



## HIT Standards Committee DRAFT Summary of the May 20, 2015 Meeting

### **ATTENDANCE (see below)**

### **KEY TOPICS**

#### **Call to Order**

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 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 (3-minute limit), and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves.

#### **Remarks**

Acting Deputy National Coordinator and Chairperson P. Jon White declared that he could not comment on legislative activity. He announced that he posted a blog that morning about a new process for advisory committee recommendations. The current structure of standing workgroups will be sunset and new task forces convened for rapid cycling and improved efficiency. It is difficult to divide NPRMs and other issues among the current workgroups. A task force structure will be a better use of time and coordination with HITPC.

#### **Remarks and Review of Agenda**

Vice Chairperson John Halamka declared that he was not prohibited from commenting on legislation. He referred to his blog and his comments on various bills (<http://geekdoctor.blogspot.com/2015/05/21st-century-cures-act.html>). The people writing bills lack understanding, particularly with respect to information blocking and decertification. Some of the proposals could introduce a mess. Some bills call for standards to measure interoperability, but there is no such standard. Committee members should try to explain to colleagues in Congress the things that would actually improve interoperability. The terms of 10 current HITSC members are expiring and new members will be appointed. This is a good time to think about how to best organize to deal with misguided legislation.

He noted the agenda items. The agenda had been circulated in advance of the meeting.

#### **Reaction to Proposed HITSC Reorganization**

Halamka added an agenda item—reaction to White’s announcement of reorganization. Members reacted.

Arien Malec pointed out that the HITSC was reorganized this year. Mission issues and feedback were considered. Members bought into the new structure, which was discussed well in advance. The experience with the current structure is insufficient to know how well it works. Announcement of reorganization in a blog post indicates a lack of respect. It would have been better for staff to come to the HITSC and say these are the problems we have observed: What solutions do you propose? The

combination of members' skills, dedication and institutional memory is what makes for success. He emphasized that he was not happy with the way the reorganization was announced. The substantive challenges should be addressed first. A steering committee was established to address such issues and could be used effectively.

White apologized and stated that no disrespect was intended. Although staff is open to discussion, change is definitely needed.

David McCallie said that over the 6 years of his membership he has learned how difficult it is to get standards in place. Brute force and process approaches do not work. A top-down approach does not work.

Eric Rose noted that the workgroups are composed of persons with specific expertise. He did not understand the reasons for dissolving the groups.

Steve Posnack, ONC, reminded them that he talked about a task force structure during a presentation in November. The current structure requires a high level of staff resources. Staff has a lot of experience with the current structure and wants a change. Task forces allow the bringing together of experts with very specific skills. Standing workgroups can miss the context. A more interdisciplinary approach is needed as well as better timing of advice. ONC staff must be nimble in responding to short term issues.

Halamka summarized that focus should determine structure. ONC should define the functions.

Wes Rishel explained that he has learned the futility of commenting on legislation. The constraints under which staff works must be understood. Staff is not allowed to talk to lawmakers about how government works. He recalled that he had learned the hard way about government levers and the practice of government. As a member of the Privacy and Security Tiger Team, which was formed to address the lack of tigerosity, he learned how institutional memory or the lack thereof greatly affects what happens. Institutional memory at the member-level is very important. Members had to educate staff to understand what actually happens in roll out. He expected that debate will be futile in changing White's decision.

Dixie Baker referred to White's statement that in the light of recent experience we believe task forces will be a better structure. What are those experiences? Acknowledging that her term is soon ending, she talked about the importance of having privacy and security subject matter experts on the committee. They have had great influence on existing law. Staff may not even realize what subject matter expertise is needed. It would be a mistake to abandon subject matter-based workgroups with a task force focus.

Stan Huff commented on his frustration with the HITSC being presented with specific questions. A better approach would be to consider what the world should look like in 5 years and how to get there. This is a group of brilliant people who can lay out a vision. The Interoperability Roadmap and Strategic Plan do not fill that function. He suggested having a 2-3 day retreat.

Malec commented again. The proposed structure will reinforce a tactical, short term approach. If the current structure is not working, ONC staff should examine its approach. According to McCallie, the biggest flaw is the separation of policy and technology. The Privacy and Security Tiger Team was a good experience because it was composed of both HITPC and HITSC members. Will the HITPC also be restructured?

