HIT Standards Committee
DRAFT
Summary of the December 18, 2013 Meeting

ATTENDANCE

The following members attended the meeting:

- Dixie Baker
- Steve Brown
- Anne Castro
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- Jamie 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
- Sharon Terry
- Andrew Wiesenthal

The following members were absent:

- Jeremy Delinsky
- Keith Figlioli
- C. Martin Harris
- Anne LeMaistre
- Nancy Orvis
- Christopher Ross
- Charles Romine

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 53rd 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 (three-minute limit), 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.

Comments

Chairperson Jonathan Perlin reflected on work and accomplishments during 2013. The ecosystem is still incomplete. An incremental approach to standardization is the preferred approach. He thanked everyone.

Review of the Agenda

Vice Chairperson John Halamka asked for corrections of and additions to or approval of the summary of the November meeting as circulated. Wes Rishel pointed to a statement that in response to a question he had asked, Jodi Daniel had agreed to provide an answer. He wondered when and how he should expect her response. Consolazio interjected that Rishel should have received an e-mail response, saying that she will ensure follow up via e-mail. Lisa Gallagher said that she had an edit. Consolazio told her to send it to her. There being no additional questions or additions, Halamka declared the summary approved. He asked that Daniel's response to Rishel be attached to the summary.

> **Action item #1: The summary of the November 2013 HITSC meeting was approved, pending the addition of a response to Rishel's question and Gallagher's edit.**

Halamka declared that they must get the Stage 3 standards correct. There is some dissatisfaction in the industry. Given the one-year postponement recently announced, Stage 3 will begin in FY 2017, right before the presidential election. The current administration will bear responsibility. He went on to comment on each of the agenda items. The agenda had been distributed in advance of the meeting. He explained that given the great amount of work to be done, it is time to prioritize and restructure the workgroups as will be announced in Doug Fridsma's report.

Consumer Technology Workgroup on Patient Generated Health Data (PGHD)

Chair Leslie Kelly Hall introduced Co-chairperson Russ Leftwick.

The workgroup was asked to advise on standards readiness for the following draft recommendations for Stage 3:

- Patients have the ability to electronically submit patient-generated health information
- Provide the ability to electronically submit PGH information through structured or semi-structured questionnaires
- Provide patients with an easy way to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) (certification only)

Kelly Hall reminded members that the workgroup had coordinated with the HITPC Consumer Empowerment Workgroup and provided additional background information, much of which had been presented at the previous meeting. In formulating recommendations, the workgroups convened a listening session on PGHD and considered previously approved criteria for determining maturity and adoptability of standards. Following a slide showing the specific standards determined ready for messages, semi-structured and structured questionnaires, devise data, care plans, and collaborative care, she presented these recommendations for action:

- ONC should consider the Direct transport standard for secure messaging and data from devices
- ONC should consider the HL7 Care Team Roster standard
- ONC should consider the HL7-CCDA for structured and unstructured questionnaires
- ONC should consider the Continua standard for data from devices
- We encourage standards that support mobile access to patient data and PGHD given the proliferation of mobile devices. However, we do not recommend mandating a specific standard at this time given that might stifle innovation.
- ONC should consider an S&I Initiative to create needed collaborative care document structure to address versioning, expanded provenance, reconciliation, data governance and curation.

- ONC should consider creating a process to align consumer product and provider standards
- ONC should consider using BlueButton+ API approach to accommodate PGHD
- Trust Framework expanded for consumer/patient adoption in emerging technologies (BB+)
- ONC should ask the HITSC to prioritize consumer vocabularies to support wider consumer, patient and family engagement

She went on to show the nine recommendations of the HITPC Consumer Empowerment Workgroup, which were approved at the HITPC December meeting. She summarized, saying that PGHD are not new. Standards are available and incorporation of the objectives in Stage 3 can drive adoption.

