HIT Standards Committee
DRAFT
Summary of the September 18, 2013 Virtual Meeting

ATTENDANCE

The following members attended the meeting:

Dixie Baker
Steve Brown
Anne Castro
John Derr
Floyd Eisenberg
Jamie Ferguson
Keith Figlioli
Lisa Gallagher
John Halamka
C. Martin Harris
Leslie Kelly Hall
Stanley Huff
Elizabeth Johnson
Rebecca Kush
Anne LeMaistre
Arien Malec
David McCallie, Jr.
Kim Nolen
Nancy Orvis
Jonathan Perlin
Wes Rishel
Charles Romine
Eric Rose
Sharon Terry
Andrew Wiesenthal

The following members were absent:

Jeremy Delinsky
Lorraine Doo
Christopher Ross

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 51st meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with an opportunity for public comment, and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Remarks

Farzad Mostashari, National Coordinator, remarked on his worries at his final meeting with the HITSC. Nothing in the future is more difficult that what has already been accomplished. Implementation, validation, and testing prior to more rigorous certification is an important accomplishment. In the next 12 months, it will be necessary to make sure that the identified standards work as intended. Universal implementation is key. Interoperability cannot be delayed. Stage 2 cannot be postponed although the HITPC may discuss an extension of Stage 2. Balance must be considered. The needs of the situation must be met. The sustainability of HIEs depends on selling what people want to buy. What is the business case? What is the incentive for sharing information? The readmission adjustments have created a business case for EH sharing with post-acute care. Voluntary certification for post-acute providers is under consideration. Mostashari went on to acknowledge the difficulty of reducing readmissions. Notifications are important as well. Identification of care gaps is essential for population management. The gap between the prescription and the fill must be identified in medication adherence. Can standards support the flow of this information? Although one hopes the market will respond, the market sometimes fails. Other items on the worry list are support of portability and tracking cross vendor exchange. Finally, patient-mediated exchange and the accompanying concerns with data integrity and provenance is on the list.

Review of the Agenda

Chairperson Jonathan Perlin noted that this 51st meeting represented a transition. He talked about the importance of each of the items on the previously distributed agenda. He referred to the summary of the August meeting, which had been circulated with the meeting materials. Perlin asked for approval of the summary as circulated. No objections were heard. Perlin declared the summary approved.

Action item #1: The summary of the August 2013 HITSC meeting was approved.

Comments

Vice Chairperson John Halamka commented on his agreement with Mostashari's remarks. He commented on the importance of the agenda items, as did Perlin.

Clinical Operations Workgroup Update on Images

Clinical Operations Workgroup Co-chairperson John Halamka said that the workgroup convened three meetings and heard from several experts. Chairperson Jamie Ferguson explained some of the background information obtained from discussions with experts. He described a framework for consideration of use cases, recognizing assistance from David Clunie. Each use case scenario must define the actors, actions, content, initiation, and the systems prior to analyzing and recommending payload packages, protocols and modalities, and image quality. He told the members that the workgroup had focused on VDT use cases. View involves select, navigate, display, interact, measure, and analyze. Download may be to a local machine or media for purposes of using, archiving, or sharing. Transmit to a third party may be to a provider, an archive, or an analysis service. For each, who, what, when, where, and why must be considered. The scenarios inform the requirements for protocols.

Ferguson explained the meaning of zero footprint—no helper apps, plugins, applets, Flash or SilverLight. There is absolute zero—HTML pre-5, frames, tables, and images—and almost zero—JavaScript +/- and HTML5 Canvas. Flash (etc.) dependency pretends to be zero. Thick client spawned by a browser (or EHR app) is definitely not zero. He differentiated architectural considerations. Push architecture is easy and tempting, involves duplication of storage, and may require change management. Pull architecture uses federated and distributed queries, centralized image storage, and presents problems when links go stale or enterprises go out of business. In a brokered, hybrid, or clearing house model, an intermediary holds

images transiently. The sender pushes; then the recipient is notified and pulls. This is analogous to DropBox file sharing service and Filelink email.

He said that there is considerable experience to learn from, such as the Canadian regional repositories and the UK (IEP). The workgroup now must define a minimum set of use cases for image sharing before analyzing available standards. Probably no new standards are needed, but improvements or implementation guides may be required.

Halamka acknowledged that the testimonies revealed standards of which he had not previously been aware. Much is available with DICOM. He referred to ecosystem enablers and contrasts with the banking sector. Ferguson requested advice from the committee members on identification of use cases.

