HIT Standards Committee
DRAFT
Summary of the April 24, 2014 Meeting

ATTENDANCE

The following members attended the meeting:

Dixie Baker
Mike Lincoln for Steve Brown
Anne Castro
Jeremy Delinsky
John Derr
Lorraine Doo
Floyd Eisenberg
James Ferguson
Lisa Gallagher
John Halamka
Leslie Kelly Hall
Stanley Huff
Elizabeth Johnson
Rebecca Kush
Arien Malec
David McCallie, Jr.
Kim Nolen
Jonathan Perlin
Wes Rishel
Eric Rose
Christopher Ross
Sharon Terry
Andrew Wiesenthal

The following members were absent:

Keith Figlioli
C. Martin Harris
Anne LeMaistre
Nancy Orvis
Charles Romine

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 56th meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with two opportunities for public comment (three-minute limit), and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves.

Remarks

National Coordinator Karen DeSalvo remarked that that she appreciated the opportunity to finally meet the committee members in person. She announced the resignation of Chairperson Jonathan Perlin, who was recently selected as president-elect of the American Hospital Association. She thanked Perlin for his tireless work on behalf of health IT. She informed the committee that she is appointing Jacob Reider, ONC, as chairperson of the HITSC. Similar to the structure of the HITPC, Vice Chairperson John Halamka will officiate at meetings. Perlin will remain a member of the committee.

Review of Agenda

Perlin thanked everyone for their support and work, particularly DeSalvo for her extraordinary leadership in the aftermath of Hurricane Katrina. Much has been accomplished over the course of 56 meetings. He asked for corrections of, additions to, or approval of the summary of the March meeting as circulated. Hearing no requests for changes, Perlin declared the summary approved. He noted the importance of each of the agenda items.

Action item #1: The summary of the March 2014 HITSC meeting was approved.

Comments

Vice Chairperson John Halamka noted that given limited membership terms, the organization of members' expertise must be considered. He said that Doug Fridsma would present a logical approach for reorganization so that questions about standards readiness can be assigned to the appropriate domain. The NPRM agenda items offer an opportunity to frame HIT goals with operational realities. The challenge is to write regulations to empower users without stifling innovation. He announced that his employer had completed Stage 2 certification. As a side bar, he showed off his Google Glass and described its security. Consolazio called attention to changes in the order of agenda items.

Draft HITSC Workgroup Evolution Discussion

Doug Fridsma, ONC, presented a proposal for reorganizing the workgroups to align with the ONC interoperability strategy, which is to: support the success of Stages 1 and 2; continue to expand the value of the portfolio of standards to support ACOs, payment reform, DoD and VA systems acquisitions, and other administrative priorities; and modernize the standards portfolio to include newer, simpler, and more powerful standards. He proposed five workgroups in addition to a new steering committee: vocabulary and information models; document and data structure, transport and security, services and APIs, and certification and testing. HITPC members will be recruited to participate in the HITSC workgroups and vice versa. Cross membership is expected to enhance coordination across policy and standards as well as the education of all members. When the HITPC has a question about standards, the steering committee will describe the problem and assign it to a workgroup. The workgroup will develop recommendations for review by the steering committee. The steering committee will submit recommendations for HITSC action. As before, the HITSC recommends to HHS via ONC. Current members should contact Consolazio regarding their workgroup interests. Others interested in participating should apply through the ONC FACA database: http://www.healthit.gov/facas/faca-workgroup-membership-application. He asked for feedback.

Halamka repeated that HITPC requests must be triaged and assigned appropriately. The available expertise must be aligned with the work ahead. In response to a question about liaisons, Fridsma said that people who think across boundaries will be assigned those roles. If a use case does not fit one of the workgroups, then another group can be formed to deal with it. Andy Wiesenthal observed that he was unable to envision a use case that would not fit into one of the groups. He urged members to approve the plan without a lot of discussion. He went on to note that as one of the newer members who has been unable to connect with a workgroup, the reorganization will help to integrate recent appointees. He suggested that the workgroup chairpersons constitute the steering committee.