Discussion

Rishel spoke at length about having a precise definition of standards. Using C32 as an example, he said that any use of it beyond a text document involved negotiations about the standards. That experience demonstrated that something widely used has not necessarily been thoroughly tested. He urged the members to think about standards that are ready as being measured by their use in actual operations instead of in a "happy path." Use of the CCDA is a risk based on judgment of readiness. Having been certified or included in RFPs and not yet fully executed are not indicators of successful adoption. Regarding slide 13, number 5, is it expected that each provider would attest to having collaborated with patients? Kelly Hall said the statement was intended to refer to the work of groups or associations. Rishel went on to talk about provenance, which he said was difficult to implement at the data item level. Another way is to identify data by codes that say something about source. Codes could be modified to say the consumer stated or the consumer wrote, thereby avoiding the need to resort to full provenance. Halamka referred to a good implementation guide being incorporated into products. He said that he is not aware of the CCDA being used for the construction of questionnaires. Kelly Hall seemed to respond that "we" have created it for PGHD. She acknowledged that it was something like a chicken-and-egg issue. She hopes to mitigate any concerns by the use of the standard. Although it is new, patients cannot wait for widespread adoption. Rishel described intermediate approaches that can assess readiness, given the additional year of Stage 3. ONC could fund implementation projects. He emphasized the difference between a demonstration project with a project report and a project in which the standard was used in production with a number of users who, as a result of the experience, continued to use it. The meaningful use stages do not allow a lot of time for development and testing, but the HITSC can do something reasonable. Halamka asked about the use of CCDA to obtain PGHD on ADL and pain, saying that he was not aware of templates for these variables. Kelly Hall referred to LOINC for ADL and SNOMED for pain vocabularies. She assured Halamka that the existing vocabularies are probably sufficient and are computable; the data would come in as a result of structured questions. Halamka suggested more specificity in the recommendations. To say that the CCDA can be used in everything may be confusing.

Regarding the CCDA for semi- and structured questionnaires, Dixie Baker suggested looking at the structured data project using RSD. Referring to slide 10, she wondered how Blue Button Plus would be used to provide PGHD to an EHR. Kelly Hall talked about convening a rapid cycle group to consider a way to look at something, such as API or Health Vault. It would be a future effort. The Blue Button approach is not itself the answer.

Arien Malec cautioned the group about the use of CCDA for patient-reported data. He discovered that better information results when some structure, such as the name of the medication, is provided with the patient being allowed to write a response on strength and dose. The point is to use PGHD as the basis for a conversation with the patient involving both asking and listening. He observed that it is not clear what the use of Continua would mean. Kelly Hall referred to both messaging and structured questions; it is not an either/or issue. The hearing indicated that both are valuable in eliciting information. The Dartmouth panelist reported asking questions about reasons for not taking meds as well as open ended questions, such as what over-the-counter medications are used. Device data can also be used. Chuck Parker,

Continua, who is not a member of the committee, came into the call. He offered to supply the Continua guidelines. CCDA is used as an interface. Continua uses existing standards to combine components. Continua has demonstrated the capability. Halamka asked Parker to supply standard names and implementation guides to the committee. Parker agreed. He said that Continua has 95 certified products and devices with three cloud-based platforms. Halamka asked whether the workgroup wishes to mandate CCDA as content transmission or Continua.

Floyd Eisenberg commented that it would be helpful to parse out the types of information-sharing in the different categories and to consider the ways to manage the data. He agreed with Rishel about the category of provenance.

Steve Brown reported that the Veterans Health Administration (VA) is facing the same problems with PGHD, integration and use of the data, but the VA's problems are not addressed by the recommendations. Dealing with real meaning is difficult. Integration between LOINC and SNOMED is important. The solution must be scalable, a lot of coordination is required, and the overlap of terminologies must be managed.

Eric Rose talked about moving forward on two policy issues. The PCP is typically concerned about patient safety and the possibility of a patient reporting something serious that is then not acted on. The physician may be liable. Standards imply workflow changes, which will not be reimbursed. Kelly Hall said that the issues were thoroughly discussed in the workgroup. Providers said that PGHD are more accurate, especially about medication.

Andy Wiesenthal reported about work with LOINC and SNOMED being undertaken by an organization he is involved with. He urged coordination with that group. He suggested being modestly aggressive with PGHD and to see what happens. ONC should challenge specialty societies to suggest areas for PGHD. Kelly Hall agreed. Taking advantage of the template approach at header level allows use of things already there. Halamka wondered whether it would be helpful for the workgroup to enumerate the templates. Kelly Hall said that it could be done. Halamka said that, in addition, the workgroup should indicate available vocabularies, something testable for certification. There must be a balance between constraint and innovation. The CCDA seems like a reasonable recommendation because of the vendors' experience with it. Kelly Hall reported that she had requested the HITPC to indicate high-value areas. But the HITPC members wanted an overall approach. Halamka said having examples would help in marketing.