Discussion

Eric Rose talked about enablement of transport of a binary object that is not free text being in scope. According to him, there are three categories of image data. One is being able to transport diagnostic-level images from repository to repository. The second is the actual image for use by subspecialists, for instance, in surgery. The third is the radiologist's text report. PCPs do not want or need images for diagnostic analysis.

David McCallie declared that in addition to VDT, query should be added to the use cases. He agreed that the exchange of reports is important and went on to suggest that getting as close as possible to zero foot print be an early deliverable.

Arien Malec observed that 95 percent of the use cases not currently covered consists of textual format radiology reports, but 5 percent of unmet needs cases involves complex referrals with multi-specialists, particularly oncology and neurology. At the present time, the images for the complex cases are typically exchanged by being hand carried by patients. He requested that these intensive, multi-referrals be included as a use case.

Ferguson asked Leslie Kelly Hall for her opinion from the consumer perspective. Kelly Hall responded that she agreed on the importance of expediting the exchange of images. In addition, consumer groups are advocating for the capture of level of exposure so that patients can monitor their exposure and pass the information on to their next providers.

Halamka related his familial and professional experiences. Transporting by DVD is limited by the use of different readers and the rights to execute proprietary codes. When ED trauma patients are transferred to a higher level facility, the exchange of diagnostic-quality images prior to their arrival is desirable. For instance, the image may be needed to prepare for surgery.

Dixie Baker asked about resolutions. Ferguson replied that quality includes resolutions. The radiology community representatives indicated that there are existing standards for diagnostic-quality resolution.

Ferguson summarized. Four use cases were identified: reports for the PCP's use, which may or may not include images of non-diagnostic quality; images for specialist referrals with specific requirements for analysis; diagnostic-quality images and reports for consumer-mediated exchange; and information for consumer tracking of exposure.

Anne LeMaistre said that one should not assume that the PCP has lower requirements. PCPs serve different roles. Halamka explained that they can have a choice with escalating capability for image quality.

Andy Wiesenthal observed that the radiologist should also designate the slices of images that are most relevant to the diagnosis. Then the receiver could choose which to receive. The radiology or other specialist should serve as a filter. Ferguson referred to this option being captured under a full set.

Halamka noted several policy and legal issues in image exchange. What must be saved for the medical record? What about a pointer that may expire? Baker brought up accounting for disclosures. Mostashari reminded her that accounting for disclosures does not apply to transfers made by the patient. By focusing on VDT, the disclosure issue can be avoided. Rishel talked about a forensic data bank.

Ferguson announced that he had received sufficient input to continue the work of the workgroup.

Keith Figlioli reported that experiences of NHS Scotland should be explored. Halamka agreed to follow up.

Scenario-Based Testing Update

Scott Purnell-Saunders, ONC, Office of Certification, reported that in 2013, ONC staff: developed a proof of concept including a draft test scenario; piloted a draft test scenario with two ATL-vendor pairs; reduced testing time and test set-up burden; outlined plans for developing more scenarios; and released draft testing scenarios for public feedback. Plans for the additional scenarios are based on a clinically-plausible workflow that: for group 1 follows a patient from contact with an EP or EH through care and follow-up and will be available October 2013; for group 2 follows an EP or EH from patient care through public health and clinical quality measure reporting and will be available 2014; includes all of the 2014 Edition EHR Certification Criteria; develops into a library of testing scenarios; and will be developed and created by multiple sources, and vetted and approved by ONC. Group 1 deals with encounters and the scenarios are intake, interoperability intake, care orders, care results, and post care. Group 2 consists of reporting, privacy and security, and system. He concluded by reminding members that the group 1 scenarios are available at: http://www.healthit.gov/policy-researchers-implementers/2014-edition-draft-test-scenarios. Feedback is invited and can be submitted: http://oncprojecttracking.org/browse/CERT.

Q&A

Baker inquired about the 2014 Edition, which no longer requires that modules be tested specifically for privacy and security. What would trigger a module being tested against the security scenario? Purnell-Sanders responded that a vendor has a choice of options. The pilots indicated that the avoidance of repetitive preparations results in more efficient processing. Baker pointed out that the scenarios are not likely to trigger security testing. The scenarios make it more difficult to determine a need for security testing. Purnell-Sanders assured Baker that he will take her comment back to his group.