David McCallie expressed concern about a matrix organization being in danger of over-maximizing an axis. Most use cases cut across groups. HL7 and FHIR, which seems to be doing well, are at one level an API, at another transport, but also a data model, and possibly also about vocabulary. One must be sensitive to the vertical axis. The workgroups could be organized around deliverables. According to Malec, too much of the current work is use case-driven, which the new structure may serve to correct. With the example of immunization, the appropriate standard depends on the transmission. FHIR is an example of architecture. Any type of organization has a common failure mode. One is architecture type. He suggested adding a workgroup on architecture.

Cris Ross observed that although interoperability is crucial, it is only one issue with which his employer is struggling. There are issues with mapping, data portability, usability, workflow and efficiency, all of which the Implementation Workgroup has struggled with. He wondered how those issues would map to the new structure. Liz Johnson noted that when the Implementation Workgroup receives certification and testing questions, the decisions are already made. Regarding where EPs' concerns would be considered, Halamka noted that the HITPC sets goals, but often does not sufficiently consider the impact. He indicated that insofar as the terms of work have yet to be drafted, Fridsma can take these comments under consideration. When asked about the role of the steering committee, Fridsma mentioned coordination, standardization, triage, workgroup assignments, collation, and integration prior to action by the HITSC. He reminded the members that the charges of the workgroups can always be changed as time goes on. Leslie Kelly Hall inquired about consumer representation, saying that the consumer's voice is already fragmented. Fridsma acknowledged the need to involve consumers. However, the work of the HITPC Consumer Empowerment Workgroup should not be judicated by a HITSC workgroup. Consumer interests should be integrated into the fabric of standards. When issues arise, the structure will allow for integration across domains. The steering committee will be responsible for ensuring that consumer interests are integrated across workgroups. Jodi Daniel, ONC, said that consumers and providers should be represented on the steering committee, which will set direction for the workgroups. The steering committee can serve as a check prior to action on recommendations and send issues back to the HITPC as necessary.

DeSalvo observed that the HITPC expects the HITSC to be honest and realistic. Wes Rishel spoke about the need to work from two views. One is what can be done in a meaningful use cycle and what is the measurable impact. Getting started is the first step. On the other hand, some things take longer than the two-year cycle. The meaningful use objectives should determine the standards. All standards should relate to a performance goal. A liaison to the HITPC could help to assure that standards readiness is taken into account before recommendations are solidified. Measurable attestation goals should be ones that affect change. The HITPC is not always realistic about what can be accomplished in a meaningful-use cycle. Halamka agreed that certification-only criteria are not a great idea.

Jamie Ferguson pointed out that standards on workflow and usability are missing from the proposed workgroup structure. He suggested having a specific workgroup on that topic. Halamka suggested that the topic fell under implementation, certification and testing. Ferguson did not object. Malec talked about focusing on outcomes rather than requirements for inputs. The HITPC should focus on evergreen goals, and the HITSC can then parse them per cycles. Furthermore, there is a need to think beyond meaningful use. Halamka agreed that in the future certification can be based on outcome, rather than prescription. Ross expressed concern that too much was being placed in the new implementation and certification and testing workgroup. Documentation on who owns the various topics should be generated. Liz Johnson observed that someone should pay attention to the current state of standards, because some are not working. Eisenberg cautioned against establishing silos that do not reflect reality. When the structure of terminology does not work, it affects implementation. Rishel exclaimed that the greatest learning over time in sematic operability is the inseparability of structure and vocabulary. Wiesenthal called for action on the proposal. Halamka summarized the requested changes to the reorganization proposal:

- Add implementation to the certification and testing workgroup, recognizing that it is not a dumping ground
- Add architecture to services and API
- Add that steering committee is expected to ensure that consumer and provider interests are represented and integrated across workgroups and that there is coherence
- Refine titles and agree on terms of reference
- Recognize that the structure will change over time
- Establish a process for forming and retiring workgroups, subgroups, teams, and taskforces

Hearing no objections, he directed Fridsma to move forward with the reorganization. Perlin announced consensus on approval of the reorganization proposal, saying that the proposed structure indicates attention to the NPRM comments.

