

2. Specific tools and resources need to be made available. A number of organizations with such information came forward at the hearing. Liz Johnson said it is becoming evident that what ONC and the other sectors of the federal government are doing has use in the private sector. There must be links and synergy so that others can use the information that these government entities have.

3. More information is needed on meaningful use. Providers are focused on stage 1 only. The concern is that they do not understand what else they are going to need to do. If organizations focus only on stage 1, will they have time to get ready for stages 2 and 3?

Four overarching requests also emerged from the hearing:

1. Greater transparency of information, a cross-referenced catalog, and easy access to the necessary materials (a librarian for all of this information would be helpful).

2. Greater clarification of meaningful use, and a clear delineation between 2011, 2013, and 2015 requirements. Specifically, a request was made for a frequently asked questions (FAQ) page on the ONC Web site.

3. A clear, simple set of interoperability standards.

4. An ONC-sponsored forum for vendors and providers that would provide a less competitive forum for the exchange of information.

Liz Johnson noted that a true movement is coming about to share this information. The Workgroup is working on the blog to make sure that it is more accessible going forward. She also noted that at the hearing they collected a 4-inch binder of leave-behinds that organizations were willing to contribute to this effort.

In discussion, the following points were made:

- With regard to an ONC-hosted FAQ page, David McCallie wondered how they would deal with specific questions of whether the answers are authoritative. If these questions got hosted

on the ONC Web site, does that pose a regulatory issue? Jodi Daniel responded by explaining that usually, guidance is not regulatory. It is interpretive, though, and does hold some weight. In an FAQ environment, the answers are, of course, general. They are helpful to people in figuring out whether or not they comply, but they are usually more broadly applicable.

- Janet Corrigan asked whether people are aware that when the actual quality measures are selected for meaningful use, that there will be very detailed specifications for them. Almost turn-key specifications will be released soon.

- John Halamka noted that communications is going to be key. Retooling is going forward, and there will be clarity on primary care and specialty measures. It would be useful to have information on these issues linked to the FAQs.

- David Blumenthal asked a question regarding simple operability standards. There is an IFR that contained a set of standards and certification criteria, and there has been testimony from the Clinical Operations Workgroup that proposed a somewhat different approach after the publication of the IFR. Before, the suggestion was for a set of standards but not for implementation specifications. After the IFR, the Workgroup suggested families of standards and detailed specifications. He asked whether this reflects a change in thinking about what was required for 2011, or whether it refers to 2013. Liz Johnson responded by noting that for 2011, the requirements are fairly limited. John Halamka noted that the private sector wants to have one approach and does not want to retool as they move into 2013 and 2015.

- David Blumenthal asked about the potential impact of general counsel directing ONC that it cannot direct this field with guidance. Ann Castro indicated that this would make the Committee's job much harder over time, because the rules would have to change over time. John Halamka warned against putting this material into regulation because the climate changes so quickly.

- David McCallie noted that he heard two different levels of interoperability problems at the hearing. The detailed component is where HITSC and ONC are making progress. However, the issues heard at testimony were more at a higher level and related to the mechanism (e.g., how does a vendor get to the particular interchange) rather than the message.

- John Halamka noted that the industry is coalescing on a number of content standards and asked how transport will be addressed. The IFR specifies REST and SOAP, which does not provide any specificity.

- Janet Corrigan suggested examining some of the models that might allow ONC to disseminate this information without having to put it into regulation. She referred to the National Technology Transfer and Advancement Act. Cita Furlani suggested simply specifying the performance standards, because they addresses the goal without stating more or providing additional details.

- Wes Rishel pointed out the importance of developing an economic imperative for interoperability. If there is a compelling economic motive, that becomes the common platform.

- Karen Trudell pointed out that not all regulations are the same, and some do come out more quickly.

- Walter Suarez noted that people are clamoring for the "how." There is no intent, nor should there be any intent, of regulating the "how" in the sense of making rules to define mechanisms for organizations to put together all these standards and requirements. However, there is a need to develop a whole body of resources and literature and examples on different cases.

6. National Health Information Network (NHIN) Direct Interoperability Framework

David Blumenthal introduced Doug Fridsma's presentation and explained that NHIN Direct is an effort by the ONC to provide the best customer service possible for interoperability. ONC is hoping to provide a tool kit for those who want to accomplish interoperability at any level. The NHIN continues to be developed to answer the needs of a variety of organizations; the goal is to meet providers where they are, not where ONC would like them to be.