ONC Policy Update

Jodi Daniel, ONC, described the FDA Safety and Innovation Act section 618, which requires the posting of a report on the FDA, FCC, and ONC websites by January 2014. The report is to contain a proposed strategy and recommendations on a risk-based regulatory framework pertaining to HIT, including mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The HHS secretary, acting through the FDA commissioner and in consultation with the ONC National Coordinator, and along with the FCC chairperson, used the HITPC FACA structure to convene a workgroup. The FDASIA Workgroup was charged to provide input on issues and concepts identified by FDA, ONC, and the FCC to inform the development of a report on an appropriate, risk-based regulatory framework. Members deliberated for three months and considered information from the three agencies, public comments, and feedback from the HITPC August 7, 2013 meeting. The workgroup's output consisted of: a taxonomy for considering the parameters of HIT and what HIT might be considered for a regulatory framework; description of the current regulatory frameworks, including perceived ambiguities, deficiencies, and duplication; suggestions to promote innovation in both the short and long-term and maintain patient safety; recommendations for a new risk framework, including the stratification of HIT by risk and assessment of regulation need, and use cases.

Daniel presented the recommendations, all of which were approved by the HITPC at its September meeting. The definition of what is included in HIT should be broad but with exclusions. The patient-safety risk framework and examples should be used as building blocks to develop a more robust and transparent framework that allows application of oversight by level of risk. The agencies should address the perceived ambiguities, deficiencies, and duplication. New framework(s) with some of the characteristics aimed at stimulating innovation as identified by the workgroup may be helpful. Substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful, except for:

- Medical device data systems (MDDS)
- Medical device accessories
- Certain forms of high risk clinical decision support
- Higher risk software use cases

For the regulated software, it will be important for the FDA to improve the regulatory system to accommodate the characteristics that make software development, distribution and use different from physical devices. The new risk framework(s) should support reevaluation of what is currently regulated as well as new HIT.

The workgroup reiterated the following IOM recommendation. Vendors should be required to list products that are considered to represent at least some risk and a non-burdensome approach should be developed for this. Better post-market surveillance of HIT is needed. An approach is needed to allow for aggregation of safety issues at the national level, including federal support to enable this. FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices that discourage or limit the free flow of safety-related information. How to organize the governance of this should be addressed by a cross-agency group, which should include key stakeholders. Approaches would be provisional, to be re-examined periodically.

And the workgroup also made the following recommendations for national accountability:

- Outcomes assessment rather than product definitions
- Use of international/national standards for quality process – measureable and transparent
- Use of international/national interoperability standards to lower the entry cost
- Encourage configuration and extension to support process and solve problems
- Transparency of product and results
- Support ability to experiment or iteratively develop
- Aggregation of safety issues at a national level

For local accountability, it recommended: design, document, and prove a local control system, which could be co-owned with a vendor; and accredit the software implementation process, e.g., through an entity such as JCAHO. The local accountability scope should include the following:

- Local configuration of software
- Local extensions of software
- Ability to iteratively develop, implement, and measure changes
- Integration with medical processes
- Training of end users
- Sharing of lessons learned
- Surveillance by the organization
- Post-implementation testing

Specific recommendations were made for ONC:

- Increase the flexibility of compliance by defining the desired features, avoiding specific implementations in the description, and increasing the flexibility of compliance certification

- Avoid requirements dependent on effectively a single source
- Increase predictability by staging the definition of the requirements versus having a defined roadmap of features and establishing re-certification criteria

Specific recommendations were made for FCA:

- Actively establish a policy of "Enforcement Discretion" for lowest-risk HIT, where enforcement of regulations is inappropriate
- Assess exemption from GMP for lower-risk HIT
- Expedite guidance on HIT software, mobile medical apps and related matters
- Establish internal coordination on HIT software, and mobile medical apps policies and regulatory treatment
- Use external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA

Additional funding may be needed to appropriately staff and build FDA expertise in HIT and mobile medical apps.

According to Daniel, representatives for ONC, FDA, and the FCC will consider the recommendations of the FDASIA Workgroup in conjunction with all 39 comments received through the Request for Comment. The agencies will issue a report for a proposed strategy and recommendations for a risk-based regulatory framework for HIT, including mobile medical applications. She emphasized that these are recommendations to the agencies.

Malec explained the background of the congressional action. It was based on FDA draft guidance for a new class of devices pertaining to contrivances for diagnoses of disease, which have implications for CDS. Most EHRs are now in a form that can be viewed on devices and therefore may be classified as devices. If something is readable on a device, where is the line between mobile device and EHR? Did the FDASIA Workgroup consider that question, and did it look at who should regulate HIT software? Daniel admitted that she was unable to recall discussion of the first question at any of the 35 meetings she attended. Regarding whether CDS was in scope, according to the risk framework, some CDS is high risk, and other is low. The workgroup stayed away from considerations of which agency should regulate. She referred to the criteria in the risk matrix. Malec observed a looming issue; he heard that Congress did not intend to have software regulated under FDA oversight.