> **Action item #2: There was consensus for moving ahead with the general outline of the re-organization proposal presented by Fridsma.**

2015 Edition NPRM Comments

Implementation Workgroup Co-chairperson Liz Johnson prefaced her report on the topics assigned to the workgroup with general comments. There is no guarantee that the items contained in the 2015 Edition will be part of the 2017 Edition for stage 3. Any benefits to providers related to implementing an incremental update while continuing to gather data for attestation period in any fiscal year on 2014 Edition are questionable. The workgroup prefers that vendors focus on optimizing current code releases and begin preparation for stage 3. The proposals impose considerable cost burden on both vendors and providers. She acknowledged that the workgroup had not yet had time to consider the 2017 Edition. She opened the floor, saying that members may have other opinions.

Malec talked about bugs such as the separation of contents in transport. It may be more important to fix things than to start something new. In his opinion, performance across the HIT industry is very uneven. He strongly endorsed the idea that vendors should concentrate on improving Stage 2 rather than moving to incremental certification.

Rishel, a member of the Implementation Workgroup, observed that the proposed incremental certification has no obvious benefit to anyone. In writing regulations, staff should talk with persons who have ground-level implementation experience. They must be sensitive to the needs of users. Halamka noted that the timeframe for completing certification does not allow for proper implementation. Implementation begins before the software is ready for release. The time required for maintenance is not taken into account. Vendors and providers are still struggling with the 2014 Edition. Rishel questioned whether anything had been learned since 2009 on the timing of regulated change. Implementation is never complete. Installing a new system is very costly.

Jeremy Delinsky said that his employer will depend on market demand. He expressed concern about the reports that providers are being held hostage to their vendors because of the difficulty and expense of changing vendors. It should be made easier for providers to switch vendors. The HITPC must pay attention to this immediate issue. Halamka commented. The hardship exception allows for a provider's penalties to be waived in 2016 if objectives cannot be met due to some certification delay on the part of the vendor. However, the provider cannot collect incentives. He reported that many of his Boston colleagues say that their vendors are not meeting their business needs. A provider cannot change vendors while proceeding with meaningful use. Johnson suggested allowing quarterly reporting and attestation as a possible solution; a provider could then attest in one quarter and use the remaining quarters for upgrades. Perlin noted the need to think about future technologies and architecture and their certification. Ross said that some of the 2015 Edition is intended to allow industry to do that. His organization is changing vendors to a consolidated product. He suggested going to the workgroup's specific

recommendation. They moved to the slides, which listed the issues and questions assigned to the workgroup.

Regarding ToC, EHRs will not be able to distinguish between a 2014 and 2015 CCDA, although the 2015 Edition EHR technology must be able to receive both types. EHR technology certified to the 2014 Edition will not be able to receive and process a ToC using CCDA 2.0. There should be asynchronous bilateral upgrades. The Direct Edge Protocol Implementation Guide (IG) is too ambiguous and not sufficiently constrained. Although it would be good to have a performance standard, it is difficult to understand how it could be tested for certification. It would seem minimally that a library of derivative CCDAs would have to be available or a testing tool capable of generating the same would need to be available for vendors to prepare with. The workgroup said that for patient matching, using the year is sufficient. Ross paused for comments from the members. Halamka said that he agreed with everything. Malec said that if certification testing were sufficiently rigorous, it would not be necessary to consume large bodies of CCDAs. Fridsma talked about changing from conformance testing to outcome testing. The definition of interoperability, rather than testing, is the issue, and thinking about changing the definition of success to interoperability is recommended. A discussion about reduction of optionality should occur at the front end. Malec talked about how Surescripts needed to perform certification at several levels of receiving messages. McCallie said that the Edge protocol should be highly constrained and specific. Halamka talked about it being either highly constrained or not constrained. A HIST-to-HIST transaction can be established, though it would not have to be used. McCallie said that was the Direct concept. The Edge Protocol is a new approach. Malec recommending fixing the trust issue first. Ross referred to the location of the burden of proof that something is working well.