Stan Huff asked for additional information about templates and terminology and workflow to be able to recognize repetitive information. Is there a role for the HITSC to do something more strategic beyond adopting the best standards available? The best available is not the same as fit-for-service. What generically are the standards models needed? Having this discussion would allow the committee to have more of a strategic impact over the coming five-year period. Halamka declared that they will discuss Huff's idea under the workplan agenda item.

Rishel summarized. A thread of the discussion is that the requirement for provenance has never been implemented. An alternative is to use sophisticated vocabulary to qualify data as PGHD. The real world VA experience is that coordination is required to make it work. It is important to go through a complete process before assuming that standards can be used.

Halamka pointed to slide 10 as a good summary. Devises have not necessarily incorporated Direct. Continua will provide more information for discussion. Regarding CCDA, examples and consideration of vocabularies are needed. Kelly Hall will return to the workgroup for more discussion, revise the recommendations as necessary, and return for action. Leftwick reported that Hl 7 had successfully balloted a semi- and fully structured questionnaire. The results have not yet been published.

Clinical Operations Workgroup on Image Sharing

Chair Jamie Ferguson reminded the members that the workgroup was charged to make recommendations on the following:

- How full image sets or designated key images are shared between different facilities and specialists: the high level architecture e.g. role PACS, Archives, and EMRs
- How this is deployed with central and distributed reading facilities
- What methods and technical standards are used to push, pull, or view images in one place that originated or were interpreted in another place
- Issues encountered sharing reports and interpretations, or auditing, with or alongside the images themselves
- Inclusion of time series data in scope in addition to radiological images

The members learned about relatively new standards, such as WACO. Over the past few months, the workgroup solicited information from several organizations and individuals. Considerations of cost and burden must be balanced.

He showed a slide with recommendations in a grid format—standards for tiers 1 through 4 for each of content, encoding, vocabulary, push, pull, and view. Tier 1 is exchange of text-based reports. Tier 2 is exchange of non-radiology and cardiology images. Tier 3 is exchange of radiology and cardiology images (full study) and tier 4 is exchange of radiology and cardiology images (key images).

Discussion

Halamka said that the challenge is to use the available standards but not to require each vendor to implement all standards. Baker observed that the report is based on good information. Halamka reported that the workgroup recognized that DICOM is appropriate for coding; the problem is with transmission and the unavailability of universal readers. Workgroup members had no concerns with LOINC for vocabulary. Text-based reporting is done with Direct.

Rishel asked about vendor-neutral architecture, compatibility, and interoperability: Are there issues at that level that affect interoperability? Halamka said that the proliferation of PACs resulted in a need to store all of a patient's images in one place, and for a DICOM reader, that can be used with all vendor products and standards. Rishel responded that he was hearing work may be involved in creating the right descriptions to retrieve or view images from another organization and to work with those images. Halamka said that the challenge is how to constrain in a rapidly evolving environment. Ferguson said that the experience with these standards indicates they are working. Rishel said that the limitations of the vendor's metadata should be recognized in the recommendations.

Kelly Hall pointed out that the workgroup's recommendations include a consumer-friendly standard, JPEG. She asked about the ability for sustained URLs that can be used for advance directives and other things. Ferguson talked about the concern with maintaining pointers and a complete record over time for legal purposes. Providers perceive that they have to retain and store images in their own archives. Halamka acknowledged that storing in the cloud is a coming policy issue. Ferguson observed that although the use cases and the purposes of the images vary, the expert legal opinion is that the pointer is not sufficient.

Doug Fridsma noted consistency in using LOINC. Transport standards present several options based on use cases. What other things are consistent across tiers? Ferguson responded that the workgroup members did not identify any low-hanging fruit. Halamka concurred.

Baker inquired about certification since the standards themselves cannot be constrained. How will certification be constrained? Ferguson replied that it depends on the policy goal. Given the direction from

the HITPC, a high degree of optionality was required. Halamka observed that the policy goal is that images are accessible in the EHR and PHR.

Wiesenthal noted that the discussion was similar to one of what constitutes the legal medical record. The URL is not the same as having the image in the record where the medical decision was made. He cautioned against a recommendation contrary to the notion of a legal medical record.

Halamka declared that members had expressed no real opposition to the recommendations. However, the standards options must be narrowed for certification. Should they seek more guidance and use cases from HITPC? Fridsma said that Halamka had discussed the image standards topic with the HITPC. The message was to start somewhere, to make sure patients can have access to their images, and to consider transmission of images for referrals back from radiology to another provider. He indicated that ONC staff can use the recommendations, along with the discussion, to proceed with policy development. Halamka said that his workplace needs both loosely and highly coupled images.