Halamka suggested that staff consider John Kotter's work on managing organizational change. He noted that legislation has been introduced to eliminate the committee. Although he said that he does not want to burden staff, he suggested that they enumerate the areas for change. Perhaps a mix of workgroups and task forces is a solution.

White thanked the members for a great discussion. He said that staff put considerable thought into the decision for reorganization. Discussion can continue outside of the public domain.

Jody Daniel, ONC, appreciated the comments. ONC will go forward with reorganization and reevaluate as necessary.

### **S&I Framework - Data Access Framework (DAF) Initiative Update**

Halamka observed that the discussion put the meeting more than 45 minutes behind schedule. He asked about the urgency of the DAF presentation: Can it be moved to the end of the meeting? Staff agreed, but said that DAF has implications for precision medicine. (It became evident later that the DAF presentation must be rescheduled for another date.)

### **2015 Certification NPRM Comments**

The remaining agenda was devoted to comments on the 2015 Certification NPRM with each workgroup presenting comments on assigned sections.

**Architecture, Services, and APIs Workgroup** Co-chairpersons David McCallie and Arien Malec showed slides and distributed a draft transmittal letter stating the recommendations on the items assigned to the workgroup. The slides summarized the NPRM proposal, the workgroup's conclusions, and the respective recommendations. The following recommendations, which are described in much greater details in the meeting materials, were made:

#### Application Access to Common Clinical Data Set § 170.315(g)(7) and VDT:

Sub-regulatory flexibility to allow Health IT developers to be deemed to achieve certifiable status through participation in a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability. Rather than require strict by category functional requirements, the certification requirements should instead generalize to require that discrete individual elements of any of the currently active data included in the Common Clinical Data Set be retrievable via the API through means that could include but are not limited to "by category", "element retrieval" or other means (e.g., "active medication list"). It is possible that "by category" queries will provide useful in practice, but it is equally possible that other discrete queries may be more useful in practice.

Removal of the "XML or JSON" requirement. If the intent is to encourage Health IT developers to use HL7 FHIR, we would encourage a more explicit statement (as suggested above); otherwise, there are multiple alternative valid data formats that might be used by a functional implementation of an API (e.g., Protocol Buffers, Avro Thrift, HL7 V2 pipe-delimited message segments, etc.).

ONC provide in regulatory intent text a set of non-exhaustive means of achieving the intent of the functional requirement

It is our understanding that the meaningful use requirements allow provider organizations to meet VDT requirements through a portal OR through the API. We believe that for maximal flexibility, provider organizations should be able (but not required) to provide both means and allow each kind of access to be counted towards the numerator

Encourage ONC to allow means for Health IT modules to modularly certify towards each of the three API scenarios (get patient identifier, get document, get discrete data) individually, while stating the expectation that Health IT developers and provider organizations should ensure that the APIs work together functionally.

Look at existing (non-Health IT) developer ecosystem best practices and also collaborate with other applicable agencies on guidance on voluntary policy and governance practices sufficient to meet policy requirements  
Seek to achieve policy goals through Health IT and provider organization participation in Data Sharing Arrangements and/or public-private governance efforts  
Include sub-regulatory flexibility to allow Health IT developers AND provider organizations to be deemed to achieve certifiable status with regard to FRAND status through participation in a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability  
Accommodate documentation approaches that point (and link) to well-defined standards-based approaches or well-defined implementation guidance, rather than require Health IT developers to duplicate documentation for standards and implementation guidance.