They moved to the slide on comments on transmission certification criteria. Members expressed no additional opinions.

On VDT, the workgroup said that it is good to push Direct Edge Protocol requirement, but this is a small part towards getting to HISP neutrality. It should not be required to send or receive health information from any Direct address without an established trust relationship. Certification should follow the approach used for 2014 certification of ToC summary transmission. Ross acknowledged that there was not complete unanimity of opinion among workgroup members. Halamka talked about how this was done by his employer. A participation agreement is required. Ross acknowledged that solving trust is of enormous importance. Malec said that the data holder has made a decision to disclose to a receiver. Having made a decision to disclose, is there a level of assurance that will go exclusively to the intended receiver? The trust question for the receiver is: Did the information really come from that organization? There are different trust issues depending on the situation. Direct Trust has done excellent work on identity. Referring to competing trust registries, Ross said that ONC could help to resolve the competing interests.

Lisa Gallagher mentioned a NSTIC pilot on trust marks for which the pilot sites will be extended. The committee should pay attention to the results. McCallie explained that Direct has converted a technical solution into a policy and business problem. Rishel called on ONC to intervene regarding interstate exchange. State HIEs are responsible for the localization of trust. Since they are ONC grantees, ONC bears some responsibility. Kelly Hall repeated comments about the importance of trust. A national framework to accommodate patients is needed. Dixie Baker observed that NSTIC is not applicable to this problem. It is a governance issue; governance should be revisited. Wiesenthal opined that the market itself will solve the problem via increased concentration of the industry.

Moving on to the slide on implantable devices, members made no additional comments. Regarding clinical summary, McCallie commented on LOINC, saying that the Stage 2 requirement for 100% coding in SNOMED is not possible. Complete 100% is never possible. LOINC can never keep up with changes in medicine. Johnson went to family history; members had no additional comments. She explained that the workgroup spent very little time on the questions related to safety enhanced design. Referring to the RFC 4 response that ONC has not provided guidance on types or number of test subjects for comment,

Reider explained that he expects a formal testing process, and that formative testing may be more meaningful than summative. Ross expressed concern about being over prescriptive through both the regulation process and the certification process. Reider announced that a hearing on certification is scheduled for May 7. Rishel declared that the workgroup did not distinguish well between certification by testing and certification by work product. Johnson agreed with his suggestion to revisit the topic for additional comment. After explaining the comments on the non-percentage based measures slide, on which members made no additional comments, Johnson said that she would not go through the remaining slides.

Halamka referred to the immunization registry and said that the public health community must be respected. Ross said that the public health and meaningful use trains are not on the same track. Parsimony for query response is the goal, according to Halamka. Johnson said that an IG would help to resolve the differences. DeSalvo said that public health officials want to use meaningful use and certification as opportunities to drive public health goals. Kim Nolan inquired about the immunization registry and the need to consider changing vocabularies. She suggested that a better understanding of the issue should be obtained prior to making recommendations. McCallie reported on hearing about efforts toward common public health reporting requirements by using CCDA for reportable conditions. But state-specific templates and interfaces are required, making this a difficult and expensive problem to resolve. Johnson pointed out that in California, reportable conditions vary across counties as well. Wiesenthal reported that CDC is working on common templates, though it does not have the authority to require changes.