ONC Updates

Lee Stevens gave a slide presentation on patient matching. In 2011, the HITPC made an initial set of recommendations that included standardization of data elements and other best practices. In late 2012 and 2013, a number of industry groups began work to improve patient matching, including the Care Connectivity Consortium, CHIME, HIMSS, HealtheWay, and CommonWell. In 2013, ONC contracted with Audacious Inquiry to identify issues related to patient matching. The scope of work was limited to clinical patient matching with a focus on standards needed. Issues of data quality or algorithmic matching came up in the discussions, but were not part of the scope.

The following barriers to accurate matching were identified:

- Inconsistent formatting within data fields is widespread.
- Mistakes in data entry, such as transposition, require sophisticated software to adjust or take them into account.
- Smaller organizations and practices may not be able to afford sophisticated matching methods and algorithms, and their practice software may not offer such capability.
- Patient engagement efforts have not yet evolved to ensure that consumers can routinely access their demographic information to confirm and update it, either with the help of a staff member or independently via a portal.

Stevens presented and elaborated on initial “findings,” along with rationales:

- Standardized patient identifiers should be used in the relevant exchange transactions.
- Certification criteria could be introduced that would enable certified EHR technology (CEHRT) to capture the data attributes that would be needed in the standardized patient identifier content.
- Study the ability of additional, non-traditional data attributes to improve patient matching. Data attributes include: e-mail address, mother’s first and maiden name, father’s first and last name, place of birth, driver’s license number, passport number, or eye color.
- Develop or support an open source algorithm that could be utilized by vendors to test the accuracy of their patient matching algorithms or be utilized by vendors that do not currently have patient matching capabilities built into their systems.
- Consider adding certification criteria to demonstrate the ability of a system to generate and provide to end users reports that detail potential duplicate patient records
- Build on the initial best practices that emerged during the environmental scan by convening industry stakeholders to consider a more formal structure for establishing best practices for the matching process and data governance.
- Develop best practices and policies to encourage consumers to keep their information current and accurate.

- Work with health care professional associations and the Safety Assurance Factors for EHR Resilience (SAFER) Guide initiative to develop and disseminate educational and training materials detailing best practices for accurately capturing and consistently verifying patient data attributes.

Q&A

Malec, who had attended the ONC meeting on matching, said that deterministic matching is not sufficient. Probabilistic matching will be necessary, but there are obstacles. Using the last four digits of the social security number can boost matching. The challenge is to find the best attributes for matching that have the least privacy issues. Regarding certification, it would be better to standardize the collection of elements at registration. The meeting content will be summarized and published.

Rose suggested a use case in prenatal diagnosis and treatment; the records on the fetus will have to be connected to the newborn's record after birth.

Rishel observed that they started with matching in the context of interoperability, then matching in systems where the information originates with data quality as an issue. One of the biggest problems is the lack of feedback and corrections. Although the concern may be in searching for false negatives, the more likely errors are toward false positives. Has any consideration been given to treating these errors as adverse events and then reporting them?

Kelly Hall declared that the patient is the most reliable source of her information. There should be opportunities for patients to use identity proofing. Patients could pass on registry information. Fridsma responded that there are several unique use cases. Mechanisms to securely exchange information will help to leverage existing mechanisms.

Baker commented on the connection between matching and identity proofing. Providers doing the identify proofing is the more likely approach.

Lisa Gallagher asked to whom Stevens' recommendations were directed and how performance on matching would be measured. Stevens said that the "findings" or recommendations will go to ONC staff for discussion of how to go forward. Gallagher talked about a HIMSS white paper that described types of measures. A key performance indicator is the duplicate creation rate. She suggested that performance measures and performance indicators be considered. Stevens referred to several settings in which improvement in matching has been observed. Audacious Inquiry will submit its report early 2014.