§ 170.315(b)(6) Data portability:

An authorized user should be able to export data without developer intervention.  
At a minimum the export should be: limited to the CCD; available on demand – even if a manual process; and allow the export of one patient, a subset of patients and the entire set of patients for the setting of care

“Create” and Patient Matching Data Quality:

With regard to date of birth,... recommend that senders send as much of the date of birth as is available. For example, if day of birth is missing, the Workgroup recommends that certification criteria specify senders should send year and month if available.  
For administrative gender, ... point to applicable sections of the C-CDA implementation guide, rather than create new implementation guidance through regulation.  
Because the CAQH CORE implementation guide contains a large amount of information specific to ACS X12 documents, the certification criteria should point to the specific relevant sections of the CAQH CORE guide intended.  
The CAQH guide is specific to normalization of information on receipt, rather than on send. Because pre-normalization on send can lead to data loss (e.g., for receivers who may account for punctuation in matching rules), we recommend that ONC adopt these rules as best practice for receipt, rather than certification criteria on send.  
For send, we recommend that certification criteria clarify that Health IT systems should store last/family name distinct from suffix and populate for purposes of interoperability (for example, following C-CDA implementation guidance) accordingly.

XDM Package Processing:

Certification criteria should specifically point to section 3.32.4.1.4 of ITI 2b: “The Portable Media Importer shall verify the integrity of the media by comparing their size and hash with the value of the corresponding entries in the METADATA.XML file of the relevant submission set directory. Mismatching documents shall be indicated to the user. Media faults shall be indicated to the user.” We recommend that in addition to these requirements, the valid documents corresponding to the metadata entries be extracted and, if appropriate, be presented to the user. We note that many Health IT systems suppress or allow to be suppressed by configuration certain file types for the protection of the user (e.g., executables), and recommend that certification criteria not inadvertently require that all documents, regardless of type or security risk, be extracted.

§170.315(h)(4) Healthcare Provider Directory Query Request and § 170.315(h)(5) Healthcare Provider Directory Query Response

Certification criteria are premature at this time and recommend that ONC not include these criteria in the final rule.

Recommend that ONC consider pilot testing and production implementation prior to certification; pursuant to our previous recommendations on Core Composables and Orchestration Patterns, we recommend that pilot testing and production implementation should be aligned with the health care hourglass and the overall Interoperability Roadmap. In particular, we suggest that ONC work with developer and standards bodies to explore the use of relevant FHIR standards for access to provider directories, given the stated intent to require FHIR-based API conformance in future certification standards.

**Discussion**

Jeremy Delinsky pointed out that the API discussion started with the JASON Report. APIs are typically proprietary. API exploration by vendors should be encouraged. McCallie responded that the JASON Task Force struggled over public or private APIs and concluded that core services must be available to all, but vendors could offer additional proprietary services. Delinsky said that exchange of a core clinical data set is basic. Further regulation could lower the administrative burden for ONC.

Kim Nolan referred to public-private certification and emphasized the importance of a transparent certification process. Transparency is typically restricted in private settings. Malec said that the recommendation is a sub-regulatory mechanism. A balance of interests must be considered.

Noting the meeting schedule, White called for brief and focused comments only. Leslie Kelly Hall asked about new players that are not certified EHRs. What about the import of these data from patient apps? McCallie responded that as written in the NPRM, the requirements were untestable.

Rishel referred to the bilateral exchange being critical to the direction of FHIR. CAQH has a balanced process but has focused on administrative transactions. Should the data format be exactly the same as required by payers? Regarding private versus public APIs, private APIs should be allowed to develop before establishing a public API.

Halamka referred to the workgroup's draft transmittal letter, saying that he had heard nothing that indicated objection to its content. He asked for any disagreements and hearing none, he announced that the comments and recommendations were accepted. He proposed limiting workgroup presentations to 40 minutes.

**Action item #1: The recommendations made by the Architecture, Services, and APIs Workgroup were accepted for forwarding to ONC.**

Having been reminded about accepting the summary of the April 2015 meeting, Halamka asked the members if anyone opposed acceptance. Hearing none, he called the summary approved.