2015 Edition NPRM Comments

Clinical Quality Workgroup Co-chairpersons Marjorie Rallins and Danny Rosenthal went through the slides on the topics assigned to the workgroup and summarized the comments. Starting with proposals on Health eDecisions and the ease with which EHR technology could be developed to consume CDS Knowledge Artifacts (KA), the workgroup said that it can be done. But standards are immature and likely to be technically challenging because there are no shared data model or standard data elements and value sets. The workgroup suggested constrain to a few ECA rules only and linking to specific eCQMs. McCallie explained his opposition to ECA. Rosenthal responded that voluntary certification offers an opportunity to see how the binding works; he agreed with the challenges. McCallie added that the notion of an order set standard is more tractable. A common order set catalog could be developed.

Eisenberg explained that his concern in the advantage of ECA rules includes vocabulary binding. The challenge is the event action rule. Clinical quality framework is a good place to do this kind of testing. The issue is how much to push via rules versus development. Malec said that population-based measures are generally decoupled from EHRs and may lend themselves to new classes of HIT. Someone said that specialty societies are generating measures, order sets, and so on, but they are not necessarily used. Is it the role of government to get the specialties to agree on standards? Reider said that ONC staff has met with several societies about this issue. Fridsma said that the value is getting clarify on guidelines so that they can be translated. Translating loose guidelines into something computable is a difficult but important.

Rosenthal went to the next slide. A CDS artifact repository and implementation guidance are needed. A tiered system should be applied to CDS KA (and CQM), focusing on common areas (80% labs, drugs, core patient demographics, and vital signs) so that they are aligned in a consumable way and can be exchanged and reused for many purposes. There is ability to map the CDS KA standard to data within the EHR technology (including medications, laboratory, and allergies information), which will be made easier by addressing the recommendations above. Regarding the ability to store and auto-configure a CDS KA in EHR technology, the workgroup did not understand what was meant by auto-configure. But if it means to consume and share, then a standard data model, logic, and implementation guidance to configure systems would be needed. On the feasibility of implementing the interface requirements defined in the CDS IG to make an information request, send patient data, and receive CDS guidance in near-real

time, the workgroup suggested that the likelihood of success could be increased if it were narrowed to just two or perhaps three of the seven interaction types listed in the NPRM. Concerning clinical quality, Rallins reported on measures and population filtering and whether current CQM standards (e.g., QRDA Category I and Category III) can collect metadata for the characteristics listed in the NPRM to filter and create a CQM report for a particular characteristic or combination of characteristics. The workgroup said that standards are not available for all of the listed characteristics. Such data may be in different systems, and not all providers have the capability to combine data sets. Vocabulary standards are not available for all characteristics. Context, in addition to vocabulary, must be understood.

A member commented on the need for a common, standardized data set. Eisenberg referred to an earlier letter (September 2011) regarding standardized data. SES and some other variables do not have standard definitions. HL 7 is doing some work on standardization of some data models. Malec expressed his concern with monolithic applications and tight coupling. Some vendors are able to support combining administrative and clinical data to produce population measures. The market should decide about interdependence or modularity. The inputs and outputs of modularity must be defined. Someone pointed to a policy issue of difficult or impossible workflows to capture and correct these data over time. The updated extension of Snomed CT uses income as percent level of FPL, which imposes an unreasonable burden for providers.

Pertaining to capture and export and the proposal to adopt the same criterion as in the 2014 Edition, the workgroup said that the standards have not been evaluated sufficiently. Members had no comments. Moving on to the 2017 rulemaking, the workgroup said that 2017 should focus on improving what goes in to Category I and improving its utilization on the receiving end. QRDA Category II was considered at a conceptual level when QRDA was first developed, but it has never been detailed or balloted in HL7. Category II has not been defined, so it is not yet a standard. QRDA Categories I and III have been balloted and are DSTUs. However, no action has been taken on reported errata since at least September 2013. CMS also has separate program-specific QRDA implementation guides that have caused confusion for implementers. No one is using QRDA III. Providers should not be submitting QRDA III data. Eisenberg repeated that Category II has never been balloted as a standard; it remains a concept only. Regarding Category III versus Category 1, Rosenthal said that the workgroup did not agree that III should be abandoned, but recommended a focus on I.