HITSC Workplan

Fridsma announced that the announcement made December 6 about the extension of Stage 2 did not change the need to proceed with the 2014 workplan. He reminded the members that they had been discussing the workplan for the past several months. Some items have been completed since the November meeting, in particular the work reported by the Clinical Operations Workgroup on image sharing. He showed slides. The HITSC workgroups will be restructured. Some members' terms will expire soon. New expertize is needed. The HITPC will submit Stage 3 recommendation in February. The HITSC will review the workplan again at the February 18 meeting. Fridsma presented a list of standards needed in five categories: quality and safety, health information exchange, consumers, ACO and population health, and privacy and security:

Category 1 – Quality and Safety

- Standards which support flexible platforms for measuring and reporting quality (QueryHealth, QRDA/HQMF)
- Standards which support measurement of EHR usability

- Standards which address current content gaps - HL7 version 2 lab orders, formulary downloads, cancel transaction needed for hospital discharge medication e-prescribing, representing genomic data in the EHR
- Standards which support defect reporting to PSOs
- Standards which support redundant data identification/reduction

Category 2 – Health Information Exchange

- Standards which support query/response of provider and patient identity in directories
- Standards which support record locatorsServices
- Standards which support consent in a query/response architecture such as granular patient privacy preferences hosted in a managed service ("pull") and sent as part of the request for records ("push")
- Improvements to the CCDA standard to facilitate unambiguous parsing, longitudinal record sharing, and bulk record sharing
- Standards to support image exchange

Category 3 – Consumer

- Standards to support representation of patient generated data including consumer device data
- Standards to support consumer friendly terminology
- Standards to support transport of data to and from patients
- Standards to record advanced directives/care preferences
- Standards to record care plans/care team

Fridsma asked Kelly Hall to review and compare the items with her recommendations.

Category 4 – ACO/Population Health/Care Management

- Standards for clinical documentation supporting new payment models (includes ICD10, smart problem lists, computer assisted coding)
- Standards needed for registry support including structured data capture and transmission to third party repositories
- Standards to support closed loop referral workflow
- Standards to support data comparability across entities including detailed clinical models
- Standards for clinical decision support, both knowledge representation and application programming interfaces (APIs) for query/response to knowledge resources

Category 5 – Privacy and Security

- Standards for securing data at rest, especially genomic data and consumer downloads
- Standards for application programming interfaces supporting modular application integration
- Standards supporting data segmentation for privacy
- Standards and certification criteria that anticipate broad NSTIC adoption
- Standards supporting digital signature

Next, he showed slides and talked about the workplan activities categorized into high, medium, and low priority at the November meeting.

Discussion

Halamka said that he presumed workgroups would be formed around the four new categories with the Privacy and Security Workgroup to continue. Fridsma called the plan a good straw person recommendation, though there may be additional categories and cross-cutting activities. He wondered whether these are the right categories.

Kelly Hall declared that she supported the new categories for workgroups.

Baker observed that since the goal is a learning health system, more on CDS and feedback is needed. Fridsma replied that the plan is clustered around functionalities. He asked what was missing, saying that perhaps there should be a sixth category. Baker talked about the merging of the research and clinical environments. Fridsma said that the sixth category may be research, with CDS placed in the safety category.

Regarding a reference to a strategic approach to standards, Fridsma talked about improving the standards being used, expanding use cases and vocabularies, and finding a more computable way for semantics. He talked about moving from a document to a data approach and PKI infrastructure. Rishel advised that they identify promising projects to work on. Halamka acknowledged that developments in the technology industry must be taken into account in planning.

Huff suggested convening a workgroup on the future, strategy and research. McCallie agreed. Someone talked about the importance of working with other organizations. Kelly Hall spoke about thought leadership. She suggested that the sixth workgroup describe the evolutionary criteria to show the way to progress, an industry road map based on evolutionary process and learning. Malec speculated that having a long term road map can overcome resistance to learning.

Halamka summarized that ONC will form five or six new workgroups under the auspices of the HITSC. Consolazio announced that ONC will publish information on member recruitment in January. Committee membership is governed by the length of terms. The terms of several members are expiring.

Rebecca Kush expressed agreement with Huff about a road map and a future workgroup. Research standards are available and will be adopted in Japan, Europe and the United States over the next few years. Having some intermediate standards would allow for linking with EHRs.

Baker opined that instead of a specific workgroup charged to look ahead, all workgroups should look ahead. Halamka said that an item on looking ahead will be added to each workgroup's list. A sixth workgroup will be formed to consider how to get to a road map.

McCallie referred to vertical, horizontal, and matric organizations, saying that the next generation of standards will likely require a matric approach, with many use cases. The underlying standards may cross workgroups.

Halamka declared general approval of the workplan presented by Fridsma.

Kelly Hall told Fridsma that advance directive should be re-prioritized to high from low or medium. She indicated that only a small effort is required.

Public Comment

None

SUMMARY OF ACTION ITEMS:

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

Meeting Materials

Agenda
Summary of November 2013 meeting
Meeting presentation slides and reports