

HIT Standards Committee
DRAFT
Summary of the November 13, 2012 Meeting

ATTENDANCE

The following members attended the meeting:

- Jonathan Perlin
- John Halamka
- Dixie Baker
- Anne Castro
- Christopher Chute
- Tim Cromwell
- John Derr
- Floyd Eisenberg
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Arien Malec
- David McCallie
- Nancy Orvis
- J. Marc Overhage
- Wes Rishel
- Charles Romine
- Walter Suarez

The following members did not attend the meeting:

- Lorraine Doo
- Jamie Ferguson
- Leslie Kelly Hall
- C. Martin Harris
- Kevin Hutchinson
- Christopher Ross
- Sharon Terry
- James Walker

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 42nd Health Information Technology Standards Committee (HITSC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment, and that a transcript will be posted on the ONC website. She called the roll and reminded members to identify themselves for the transcript before speaking.

Remarks

Farzad Mostashari, National Coordinator, remarked on the opportunity for Republicans and Democrats to move ahead together. This is a time to take stock and assess progress. Have we been too aggressive or insufficiently aggressive? The Stage 2 testing tools are being vetted for a big step forward in implementation. Interoperability is a journey. He reported that he had asked the HITPC to reconsider whether more could be done. The Stage 3 Request for Comment (RFC) asks for comments on many topics. Comments should focus on experience, not opinion, and on how something can be done rather than why something cannot be done. He acknowledged that he had asked the HITPC to reconsider making more progress on query. As the RFC was being drafted, the HITSC advised that many of the required standards were not yet available. Nevertheless, what can be done to make progress? He said that he had also asked the HITPC about functionalities that can enable innovation toward transformation and make EHRs more accessible to other applications. What can be done to have EHRs function as platforms?

Review of the Agenda

Jonathan Perlin, Chairperson, thanked everyone. He said that he had been thinking about systems. Information is important to systems of care. There are numerous levels and sets of capacities for solutions. He observed that the agenda was a robust one. Stage 3 seeks aspirational capacity. Modules are important to systems. He noted that there was a great amount of information to be presented at the meeting. He inquired about objections, corrections or additions to the minutes and hearing none announced the acceptance of the summary of the October meeting as distributed.

Action item #1: The summary of the October 2012 HITSC meeting was approved as circulated.

Comments

John Halamka, Vice Chairperson, said that the committees must decide how aspirational to be. He gave several examples of accomplishing exchange in the absence of standards. Health IT people in his state needed a provider directory for which there are no standards. A few men developed a two-page spec that was implemented with minimal cost. In another setting, the SSA established a way to request and receive medical records for use in disability determinations. There is the collective burden of everything that must be done. He posed several questions. How prescriptive should one be with API? What are the characteristics of a modular ecosystem?

HITPC Meaningful Use Stage 3 Request for Comment (RFC)

Jodi Daniel, ONC, referred to the slides and the HITPC's work on the RFC. The RFC will be published this week with comments due mid-January. ONC staff added several items to the RFC. She said that the HITSC should review the RFC and look at the need for and availability of standards and certification criteria. The HITSC can conduct a high level review now followed by a more extensive review prior to the final recommendations. Members can advise on the steps to take for standards readiness, or they may suggest a slight modification of a preliminary policy to better align with an available standard. This preliminary input from the HITSC will occur during the public comment period. A second opportunity for HITSC input will occur after the HITPC makes its formal recommendations to ONC in late spring or summer. Doug Fridsma, ONC,

informed them that the goal is to get a technical assessment only. He repeated Daniel's instructions.

Daniel said that the RFC was intended to extend the public discussion of future stage meaningful use definitions through a more formal public comment process well in advance of its formal Stage 3 recommendations; request input on specific questions; and provide some signal to the industry of potential new EHR functionalities that the HITPC may recommend to assist the industry.