In response to a question on industry readiness to adopt the HL7 Health Quality Measures Format (HQMF) R2 standard for representing a clinical quality measure as an electronic document, workgroup members said that the standard is not ready. It has not been tested to determine if it can enable processing of eCQMs, although there is limited evidence it could be done broadly in an automated fashion. Much of the data required in the measure remains unstructured (if it exists at all). The quality measure value sets are not ready for support. If the issues with value sets are not addressed, then requiring a plug and play approach to electronic CQM specifications will likely result in a material decrease in the accuracy of the quality measurements. One way to address this issue would be to establish a centralized authority to create and manage value sets. Regarding unified, modularized CDS and CQM standards for the 2017 Edition, the workgroup commented that the underlying standards have not been sufficiently tested and implemented, nor has a repository been identified to make modular CDS components (CDEs) available similar to the work currently under development for the S&I Structured Data Capture. Until standards are harmonized, tested, and widely used, certification should be outcome-based. The testing and certification processes for the electronic processing of eCQMs should require minimal levels of processing capability while not requiring full adherence to all aspects of existing eMeasure complexity.

Halamka directed them to skip to the final slide. Rosenthal reported that supplemental data are useful only if the measures define how to use them. Such data may be reported in QRDA Category I if the CDA has defined it. However, Category III QRDA requires aggregate analysis, and such analysis requires that the measure provide the instruction about how the analysis should be performed. In a sense, supplemental data can be useful if their collection is feasible and if all QRDA Category I submissions are extracted to

allow a central site to perform statistical analysis. But if they are to be evaluated at the practice or hospital site, the measure needs to define their use and then, by definition, they are no longer supplemental.

Eisenberg pointed out that supplemental data analysis at the practice level is not useful and is possibly dangerous because of the small ns leading to erroneous conclusions.

Public Comment

Gary Dickenson of CentriHealth and the HL7 EHR Work Group read a written statement: Perfect vs. Good – Are Truth and Trust the Deciding Factors? Although the platitude about the perfect and the good as enemies has been repeatedly used in HIT for more than 25 years, the terms have yet to be quantified and operationalized. He suggested that the key distinction is whether interoperability actually produces health records and information that are fit for primary use. The paper health record, as the source document, is clearly fit for primary use. As such, it has characteristics that convey truth and trust, authenticity and assurance. He suggested that perfect is the metric that establishes exchange of electronic health records and information as fit for primary use at each downstream point of receipt and access. Thus, whether there is a paper source health record or its electronic health record counterpart, truth and trust (authenticity and assurance) are equally conveyed. He recommended that the HITSC examine the electronic health record and information exchange such that truth and trust are both measured and ensured end-to-end.

Alison Chi, American Immunization Registry Association, said that RxNorm does not support inventory management of vaccines and integration of bar coding. Her organization supports CDX and NRC codes