Rose acknowledged that the issue is hugely controversial. Apparently the workgroup did not consider clinicians' frustration with software defects, such as EHR miscalculations and showing pages for the wrong patient. These defects affect safety and should be regulated. Why was there no discussion of defects? Daniel responded that the workgroup was charged to identify issues in and scope of regulation. It was not asked to identify what should or should not be regulated although there was some discussion of that as a concern. Rose suggested doing more work on understanding problems and defects.

Kelly Hall pointed out that EHRs are currently under FDA authority, but the FDA has not acted on that authority. Daniel said that the workgroup members talked about avoidance of regulatory duplication with ONC certification. FDA staff is working closely with ONC staff.

Malec opined that the current registration under section 510 (K) works well and does not require fixing.

Daniel went on to report on the status of the HITPC's work on meaningful use Stage 3. The HITPC approved the Meaningful Use Workgroup's framework, which consists of the following "outcomes" that are consistent with the National Quality Strategy Priorities: improving quality of care and safety; engaging patients and families in their care; improving care coordination; improving population and public health; affordable care; and reducing disparities. The workgroup's recommendations will be submitted to the HITPC in November and will consist of: detailed recommendations on functional

objectives expected to build on the outcomes framework; the potential for an optional functional deeming pathway for attestation; and eCQMs.

Daniel announced two upcoming HITPC virtual hearings: advance directives on September 23 and accounting for disclosures on September 30. The HITPC Certification and Adoption Workgroup has been charged with recommending a process for prioritizing HIT capabilities for voluntary EHR certification that would improve interoperability across a greater number of care settings, including ineligibles. John Derr and Stan Huff are liaisons. The ONC Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments was published September 9.

Q&A

There were no additional questions.

ONC Standards Update

Doug Fridsma referred to his detailed activities matrix, which was circulated in advance with other meeting materials. He described current priorities for the S&I Framework in three time frames. Short-term priorities (0-6 months) are: structured data capture (SDC), query strategy and query basics (DAF), APIs, and quality and CDS. Mid-term priorities (6-12 months) are the same as the short-term priorities. Long-term priorities (beyond12 months) are SDC, targeted query via DAF, and EU-US eHealth Cooperation.

He went into detail on SDC, which will provide an infrastructure to standardize the capture and expanded use of patient-level data collected within an EHR. The use case focuses on the generic functionality required to access a form or template, generated by a CDE, form, or template library, displayed in an EHR system, and saved or stored in a structured, standardized format sent to an external data repository.

The Technical Work Stream Workgroup focused on the development of four guidance areas: CDE attributes, form and template structure, EHR interaction, and auto-population. Two implementation guides are targeted for development based on REST/OAuth and SOAP/SAML. Technical work streams consist of one on forms and another on standards. A standards solution plan has gone through consensus and will be established after the publication of the IHE ITI Volume 10 Framework with updates made to the IHE RFD Profile. The Public Health Workgroup is reviewing user stories. Pilot outreach to EHR vendors is ongoing and includes GE, Greenway, and QuadraMed.

Fridsma continued, moving to a description of the data access framework (DAF), the value of which is expected to be demonstrated through two work streams that will enable providers to access their own patients' data both locally within their organization and also from an external organization. Local data access is a standardized way for providers to access their patients' data within the health organization's internal HIT system. Targeted data access is a standardized way for providers to access a known individual patient's data from an external organization. DAF will leverage existing industry standards to create a framework that demonstrates modularity and substitutability for a limited set of standards combinations based on identified business requirements of the community. It will be built incrementally by first focusing on local access via intra-organization query and then targeted access via inter-organization query. Finally, multiple data source access via distributed queries is a future goal but is not in-scope for this initiative. The initiative participants are defining the use case for local access, which will focus on enabling a standardized way for providers to access already documented patient data within the organization. The data can be accessed based on a specific clinical criteria (for example, HbA1C >8 percent) or document metadata (document type, author, date created), both at the individual patient and population levels. DAF launched in July and achieved charter consensus on August 28. Use case discussions kicked off August 14 and the User Story Workgroup launched August 29. The community is

reviewing close to a dozen user stories and prioritizing key ones for inclusion in the use case. Patient portability is one example.