Michelle Nelson Consolazio, ONC Meaningful Use Workgroup Lead, read through the section of the RFC on measures and objectives and the certification criteria. Members had been given the document with the other meeting materials. She reminded them that Halamka and others had advised on the availability of standards several months ago. The measures and objectives are organized into five domains:

- Improving quality, safety, and reducing health disparities
- Engaging patients and families
- Improving care coordination
- Improving population and public health
- Information exchange

In addition, there is a section of overarching questions. As she read through the first four domains, she showed slides that listed: the Stage 2 Final Rule; the draft Stage 3 measure, objective and certification criteria; proposed future state and questions for which responses comments are requested. As she read through the list, she noted those areas in which standards readiness may be absent or questionable. She reminded them of those areas in which the HITSC through its workgroups had responded to the Meaningful Use Workgroup's questions on the availability of standards and also noted where the Meaningful Use Workgroup in certain instances had not accepted the advice on standards.

Members' Responses to the Draft

Perlin observed that the preliminary recommendations for Stage 3 were indeed aspirational. Standard maturity levels can be used to delineate where standards are ready to go, where standards can be made ready and where they are truly aspirational. Many philosophical issues are embedded in the draft. There is no product that can do all of these functions. He asked them to start with the big picture.

Halamka declared that although the recommendations appear overwhelming, thoughtful responses can be obtained to revise them accordingly. He wondered about imposing an architecture that does not yet exist.

Arien Malec talked at length about his objections. He noted that the timeline should back track to provide sufficient time. Every certification criterion impacts providers; each has a significant cost. The HITPC should not play product manager. One thing that worked well in Stage 2, when he was employed at ONC, was to look at the broad schematics and then work back to identify what must be done to reach that stage. That approach is not obvious for Stage 3. Because there is only one year to do this, it would be easier to work with a set of broad themes and policy objectives. The RFC is missing the mark.

Dixie Baker said that she expected to see more specialization and modular certification in Stage 3. Therefore, interfaces between modules are most important. She referred to the future state for an objective pertaining to the review and acceptance of patient updates in EHRs and wondered how the future state differed from the Stage 3 cell. She also observed that with regard to information exchange and response query, the response should be accompanied with patient consents.

Wes Rishel commented on the aggressive time line, saying that three years may be required. He referred to the C32 as the finest example of standards development known to him. Following the initial version, implementers saw problems and wrote a new version. Although there may be remaining issues (most likely the problem list will require additional revisions), that is how things get done. The committees should focus on implementation using the problem list and follow the evolution of the patient via the problem list. A different view on interoperability is needed. Instead of the view that one day there will be a common chart, graded interoperability across organizations, like windows, should be considered. Transitions to different modalities of care do not require common charts; they simply need a small window. Although API may be every CIO's pipe dream, one must be careful for what one asks. The need for secondary vendors can be minimized by asking for data. Hospitals are making process in admission rates by using natural text since a standardized measure is not available.

David McCallie reiterated the need to be clear about the time frame. He said that certification criteria not coupled to measures force vendors to do something for which the purpose is not known. Hence, the HITPC becomes project manager. He indicated disagreement with certification for the sole purpose of a function. The care plan proposes going into new territory without sufficient planning and development time. The certification criteria regarding CDS rules pulled from a central repository are telling users how to do something rather than focusing on an outcome that fulfills a purpose. He went on to say that the consent thing is on thin ice and is overly managed. The burden of consent must be reduced, perhaps by using something similar to Surescripts.

Rebecca Kush commented on query for research trials, pointing to the difference between finding a trial for a patient and seeking patients for a trial. The functions should be separated. She volunteered to provide a comment for MU05. She went on to mention the opportunity for remote management of a form for research data collection purposes.

Stan Huff emphasized the problems with the long list of process steps, which he opined will constrain innovations and creativity for improving patient outcomes. The list is too long. There should be more focus on creating incentives for improving outcomes. Consideration should be given to changing the current paradigm; PCAST was considered some time ago and then dropped. The long list does not recognize the considerable variation of importance and value among the objectives. For example, the lab exchange has much greater value than most of the other objectives. This overly long and prescribed list contributes to lost opportunities.