2015 Edition NPRM Comments

Privacy and Security Workgroup Chairperson Dixie Baker introduced new Co-chairperson Lisa Gallagher, who was appointed to ensure continuity when Baker's term expires in May 2015. Slides prepared by staff described first the proposal topic assigned to the workgroup, followed by the PSWG's recommendation and rationale. The Privacy and Security Workgroup (PSWG) reported on the NPRM 2015 Edition topics assigned to it, as well as some additional items requested by staff. Regarding the three paths to modular certification, the workgroup agreed that any purchaser should be confident that privacy and security are assured. Having each EHR module implement its own security solution (2011 approach) is not ideal; for the strongest security protection, each EHR Module would use a common set of enterprise-wide security services. Path 2 of the HITSC's 2013 recommendation recognizes this ideal. The 2014 approach (certifying EHR Modules privacy and security only at the vendor's request) presents the risk that an end user could purchase a set of modules that would not provide the protection needed to counter risks present in that environment. However, the privacy and security criteria are not equally applicable or useful to every criterion in each of the other functional areas (i.e., clinical, care coordination, clinical quality, patient engagement, public health, utilization) because each criterion is designed to address specific risk conditions that may or may not be present. The workgroup therefore recommended that ONC: revise each privacy and security criterion to specify the conditions under which it is applicable (similar to how the end-user device encryption criterion currently is written); and allow each criterion to be met using one of the three paths the HITSC recommended in 2013. This can be accomplished by modifying the wording of the criteria in the regulation to include the condition(s), or by providing the condition(s) as guidance. In either case, the condition(s) and paths would need to be incorporated into the test procedure. If this approach is accepted, Baker said that the PSWG would be happy to work with ONC staff to help with the implementation. In response to a question from Halamka, Steve Posnack, ONC, said that staff has worked to include HIPAA regulations in certification. However, certification can be redundant, overly specified, or unnecessary because of other factors working in the environment. Baker said that organizations should be able to assume security of protected information. McCallie declared that if the policy is that privacy and security should be a part of certification, this is the least intrusive means possible. Posnack agreed, saying the limits of what certification can ensure must be recognized. Wiesenthal asked about put-together components, which imply plug and play. Gallagher

reminded them that the recommendation pertains to certification of modules only. Posnack said that the EHR Module is defined within the scope of certification. Complete is being discontinued. According to McCallie, the definition of module rules out robust testing of security. Penetration testing is the ideal. Someone asked about connected pieces that are not tested: Who is responsible? It will be difficult for small isolated providers to do full risk assessments.

Regarding the proposal for two-factor authentication (2017), the PSWG reported that it cannot recommend a specific set of standards for this purpose. The workgroup members were not aware of any meaningful use measure or other health care policy that would warrant a general requirement for a two-factor authentication capability. However, if the ONC decides to add such a requirement, the PSWG suggested that a product presenting proof of having passed a DEA audit of its two-factor authentication capability should be considered as having met the certification requirement for two-factor authentication for an EHR, but not necessarily for remote access. The PSWG observed that the two use cases (e-prescribing of controlled substances and remote access) highlight the need for health care engagement with the NSTIC program. Regarding the proposal to eliminate the functionality for select users to disable audit logging, the workgroup suggested no change from the 2014 Edition.

Baker said that organizations may want to turn off the audit log because the volume of transactions fills up storage space. McCallie added that maintenance may require shutdowns. The turn-off itself is auditable. Returning to two-factor authentication, Malec asked about the definition of remote access, saying that differentiating remote and non-remote access is not good security policy. Baker said that the distinction and requirement came from the HITPC Privacy and Security Tiger Team; she did not recall the definition. Malec talked about different firewall configurations, arguing for the removal of the term "remote." Baker said that though the policy recommendation is actionable, something pertaining to who, what, where with what device should be added. Others agreed. Anne Castro wondered about a qualification to turning off audits. Baker reminded her that the recommendation pertains to certification. The product itself cannot differentiate the purpose of turning off the log.

Moving on to the query action in section 7.6 of the ASTM E2147 standard, the PSWG is not aware of any need to define query or any problems developers have encountered regarding query. The workgroup recommended that Section 7 be referenced in its entirety, rather than individually enumerating those parts of Section 7 that are not labeled optional. Concerning a baseline or minimum set of actions for the purpose of audit, the PSWG was opposed and did not recommend that ONC specify other actions in an updated standard for the 2017 Edition, or that ONC consider any additional standards. Since OCR has not yet issued its final rule, the PSWG believes it is premature to include an Accounting of Disclosures criterion at this time. Moving on to other items, Baker said that the PSWG encourages and supports further piloting, direction, and standards development for Blue Button Plus (BB+). However, prescribing specific standards that BB+ must use could potentially constrain the momentum surrounding its technological advancement. The PSWG believes that ONC's solicitation for comment on standards related to disaster preparedness is premature; there are unresolved policy questions that must be answered prior to any attempt to determine what standards EHR technology should use to support the provision of care in disaster situations. Posnack explained the intent of the question on 7.6, and Baker agreed to re-examine the issue.