**Action item #2: The summary of the April 2015 meeting was approved as circulated with the meeting materials.**

**Content Standards Workgroup** Chairperson Andrew Wiesenthal and Co-chairperson Rich Elmore reported. They said that they had already agreed to greatly abbreviate the oral report insofar as the recommendations contained no showstoppers. Elmore began the report with slides on overarching themes. Referring specifically to standards, he said that the following are not ready: clinical decision support, DS4P, esMD, virtual Medical Record, Quality Improvement and Clinical Knowledge data model,

and electronic Delivery of Service. The NCPDP Formulary and Benefit Standard and CCDA Care Plan Template should be reconsidered. Testing requirements and gold standards should be delivered prior to, or with, the final rule. The workgroup provided 28 slides with specific comments on the assigned following items:

- Medication Allergy List, p.57
- Computerized Provider Order Entry – Medications, p.38
- Computerized Provider Order Entry – Laboratory, p.38
- Computerized Provider Order Entry – Diagnostic imaging, p.41
- Drug-drug, Drug-allergy Interaction Checks for CPOE, p.41
- Drug Formulary and Preferred Drug List Checks, p.63
- Electronic Prescribing, p.113
- Structured and Codified “Sig”, p.115
- Incorporate Laboratory Tests and Values/Results, p.120
- Transmission of Laboratory Test Reports, p.123
- Pharmacogenomics Data – Request for Comment, p.236 (first 4 bullets)
- Decision Support – Knowledge Artifact, p.94
- Decision Support – Service, p.96
- Clinical Quality Measures (all sections), p.138
- Electronic Submission of Medical Documentation, p.222
- Transitions of Care, p.98
- Updated C-CDA Standard, p.99
- Valid/Invalid C-CDA System Performance , p. 102
- C-CDA Data Provenance, p.110
- Consolidated CDA Creation Performance, p. 202
- Clinical Information Reconciliation and Incorporation, p.111
- Incorporation System Performance, p.111
- Care Plan, p.136
- Common Clinical Data Set, Updated C-CDA, and Diagnostic Image Reports, p.160
- Application Access to Common Clinical Data Set, p. 205

### ***Discussion***

Halamka said that Argonaut balloting that is underway will fill some of the standards gaps. At the June 11 meeting, they will agree on which proposed standards are too immature to recommend. Many federal agencies want to use these standards in their work. However, to put immature standards into regulation is irresponsible. It is better to focus on functionalities.

McCallie agreed with the list of immature standards. Most likely many immature standards will never become mature and will be replaced with other models. He and Josh Mandel are working on a project to expand plug-ins to integrate with CDS. Wiesenthal noted that some standards may come from specialty associations.

Kelly Hall said that emphasis should be on a common query approach and getting the information into the record. But potentially certifying developers to ensure that CDS is done in a responsible way would be a good thing. Did the workgroup discuss that aspect? Not including patients in CDS design is narrow-minded. Floyd Eisenberg said that there is a comment in the slides about including patients in CDS. HL7 CDS development includes metadata standards on origin, last update and supporting evidence. A

grading mechanism is not included. Wiesenthal said that there was no discussion of the issue of curating the developer.

Malec announced that he preferred detailed reports over overviews. CCDA version 2 would require a work upgrade for everyone. It is questionable whether the expected improvement in interoperability justifies the required work. Did the workgroup explicitly consider cost-benefit? Elmore and Wiesenthal indicated that only improvement of what would be sent was considered.

Rishel referred to preferring the future of FHIR. Elmore said that they agreed with the API Workgroup. Rishel went on to say that asynchronous bilateral crossover may not apply here. Not requiring something does not mean the vendor will throw it away if previously certified. He predicted that 50% of the current vision for FHIR will never come about in a recognized form. But many unexpected things will result.

Halamka declared that he had heard only friendly comments, indicating no objections to the concepts presented. He asked about any disagreement. Hearing none, he called the report accepted.

**Action item #3: The recommendations and comments of the Content Standards Workgroup were accepted for forwarding to ONC.**