Mostashari asked them to balance eyes on the prize with feet on the ground. A long list of little stuff will begin to create a national infrastructure. Each criterion is not just a functionality but something that results in a public good. For example, dose added to structured SIG and other things are clear incremental advances, which, if done by everyone, will have a considerable result. He acknowledged that the list may be improved by categorization. The next chance will not be until 2018. He agreed that the list is disjointed and should be organized around themes

tied to outcomes, which should in turn be prioritized. He asked them to consider what can be done in a low regret manner.

Perlin said that the HITSC has a clear charge to identify themes.

Fridsma noted that much work must be done. He suggested an approach starting with going through the list and dividing the items among the workgroups for iterative feedback. Members can use bullets and ideas without a lot of detail. Objectives and certification criteria can be categorized by resources and time required. The functionalities that can solve numerous solutions can be identified. A strategic approach to standards is needed. He suggested that they respond, but not necessarily react, to the HITPC's work on the RFC. Thought should be applied to the maintenance of standards as well as to which standards are the most important to the yet-to-be-identified themes. First, they can identify things not to deal with immediately. His offered on behalf of his team of workers to triage and divide the items among groups. Perlin asked if anyone objected to Fridsma's offer. No objections were heard. Someone called for suggestions on themes.

McCallie told Mostashari that he should not assume progress is made only via meaningful use criteria. The industry advances on its own. Perlin indicated that it would be wise to take advantage of the meaningful use stage markers.

Privacy and Security Workgroup Update

Dixie Baker, Chairperson, reported on the current efforts of the workgroup. She explained that the 2010 Edition of the EHR Certification Program introduced certification of Complete EHRs and EHR Modules.

The modules were certified against all privacy and security criteria. The 2014 Edition introduced changes aimed at streamlining the certification process and reducing regulatory burden. It eliminated the requirement for modules to be certified to the privacy and security certification criteria and introduced Base EHR definition, a set of core attributes, including privacy and security, that each Certified EHR Technology (CEHRT) adopted by an EP, EH or CAH must meet. The members of the workgroup are considering whether the pendulum might have swung too far. For the 2016 Edition, might it be possible to require that each EHR Module be certified against some minimal set of privacy and security criteria, without imposing unreasonable regulatory burden?

ONC staff asked the workgroup to provide recommendations for certifying EHR Modules under the 2016 Edition of the EHR Certification Program, including identifying the minimal set of privacy and security standards and certification criteria. ONC staff told the workgroup to anticipate future broad adoption of NSTIC-based authentication, and that the recommendations should be compatible with NSTIC. After explaining the difference between and criteria for modular certification and complete certification, Baker presented preliminary recommendations, saying that they are still a work in progress. For the 2016 Edition, the workgroup recommended that each EHR Module presented for certification be required to meet each privacy and security certification criterion in the minimal set, using one of the following three certification paths:

- Demonstrate, through system documentation and certification testing, that the EHR Module includes functionality that fully conforms to the privacy and security certification criterion.
- Demonstrate, through system documentation and certification testing, that the EHR Module has implemented standards-based service interfaces that enable it to access external services necessary to conform to the privacy and security certification criterion. (The workgroup will recommend standards for service interfaces.)
- Demonstrate through documentation that the privacy and security certification criterion is inapplicable or would be technically infeasible for the EHR Module to meet.

She informed the members that the workgroup considered an additional path but had made no decision: Demonstrate through system documentation that the EHR Module has implemented non-standards-based service interfaces that enable it to access services provided by other certified EHR technology to conform to the privacy and security certification criterion. She reported that arguments against this path consisted of the position that non-standard systems should not be encouraged and that the path may be superfluous in that any criterion using this path would also qualify under the first or third path above.