Also, a IHE short proposal will be submitted to the ITI committee for both local and targeted data access work streams by September 29. The Targeted Data Access Work Stream Workgroup will be working on use case development from late October through December 2013.

Next, Fridsma referred to, showed, and talked about the activities matrix spreadsheet. The matrix listed each of the standards topics identified by the HITSC and staff for the workplan many months ago, the current status of each cross-walked with the S & I projects, potential new areas for S & I development, and ballot status, along with priority categories. He requested input on priorities.

Discussion of Priorities

Halamka reminded the members that the workplan began with listing gaps in standards per possible Stage 3 requirements. The list is a long one. Now they must look at advancements and implementation, consider the resources limited by volunteer time, and take into account the environment. At the October meeting, they will reduce the list to a realistic workplan.

McCallie observed that much information had been reported very rapidly. Regarding data portability and DAF, what is the patient use case? Fridsma replied that one use case is the patient who wants her record in order to move to another provider. Another use case is asking questions to get responses from the EHRs. He added that patients who move to new providers and new systems should not be penalized. McCallie said that any export-import format would have to be standard based. However, the second use case may not need to be standards-based.

Nancy Orvis indicated her approval of the three priority categories. She urged maximum use of the Canadian and UK experiences. She wondered where members and their respective organizations can best engage. Fridsma replied that that is something to take into account in prioritizing. He instructed the members to use the matrix to individually designate priority preferences. Staff will compile the members' responses to use to target their energies. Orvis related a personal experience with receipt of a hard copy discharge summary in lieu of the required electronic copy and wondered why and to what extent this is happening. Fridsma directed her to the use of the spreadsheet to add topics and designate priorities.

Rishel acknowledged that he was out of order. Though his experience as a volunteer board member of a HIE in rural area of California, he learned that certified vendors are imposing charges for running lab interfaces. This is a barrier of which the committee members should be aware. There is a difference between being certified for something and actually doing it. He said that his comment may be more closely related to the S&I Framework's documentation of the trial use of a standard. A standard set of questions is needed for reporting the results of a trial. Perhaps the Implementation Workgroup should take this on. Fridsma acknowledged receipt of Rishel's suggestion.

Baker agreed with Rishel that many barriers do not easily fit into the topics of standards or policy. She pointed out that when ESMD was presented to the Privacy and Security Workgroup and the Clinical Operations Workgroup, she had asked what ONC needs from the workgroups pertaining to the ESMD digital signatures. She requested a response from Fridsma. The Privacy and Security Workgroup was briefed on data segmentation, but with no indication of what staff wanted back from the workgroup. She went on to remind Fridsma that the NwHIN Power Team had made its final submission on transport standards to the HITSC at the August meeting. The recommendations were accepted and a formal transmittal letter has been sent to ONC. She asked that the completion of the work be noted on the matrix. Fridsma said that since Joy Pritts is the lead on data segmentation, he will check with her to ask about outstanding work. Regarding ESMD, there are remaining questions about its fit into the portfolio. He promised to take Baker's questions as "action items" and to get back to her. Baker went on to point out

that consumer download is addressed by the HIPAA omnibus rule. Providers are not responsible for data after receipt by the consumer. Fridsma declared that the topic can then be check off the list.

McCallie noted that although the ESMD standards may be complete, the implications for provider workflow remain profound. He wondered where and by whom workflow concerns will be addressed. Baker reminded McCallie that the Privacy and Security Workgroup has not yet signed off on ESMD.

Halamka talked about the need to delineate criteria for separating the realistic from the aspirational in order to finalize the workplan. He asked the members to respond to Fridsma's request to use his activities matrix spreadsheet to submit their individual responses to the priority-setting exercise. Responses will be compiled and used to guide discussion at the October in-person meeting. By submitting their individual responses, much repetitive discussion can be eliminated.

Once again, Perlin thanked Mostashari for his many contributions.

Public Comment

Shelly Spiro, Pharmacy HIT Collaborative, commented on the importance of standards for involving pharmacists in managing patient care and engaging patients. She described the use of the C-CDA in part D. CMS has recognized the adoption of the electronic, structured C-CDA document for 2014. CMS has asked for comments. The Collaborative urges the adoption of a recommendation of the C-CDA for reconciled medication lists.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the August 2013 HITSC meeting was approved.

Meeting Materials

Agenda
Summary of August 2013 meeting
Meeting presentation slides and reports