Doug Fridsma defined the NHIN as a set of policies, standards and services that enable the Internet to be used for secure and meaningful exchange of health information to improve health and health care. Health care information is being exchanged using the NHIN in a limited way. The plan is to continue and strengthen the system, and enroll additional participants. Support for this current system is strong and it will continue to be available.

In the fall of 2009, the HITPC established the NHIN Workgroup. Some of the assumptions that have come out of this group are that interoperability is not "one size fits all," and that groups will be at different stages of exchanging information. The NHIN needs to support different ways of achieving interoperability and maintaining privacy and security. It must start where groups are currently and help them get to the kinds of exchanges that are anticipated for 2013 and 2015. Within that framework, the HITPC NHIN Workgroup developed the following statements:

- Interoperability is not "one size fits all."

- Over time, information exchange should be broadened to foster existing and new exchanges, and support increased interoperability, always maintaining privacy and security.

- There is a need to support existing exchange and the foundation for the future and to be cognizant and supportive of state-level and enterprise-level information exchange. The work for 2011 should not inhibit more robust information exchange in 2013 and 2015.

NHIN Direct was established based on these principles. Doug Fridsma noted that NHIN Direct will only solve part of the puzzle. Other services can be layered on top (e.g., common provider index, developed trust mechanisms, complex multi-party routing, etc.). He then presented the NHIN Direct work plan, which includes draft specifications and services in 2 months, and a

deployment of early implementation by September or October, 2010. The project deliverables include specifications and service descriptions, process recommendations, policy recommendations, and targets relating to marketing and awareness.

As part of this process, the group wants to refine the modeling process and interoperability framework, as well as ensure that there is good communication throughout this process. A blog has been created to allow for enhanced communication with all concerned parties.

The discussion that followed included the following points:

- John Halamka characterized NHIN Direct this as an exciting way for interested parties to come together to test new things and try new ideas.

- David Blumenthal commented that it would be ideal if a group such as a state health information exchange (HIE), extension center, or even a private HIE could be included and discuss options with providers. He noted that a trauma center will need to exchange a lot of information, and will need a higher level of exchange than a small primary care practice. Input received points to the need to be flexible and innovative, and to keep options open for organizations of different sizes and abilities.

- David McCallie noted that the focus at first was on the simple aspect, the considerations of small offices that could be stood up without an HIE. The more important angle is the direct aspect, the ability to move information from point A to Point B without any side effects. That is a core requirement that should be preserved. He likened it to the difference between posting something on a Facebook wall versus sending a private e-mail.

- In response to a question, David Blumenthal explained that NHIN Direct is running in an open-source environment and will be a government service for the private sector.

- Janet Corrigan indicated that NHIN Direct might be a good way to whet the appetite of the industry, which will want to have more after they use it. She asked about whether the Committee should be considering measures that would encourage providers to use NHIN Direct, effectively driving them to it by giving them standards to meet.

- Marc Overhage noted that if a trauma center chooses the platinum version, and the other providers in the community are bronze, then the trauma center loses. Also, he noted that organizations like single solutions. Providers by and large do not have the energy to do things two or three different ways, especially smaller providers, and so a single solution is attractive. Finally, he urged clear communication about NHIN Direct.

- Doug Fridsma explained that this work cannot be done in the abstract. There is a difference between producing software in order to create a production environment, and producing software to see if the specifications are actually correct. NHIN is aiming for the second, not the first.

- Stan Huff suggested that depending on the outcome of the experiment, in the future the Committee might recommend some or all of it as a standard of implementation. In Utah, it is causing some confusion. The state is on the cusp of making a big investment in a propriety solution for a statewide health exchange. That will require a great deal of work, and the state sees NHIN Direct as a new tool that potentially could be part of the solution. He also noted that with open source, there is no guarantee that what is being produced is going to be interoperable. No part of the existing open consensus community was a part of NHIN Direct's creation.

- John Halamka clarified that the goal of NHIN Direct is to leverage well-described, existing business uses for transport of information.

7. National Information Exchange Model (NIEM)

Doug Fridsma shared lessons learned from the Health Information Technology Standards Panel (HITSP), including the following: standards are not imposed, they are adopted; standards should be harmonized and commissioned based on clearly articulated priorities; and adoption is accelerated by tools including vocabulary registries and easy-to-use sources for implementation guidance. As consideration is given about how to continue the work of HITSP, there should be a movement toward more "computational" specifications and ensuring that the use cases and standards can be linked from inception to certification.