Based on the nine required criteria for privacy and security, the workgroup identified a minimal set of seven to include: authentication, access control, and authorization; auditable events and tamper resistance; audit report(s); automatic log-off; emergency access; encryption of data at rest; and integrity. The next steps are to select recommended interoperability standards and solicit public comments through the ONC blog. Baker asked for members' opinions on inclusion of this path: Demonstrate through system documentation that the EHR Module has implemented non-standards-based service interfaces that enable it to access services provided by other certified EHR technology to conform to the privacy and security certification criterion.

Discussion

A member commented that the goal should be to achieve a policy outcome protecting the integrity of the data, which may be difficult with modules. Baker repeated that the workgroup will call out the privacy and security interoperability standards. Someone mentioned a set of standards for stability. Baker said that the standards must be testable. Several members indicated support for including that path.

The nine certification criteria are in the regulation. The point is to make the paths testable. One path is to constrain it to make it testable. Another is to allow proprietary interface. In response to a question about the extent to which the preliminarily recommended approach addresses the vocal and detailed concerns voiced after Stage 1 and during the Stage 2 NPRM comment period, Baker responded that the workgroup examined the list of certified modules and characterized the capabilities, such as documentation and drug – drug interaction, and decided that privacy and security may not be required for all.

Absent well-understood standards, the notion of proprietary mechanisms of security and privacy being relegated to a black box even if testable at some level of functionality may leave open the possibility of a missed functionality because there's been no scrutiny by a broader community and a broader review, according to one member.

If people are not using standardized approaches, they should at least be transparent in how they do it. They should be transparent about the standards or what the API is. Transparency is

necessary in order to review. According to Baker, that is the reason for including system documentation in the paths. When a vendor sells a product that is intended to interface with something else, the system documentation will include detail about integration with the external module. So in the third pathway, the system documentation should describe how it interfaces with external modules. Someone suggested that the recommendation would be strengthened by calling this out rather than burying it in system documentation. However, the extensive documentation required in previous stages was one of the main complaints and the workgroup wants to limit required documentation.

McCallie declared that the task is almost an impossible one and will eventually fall to human judgment. Module has not been specified. A module can be anything under the sun. Therefore, it is impossible to specify how a set of standards for security could be tested. Although modules could be constrained in a highly specified way, no one has the appetite to do that. It falls back to demonstrating the approach and how security requirements are addressed in a module. If a standards-based service is used, it can be tested. There is no predefined set of APIs that can be enumerated. It will be based upon the judgment call of the examiner.

Rishel talked about his concern with the dependence on someone's judgment. Who will decide that an explanation is acceptable? The certifying organizations are recruited and trained to follow the government guidance very precisely. There is always an incentive to pass the vendor to establish a reputation for being easy to work with. Perfection is not the goal. The goal is to be better with some nominal cost. He went on to say that tamper resistance was not clear. Is there a standard that does not require a re-architecting of the module? Baker explained that tamper resistance is in the regulation and refers to the audit trail. There is nothing in the list that gets to the issue of code. The regulation does not define module; it is anything that is not a complete EHR, according to Baker. Rishel indicated that amendments should be included in the minimal set.

Tim Cromwell announced that Mostashari had asked him to walk through the VA and DoD plans for open source, which may validate the path being discussed. The departments acknowledge that in the production of the IEHR, modules will be purchased from vendors and proprietary standards will be in those modules. But the technical expectation is that the APIs will be available in open source. Baker confirmed that the pathway under discussion would apply to proprietary standards inside the module as long as the APIs are available. Open source is not required but transparency is necessary. The product is not required to be open source, just the API.

Regarding one pathway, Baker said that the 2014 Edition refers to modules that were technically infeasible to implement. The second pathway was intended to recognize profiles of standards. Profiles would have to be developed.

Perlin asked Halamka to summarize, which he did. The purpose is to protect purchasers from modules that are misbehaving or are security risks by requiring features and functioning within the module, called by the module, or because of the nature of the architecture. Either standards- or non-standards-based when doing the calling should be permissible. The enumeration of very specific testable standards will be difficult. Perhaps the second and third paths can be collapsed. Transparency should be required.