**Transport and Security Standards Workgroup** Chairperson Baker said that she needed more than 40 minutes. She showed slides and reported on the assignment. After reviewing the HITSC-approved criteria for standards readiness, she said that SHA-2 and NIST 800-92 are ready, but DS4P, esMD and HL7 IG for CDA Release 2: Data Provenance, Release 1 (US Realm) (DSTU) are not. The workgroup agrees with the proposed approach to privacy and security certification ( which is very close to the workgroup's previous recommendations) and recommends adding privacy and security criteria to the clinical module (add integrity criterion involving transmissions) and to the care coordination module (add amendments criterion to support patient requested amendments). It recommends adding authentication, access control, and authorization; auditable events and tamper-resistance; and integrity to the design and performance module and API criterion. The workgroup recommends the addition of certification criterion stating that certified HIT should be capable of recording an audit trail of all security-relevant events and of NIST SP 800-92, sections 2.1.2 and 2.1.3, as standard for specification of auditable events, in addition to ASTM E2147-01. Regarding the ability to disable the audit log, no change from the 2014 Final Rule is recommended. It suggested a language change for automatic access time-out: "Automatically terminate access to protected health information after a configurable period of inactivity, and reinitiate session upon re-authentication of the user." It agrees with the proposed change for end-user device encryption. The workgroup suggests adding reference to FIPS 140-2, Annex A (which includes *Guideline for Transport Layer Security (TLS)*), to support proposed new certification criteria for application access for patient engagement and the Common Clinical Data Set. It agrees with the change in testing approach for integrity and agrees with moving to SHA-2 in the 2015 Edition.

**Discussion**

Halamka noted that although granular choice is important, more experience with the standard is essential. A number of the proposed standards are immature; it is not reasonable for staff to directionally propose.

White wondered about an approach of agreeing on the functionalities. Baker assured him that the workgroup agrees that ONC should strongly support these standards development efforts. To do so communicates direction to the industry. But direction is very different from setting something into law. To encase something into law that is not ready would be irresponsible.

Halamka said that they can agree not to mention HDP. Others may be nearly ready. But what about a ranking system? Baker said that these are not functional specifications. These specifications are not ready. Halamka said that at the June 11 meeting, they can group the proposed standards as ready, not ready, in-between. McCallie talked about architectural level requirements; then vendors can figure out how to do it. But DS4P is highly specific and requires more challenging architecture. Some of the proposals involve metadata problems with secondary requirements for the use and reuse of data elements that vendors have not thought about before. It is a multi-year problem.

Malec referred to functional requirements in the API space. Some EHRs already have APIs. There is a body of ongoing work. But with DS4P and data segmentation for behavioral health, many fundamental questions have yet to be worked out. There is no adoption. He asked about integrity: Is it proposed for transport only? Baker said yes. Regarding auditable events and time outs, are these to be configurable? Baker said that organizations should be able to configure their time out. Malec posed two scenarios for certification, saying that he is concerned about management decisions being made by developers. Baker acknowledged that the scenarios were not discussed by the workgroup. They may be examples of tradeoffs between security and safety. Workgroup Co-chairperson Lisa Gallagher said that providers definitely expect configurability. She said that the workgroup did not consider ONC's questions in the context described by Malec. She indicated that the issue could possibly be revisited in the workgroup.

In response to a question from Kelly Hall, Baker confirmed the recommendation that auditable events be added to existing API criteria.

Halamka suggested that Baker and Gallagher may want to do some wordsmithing to include the edge case described by Malec. Otherwise, the comments can be forwarded unless objections were heard. None were heard, and he declared the recommendations and comments accepted.

**Action item #4: The recommendations and comments of the Transport and Security Standards Workgroup were accepted for transmission to ONC.**

**Public Comment**

Thompson Boyd, Hahnemann University Hospital, submitted a written comment at the meeting web site. He said that he agreed with McCallie on an outcome construct rather than a process construct. The output of the Data Provenance Task Force in January 2015 was very good and served as the basis for comments to the NPRMs.

**2015 Certification NPRM Comments Continued**

**Implementation, Certification, and Testing Workgroup** Co-chairperson Cris Ross began with several general comments. Balance is needed between benefits received from lofty goals proposed compared to the cost and time commitments required for implementation. ONC and ANSI should ensure ACBs and ATIs behave consistently to reduce variability and ensure all developers are held to the same level of requirements. Estimates related to cost (\$100M) do not include additional direct and indirect costs incurred by providers and vendors to analyze and prepare for regulatory requirements including development, training, etc. While it is a positive development to recognize other care settings (e.g. long term care) that may benefit from use of certified health IT, ONC needs to ensure appropriateness based on current baseline and feasibility for implementation. Comments specific to assigned items include the following:

**Gap Certification Eligibility Table**

Regardless of whether a product was certified via gap certification or via traditional testing, end users should have the same level of confidence in all certified products.