Doug Fridsma described a process of bottom-up innovation within a coordination framework, and use case development and functional requirements. This represents an effort to harmonize existing standards, by developing implementation specifications and draft standards and then working with standards organizations to help fill in any gaps that are identified.

The NIEM started as a Department of Justice initiative, but the processes have now been generalized. The NIEM supported data integration and reporting for Recovery.gov and is used by HHS to support child and family services. The NIEM is recommended by the Office of Management and Budget OMB as a best practice, and is used by state and local governments.

Doug Fridsma explained that an implementation specification becomes a description of standards, services, and policies, such that an organization can implement them. The IFR requires that implementation specifications be supplied to the community in some fashion. Testable specifications must be created. A reference implementation is a way of testing to ensure that the specifications are correct. At every stage of reference implementation, there must be feedback. Testing must be done in real-world situations, and the ONC needs to serve as the coordinator of these pilot demonstrations.

In discussion, the following points were made:

- Chris Chute said that while the NIEM is many things, few would accuse it of being a model. There remains the question of how to carry out cross-application, cross-use-case harmonization in the absence of a model framework. What seems unclear is how to address the cross-use case harmonization.

- Doug Fridsma commented that there is not the equivalent of the RIM construct that helps with integration across the various use cases. However, the fact that there is not one does not mean that there could not be one. He acknowledged that there isn't an existing semantic model within the NIEM process at present. It may be possible to move forward significantly before having to address this.

- Wes Rishel raised a list of challenges that HITSP faced, as follows: badly chosen use cases, tending to focus on things that weren't automated; impossible deadlines; no feedback loop; and unmixable intellectual property. He asked how NIEM will deal with these issues. Doug Fridsma responded by noting that, regarding use cases, the goal is to listen to the community in a similar way as NHIN Direct, and solve the simple problems and the ones that people care most about. There needs to be some manner of structure or coordinating function for prioritizing among use cases. There will need to be some notion of how to choose use cases that is driven by is perceived as important. The problem of impossible deadlines has not been solved. Regarding intellectual property, Doug Fridsma said he is not sure there is a solution for that just yet, but it clearly is an issue that needs to be addressed.

- Wes Rishel noted that this represents an opportunity to demand changes inside the government of standards-development organizations (SDOs) that have been hard to accomplish. If some development money can be put towards this effort, the issue will be more well recognized, and potentially solved.

- Walter Suarez suggested transitioning to a domain-driven use case approach, in which domain experts around a particular group of messages and exchanges are gathered together to identify issues to address regarding harmonized standards and then work on them. He also suggested considering who the audience is going to be with respect to educational materials produced. Is the documentation going to be readable by a physician, by someone who does not work in health care at all, by an IT person, a vendor, a standards development group?

- It was noted that a more fundamental level of sharing among organizations would be useful. There should be a shared infrastructure for value sets, computable models that are the same representation across those organizations. That fundamental level of harmonization across the standard organizations is strategic and would add value.

- David McCallie observed that the challenge will be to maintain a balance between how much of this work and development is top-down and how much is bottom-up. Frameworks that are excessively top-down become irrelevant; those that are too bottom-up are chaotic. Grounding the work in real-world implementation and use would be the best remedy, and that is part of the design in this case.

- David Blumenthal commented on speculation outside the Committee that the NIEM is some manner of Trojan Horse for government control over health care information, that because it is a government-generated mechanism, it might make it inevitable that its information would be transmittable to the CIA, NSA, Department of Justice, etc. For the

record, he said, the answer to that question is, absolutely no. The ONC would not participate in a standards development process that led to that.

8. Privacy and Security Workgroup Update

Privacy and Security Workgroup Co-Chair Steve Findlay noted that the Workgroup is going to focus on consent management and its challenges. Also, it is reviewing existing security policy in Health Insurance Portability and Accountability Act (HIPAA) rules. Workgroup Chair Dixie Baker is on the HITPC's Privacy and Security Workgroup, which will be working with this group, and a new ONC white paper on consent management will inform these efforts.

Also, the Workgroup will be developing a series of four educational sessions on consent management in April and May. The HITPC will focus on policy issues; this Workgroup will focus on standards. Two of the four sessions, which will be open to the public, have been scheduled for April 1 and April 23.