ONC Updates

Doug Fridsma reported on the S & I Framework activities, using his slides to show the current status of 12 projects. He reported in detail on the BlueButton project. Since its introduction by the VA in 2010, the use of BlueButton has grown into a movement – a commitment by many of the country’s largest data holders, including the federal government – to get personal health information out of proprietary silos and into the hands of the consumers who want a holistic picture of their health and health care. Many governmental and commercial organizations now use this concept. Today, BlueButton means letting consumers download an ASCII file of their personal health information after they log onto the data holder’s portal. But the data are not structured to interact with apps. The ABBI project was undertaken to identify, define, and harmonize: implementation standards, tools and services that facilitate the automated push and automated pull of patient information via the BlueButton; content structures and specifications for the BlueButton so that information downloaded is machine readable and human readable; and protocols around identification and credentialing, and protocols around access and authorization, that facilitate the automated push and automated pull of patient information via the BlueButton. He referred to two push use cases. In one case a patient can specify in a data holder’s system to be sent an updated copy of his/her personal health information as it becomes available. He gave an example of a pull use case: A patient can direct a third party application to periodically have access to his/her personal health information via the Internet. The data holder will ensure the data are made available and follow certain privacy and security standards. For each, Fridsma delineated assumptions as well as what was in and out of scope. The work includes production of reference implementations, technical implementation guides, workflow guides, policy FAQ guidance, CCD and C-CDA style sheet library and a brand guidance.

Q&A

Referring to the use cases, Chris Chute remarked on the similarity of BlueButton with health information exchange writ large. Why reinvent standards for this use case? Fridsma talked about the need to get this done quickly and to see where the C-CDA works. Is there a way that existing software can be used? For push, Direct is being examined.

McCallie noted the opportunity for progress and accomplishments.

Public Comment

Robertson indicated that she was not monitoring Twitter for questions.

Lindsey Hogle, Academy of Nutrition and Dietetics, talked about nutrition inclusion in certification criteria. Vendors already provide this function but there are no standards. Her organization is working on translating a dietary vocabulary into SMOMED. She talked about two HL7 efforts that are relevant for standards development. She reminded the group that transmission of diet orders and food allergies are issues of patient safety.

Clinical Quality Measures Lessons Learned and MU Stage 3 Roadmap

Clinical Quality Measures Reboot

Kate Goodrich, Centers for Medicare and Medicaid Services (CMS), talked about efforts to identify measures in the six domain priorities of the National Quality Strategy and to have core measures across domains. There are gaps in quality measures. Measures are currently excessively provider centered. The use of EHRs provides an opportunity to reboot. Staff is

aligning measures across the several CMS physician programs and hospital programs. A goal is for a solo physician or a group physician to be able to report on a single set of measures. Another goal is for registries and EHRs reporting methods to grow. This requires continued standardization, testing and evolution of testing methods for e-measures. The alignment and coordination of value sets is also underway in conjunction with NLM. CMS works with other organizations, such as NQF, beyond its sister federal government agencies.

Q&A

Halamka referred to skip and abstract methods of reporting and expressed appreciation for converging quality measures to a small set of e-measures. Goodrich confirmed that a goal is to eliminate the need for record abstraction and to rely on EHR measures. He told her that CMS should work on reducing or simplifying measures' numerator and denominator exclusions.

Floyd Eisenberg asked about the future of retooling measures. Goodwin responded that although retooling was necessary for Stages 1 and 2, CMS staff wants to phase out retooled measures to the extent possible in preference of de nova measures. Staff is trying to identify criteria for registry participation, hoping that registries will provide more rapid reports for feedback for CDS.