NSTIC Hearing Update

Baker thanked former Co-chairperson Walter Suarez, calling him the most conscientious and reliable colleague with whom she has ever worked. Suarez will continue as a member of the workgroup. He reported on the March 12 NSTIC hearing, of which he was the primary organizer. He showed slides and reviewed the objectives, listed the invited panelists and the panels, and gave an overview of each of the four panels. NSTIC was established three years ago by executive action. He reviewed slides that summarized major conclusions from each panel. Overall, workgroup members and others gained a better understanding of NSTIC as collaboration between the public and private sectors to achieve the capability

for federated identity both within the United States and throughout the world. NSTIC should be viewed not as a set of new standards, but as an effort to provide a framework (with common principles) that leverages existing standards already in wide use. These are the same standards used in the new Blue Button+ standard. The use of high-assurance patient identities can improve the matching of patient records, thereby enhancing patient safety and the quality of patient care. Active health care industry involvement with the IDESG and NSTIC community is needed to help ensure that health care use cases are addressed. Increased collaboration among government health care agencies, primarily FDA, DEA, CMS, and ONC, is needed to uniformly implement NSTIC in federal health care activities. Standards should be evaluated for maturity and adoptability, using HIT Standards Committee evaluation criteria. Committee members were invited to review the written submissions at http://www.healthit.gov/facas/calendar/2014/03/12/privacy-security-workgroup's-nstic-public-hearing.

Discussion

Halamka referred to slide 5 and wondered how to get organizations to commit to OAuth and OpenID. He also referred to his RFID inventory, asking which is his patient health care identifier. He has many identifiers for different purposes. Kelly Hall suggested that he simply select one or two. McCallie said that it is a business, not technology, problem of issuing trust and is analogous to but more complex than the Direct Trust problem. Many want to be the origin of trust. Gallagher commented that NSTIC is defining an ecosystem for citizens to use. The INOVA pilot offered patients an opportunity to create digital identity. The CMIO indicated that it was a business advantage to simplify the intake process. Another pilot at Georgia Tech is defining components of trust that can expand across individual communities. The trust marks research is expected to be applicable in several sectors. Sample description documents have been produced.

Malec talked about NSTIC solving password problems for patients. But for the provider sector, the on-behalf-of relationship problem must be solved. Gallagher responded that one of the potential pilots would look at a related issue. Ross asked about bringing one's own device: What may be the solutions? What about the suitability of NSTIC? According to Gallagher, some part could possibly be leveraged. Suarez said that the verification of the individual is the first step. Halamka reported that Google Glass is registered and a physician logs in, is authenticated, prints a code, and can walk into the assigned patient's room.

Joy Pritts, ONC, clarified that NSTIC can mix and match levels of assurances. McCallie said that the real issue is getting people to agree to participate in the ecosystem, which involves trusts and contracts. Vested interests prevent a national system for identity trust. Suarez announced a conference at NIST June 17-18. More information is forthcoming.

ONC Updates

Steve Posnack announced that the draft FDASIA report, a joint effort of FDA, ONC, and FCC, has been posted for public comment. He urged members to review and comment on the draft report. The report includes a proposal for ONC to lead a HIT safety center. A workshop at NIST (with a webcast) on the content of the report is scheduled for May 13 -15. Hearings on topics related to certification and meaningful use are scheduled for May 7, 13, 20 and 27. The next HITSC meeting is scheduled for May 21.

Public Comment

None

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the March 2014 HITSC meeting was approved.

Action item #2: There was consensus for moving ahead with the general outline of the re-organization proposal presented by Fridsma.

Meeting Materials

Agenda
Summary of March 2014 meeting
Meeting presentation slides and reports