9. Clinical Quality Workgroup Update

Clinical Quality Workgroup Chair Janet Corrigan explained that the Clinical Quality Workgroup is in a holding pattern, waiting for HITPC direction on 2013 and 2015 measures. Retooling efforts for 2011 are well underway, and will begin to roll into the National Quality Forum (NQF) starting in April. Work should be completed by early fall. As a part of this work, the Workgroup will be identifying value sets—there may be some opportunity to use this as a test case of sorts. The Workgroup communicated with the HITPC to emphasize that clarity is needed about the types of measures they are looking for 2013 and 2015, because the work timeframe is 18 months to 2 years. Most of the "low-hanging" fruit was picked for 2011, so heavier lifting will be involved going forward. Also, there is the possibility that there are more useful measures existing in well-developed HIT systems that have not yet been brought forward. Outreach is needed to determine whether some other measures can be brought in.

Floyd Eisenberg noted that at the last meeting, Wes Rishel asked whether C32 is enough information to manage quality measures. He recanted his previous answer and stated that it is not sufficient, but it is helpful. Some of the inclusion criteria are not there. CDA is the parent standard from which CCD could be a floor. CDA represents almost, but not entirely all, of what is needed.

At this point in the meeting, the committee approved the minutes from the last meeting.

> **Action Item #1:** Minutes from the last HITSC meeting, held on February 24, 2010, were approved by consensus.

10. Clinical Operations Workgroup/Vocabulary Task Force Update

Clinical Operations Workgroup Chair Jamie Ferguson noted that the rural providers and safety net types of providers are having particular difficulty digesting and implementing updates. Having a less frequent update schedule can be important for these providers. There was a desire expressed

at a hearing held the before this meeting to remove licensing barriers, and general support for SNOMED. The Workgroup also heard a consistent recommendation to enable and facilitate alternative display names. Clinician-friendly text that describes the code is necessary.

Plans for the Clinical Operations Vocabulary Task Force are to refine input from the previous hearings into recommendations for next month's meeting. They also plan to hold a public meeting some time between now and May to understand the framework of ONC contract awards and explore how that might relate to vocabulary work. In addition, a meeting is planned to explore the claim attachments in relation to meaningful use. Jamie Ferguson commented that the recently passed health care bill requires a claim attachments final rule to be issued by the Centers for Medicare and Medicaid Services (CMS). The potential addition of the CCD as one of the CDAs on the list could make that highly relevant for meaningful use, possibly in 2011, but more likely in 2013.

11. Report on Certification NPRM

Steven Posnack and Carol Bean discussed the certification programs that are being put together per the following statutory authority:

> §3001(c)(5) of the PHSA requires the National Coordinator in consultation with the Director of NIST to "keep or recognize a certification program or programs for the voluntary certification of HIT… such program shall include, as appropriate, testing… in accordance with §13201(b) of the HITECH Act."
>
> §13201(b) "…the Director of NIST shall support the establishment of a conformance testing infrastructure… may include a program to accredit independent, non-Federal laboratories to perform testing."

The testing bodies for these certifications will need to demonstrate that they are competent to test and certify EHRs and EHR modules. This relates to some of the issues that were not fully addressed in the interim final rule. Temporary and permanent certification programs have been established. The temporary certification addresses meaningful use Stage 1. The permanent certification looks at meaningful use stage 2. The HITPC made a series of recommendations, upon which this program was built. These recommendations include: (1) focus certification on meaningful use; (2) leverage the certification process to improve progress on privacy, security, and interoperability; (3) improve the objectivity and transparency of the certification process; (4) expand certification to include a range of software sources (e.g., open source, self-developed, etc.); and (5) develop a short-term certification transition plan.

The ONC is proposing to get reports form the certifying bodies on a regular basis and compile them on a Web-based service. That way, a potential purchaser could go to the Web site to see what products are certified against what criteria, determine what is missing, and how to fill in gaps. This will also be a resource for CMS, should there be need to validate certification numbers. In essence, the service would be a public-facing resource, available to any interested party.

Carol Bean explained that these programs are not certifying the integration of modules—they are certifying individual installations, unless it is an in-house, privately developed system. They are not going to certify anything related to meaningful use beyond the electronic health system itself.

The discussion that followed included these points:

- It was explained that if 80 percent of a system was self-developed and the remaining 20 percent is a certified, off-the-shelf product, then that portion of it would not need to be certified again. No double-certification will be necessary.

- The challenge with any regulatory process is catalyzing the marketplace. This program aims to provide an environment where it is fruitful for a number of organizations to become certifying bodies.

12. Public Comment

Robin Rayford publicly thanked the sound technician and the individual updates the Web site.

SUMMARY OF ACTION ITEMS

Action Item #1: Minutes from the last HITSC meeting, held on February 24, 2010, were approved by consensus.