John Derr inquired about long term and post-acute care. Goodwin said that the statute defines EPs. She said that she hopes EHRs can spread across the entire continuum of care. However, post-acute care settings in general are less technologically advanced than other components of the care system. There is no time line for including post-acute care. Derr acknowledged that the statute does not include post-acute providers. Goodwin offered to meet with him as a representative of the Long Term and Post Acute HIT Collaborative.

Value Set Authority Center

Ivor D'Souza, National Library of Medicine (NLM), reported on the Value Set Authority Center (VSAC). A Web user interface for human consumption and an API for machine consumption have been developed. His slides showed how the Websites work. Data and codes can be downloaded. This effort required cleaning 1,558 unique value sets with 84,228 unique codes into 94 quality measures in four months. In 13 rounds of corrections, staff corrected more than 4,100 codes and 370 value sets for the 94 measures. In order to avoid such a burdensome effort in the future, the HHS partners have agreed on two process initiatives -- governance process for value set editing, approval and publishing, and value set review to validate against purpose of measure. Next steps also include tooling for value set maintenance and authoring; opportunities to improve value set consumption; and integration with the Measure Authoring Tool (MAT). The VSAC opened October 25. ULMS credentials are necessary to access the measures. There are multiple ways to access information.

Q&A

Nancy Orvis asked about the value of the site for clinicians trying to find a good measure. D'Souza said that the site was not designed for that purpose. The MAT can help when it is in place. VSAC staff is working with EMR vendors who support hospitals. They will download the value sets for implementation in hospitals. The site contains a statement that it is not the place to come for CQMs. Authoring searches for what is in the system can be conducted. Eventually, the site will have human editors to help. If there are no extant value sets, searches of the ULMS can be run. Halamka noted that CMPT cross walks are available at the site.

Eisenberg asked about a comment feedback that goes back to the originator. D'Souza indicated that NLM staff is working with ONC on maintenance. New code sets using ULMS may alert editors. Staff is looking for the best approach for triggering changes—immediately or at a specified time. Staff is also looking at opportunities to reuse value sets.

Rishel noted that this national level process is replicated at the hospital level. Work flows require configuration management. There is a tremendous opportunity to build configuration management tools on top of this. The API would need to support bulk transfers. D'Souza indicated that the API does support bulk.

CTS2

Christopher Chute, Mayo Clinic and a committee member, reported on CTS2 and the Secondary Use of EHR Data (SHARPN) consortium. CTS2 is a joint project of the Object Management Group (OMG) and HL7 for functions of read, query, distribution, update and federation. It is an API specification that defines the semantics, syntax and valid interactions. It is a blueprint for software (not software itself), which enables CTS2 clients and services to interoperate. The CTS2 standard is a collection of relatively small standards and a set of assembly rules. Goals include distribution and federation with the former meaning that different organizations can publish different aspects and the latter meaning that organizations can share knowledge and information. It is built from the bottom up using the Resource Oriented Architecture (ROA) approach. Each component can be implemented by itself or embedded. Re-use is facilitated. This is an interim value set service making the NLM content available. All content comes from NLM and a layer of CTS2 is added; it is a re-servicing of the same content. It can be used by anyone.

United States Health Information Knowledgebase

Michael Fitzmaurice, AHRQ, described the United States Health Information Knowledgebase (USHIK), a set of six information models, one of which is meaningful use. It is a one-stop shop for quality measures with user-requested download formats available in XML, Excel, PDF, SVS, CSV and CTS2. They are available by selected sets of CQMs and value sets for all CQMs, all in one combined flat file format—CVS. Version comparisons will soon be available. He reviewed slides of the website, showing these features. Fitzmaurice concluded by mentioning the ways in which USHIK is beneficial to AHRQ, the lead agency for supporting CQMs. Standardized measures enable more uniform, accurate, computerized and valid health data, which contributes to higher quality research and operational data and, subsequently, to more robust research findings. USHIK is linked to the Mayo Clinic's API described by Chute. Bulk download is possible.

Q&A

Kush asked D'Souza about linking with CDE vocabulary services at NCI. He replied that staff is trying to coordinate and will not consolidate or duplicate efforts. NIH institutes are working together on using the CDE, hoping to build a platform for those who need it. According to Kush, this approach will exclude many in the research community. D'Souza offered to take her concern back to NLM and NIH.

Eisenberg wondered whether depending on interest and preferred format, one can go to any of the sites to obtain the latest information available at VSAC. Someone said that CTS2 is unique to the Mayo site.

Certification Test Wave Update

Carol Bean, ONC, began with a review of the HIT certification program, which recently transitioned from a temporary to permanent program, and is now named the ONC HIT Certification. The new structure separates testing and certification. Temporary program certifications are not affected by the change. The ONC Office of Certification manages the ONC HIT Certification Program. The National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology (NIST), accredits Accredited Testing Laboratories (ATLs). The ONC-Approved Accreditor (ONC-AA) accredits and oversees ONC-Authorized Certification Bodies (ONC-ACBs). A NVLAP Accredited Testing Laboratory (ATL) tests Complete EHRs and/or EHR Modules. One of the ONC-Authorized Certification Body (ONC-ACB) certifies HIT, including Complete EHRs and/or EHR Modules. Developer and vendors design the Complete EHRs and/or EHR Modules.

The ATLs are the following:

- Certification Commission for HIT (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- SLI Global Solutions

The following are ACBs:

- Certification Commission for HIT (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- Orion Register, Inc.

The certifying bodies now must accept the results of all test labs. ONC reviews and posts the certified product to the CHPL, which now lists over 1,600 unique products and more than 800 vendors. More than half of the vendors have products that were used in attestation. According to Bean, these numbers indicate that the market is robust and active. Bean turned to a description of test method development for the 2014 Edition. The final rule was published September 4, 2012. It defines the 2014 Edition Certification Criteria and is aligned with Stage 2 meaningful use. Draft test methods were developed during September – November 2012. The draft test methods were posted on the ONC website in seven waves for public comment commencing September 7 and extending through November 22, 2012. The public comments will be reviewed and used to update the test methods. ATL and ACB training and evaluation is underway. The final test methods will be published in mid-December, after which testing and certification will begin January 2013. Nine test tools based on performance with data supplied by the test methods not the vendors will be used. They are Transport Testing Tool that includes C-CDA, Direct, and SOAP; Direct Certificate Discovery Tool; Cypress Tool; HL7 v2 Syndromic Surveillance Reporting Validation Tool; HL7 v2 Immunization Information System Reporting Validation Tool; HL7 v2 Electronic Laboratory Reporting Validation Tool; HL7 v2 Laboratory Results Interface Validation Tool; HL7 CDA Cancer Registry Reporting Validation Tool; and e-Prescribing Validation Tool.

Bean described unit-based testing, reminding them that they had previously been informed of this approach via the Implementation Workgroup. Unit-based testing reflects a typical clinical workflow in multiple care settings and allows persistence of data elements (i.e. model for data threading). And it maintains testing flexibility (e.g. add/remove —unit test). The approach was developed based on 2011 Edition Certification Criteria and will be re-evaluated against the 2014 Edition Certification Criteria. There are five unit scenarios: medication management, emergency department, interoperability, outpatient and inpatient.

Q&A

McCallie referred to the several bodies that validate CCDA documents and asked to what extent the testing process will validate the CCDA. Bean expressed some uncertainty, saying that the pieces are there but are not yet glued together. The CCDA validator is shown on one of the process slides. The tester may need to inspect data values. The tooling and the data can be modified. She offered to have a more complete answer at a later time. McCallie was concerned about multiple, inconsistent validation tests. Bean invited others involved in the validation to work with her to promote consistency.

Next Meeting

The next HITSC meeting is scheduled for December 19 and will be convened virtually.

Public Comment

None

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the October 2012 HITPC meeting was approved as circulated.

Meeting Materials

- Agenda
- Summary of October 2012 meeting
- Presentations and reports slides