ONC and ANSI should minimize variability across ACBs and ATs, and ensure they are behaving consistently in what requires re-testing or certification versus gap certification. ONC should consider a form of standardization or defined set of criteria for how an ACB assesses vendor products for gap certification.

#### Common Clinical Data Set Definition

Generally supportive of semantic change to CCDS .

Inclusion of Unique Device Identifier (UDI) is problematic for a number of reasons particularly for ambulatory practices.

Inclusion of immunizations mapped to NDC codes may be problematic as most providers do not include NDC codes when documenting immunizations; these may be missing from historical immunizations, and because immunizations are often received outside of the practice setting.

#### Consolidated CDA creation performance

Further constraint of optionality C-CDA standard is needed before additional testing at certification will provide assurance that in-field C-CDAs map appropriately.

A gold standard C-CDA is a good concept, but more clarity is needed around who will develop and maintain for reference.

Consider ongoing, non-mandatory test frames to allow for developers and end users to test C-CDAs against to ensure interoperability.

Look to HIPAA X12 for lessons learned.

ONC should provide further details to ACBs as to what specific aspects that C-CDA testing should focus on.

#### ONC Health IT Certification Program and Health IT Module

ONC should clearly articulate what field surveillance of a deployed system would entail. The workgroup supports recognition that deployed versions of a lab-tested system vary in performance from site to site, though variations are often a result of site-specific user training, configuration or usage issues.

Alterations to the standard or lab tested implementation should only require documentation if alterations affect the achievement of MU or other programs.

ONC should limit with specificity what is meant by the audit and/or the requirement to document and report changes to the standard deployment of the lab-tested system to prevent undue burden on developers and sites.

Ross continued to report, showing a slide with comments and recommendations on each of the remaining assigned items:

- Base EHR definitions
- Retesting and certification
- Safety enhanced design
- Web content accessibility guidelines
- Design and performance
- Request for comment on summative testing
- Encounter diagnoses
- Medication dosing
- Implantable device list
- Pharmacogenomic data

- Data portability
- Automated numerator recording

### **Discussion**

Wiesenthal referred to implantable devices. A hierarchy is going to be incorporated in SNOMED CT within the next few months. Related to the request that the encounter diagnosis be the billing diagnosis, in the future billing will not be based on encounters.

Malec endorsed better constraint of CCDA version 2, saying that ONC should have a work plan for so doing. He wondered whether any workgroup had addressed quality management system changes. Consolazio responded that the topic was assigned to the HITPC Implementation, Safety and Usability Workgroup. Malec wondered about the experience of that group. Requirements may be too restrictive. Staff should look at other quality management systems. Malec continued. Regarding summative and formative testing, he observed that formative testing makes it possible to introduce changes into the software. He recommended saying either summative or formative is applicable: What was the workgroup's thinking? Ross acknowledged that Malec made a good point, but he pointed out that it depends on the heterogeneity of the environment. The point is which type of testing would have the most impact for the clinician. There were different viewpoints among workgroup members. But requiring formative testing was considered too difficult. Malec urged making it optional.

Baker commented on slide 22 pharmacogenomic data, saying that there is evidence of improved outcomes for select markers. The IOM EHR Action Collaborative is doing relevant work. She suggested that ONC follow this effort. Ross agreed with her suggestion.

White announced that he participates in the IOM group. He noted that some of the recommendations apply to the CMS incentive program rather than to the certification program.

Eisenberg said that he shared Malec's concern about formative and summative testing. The Content Standards Workgroup agreed with the comments on calculation of the numerator. In response to a question about CDS, Ross said that CDS was not part of the workgroup's assignment.

Nolan said that the Content Standards Workgroup made the same recommendations on pharmacogenomics data codes. She referred to the slides for details.

Halamka asked about objections to forwarding the report to ONC. No objections were heard.

### **Action item #5: The recommendations and comments of the Implementation, Certification, and Testing Workgroup were accepted for transmission to ONC.**

**Semantic Standards Workgroup** Co-chairperson Jamie Ferguson began with general comments. The common data set items should align with Clinical Data Acquisition Standards Harmonization (CDASH) as closely as possible. Pending codes do not belong in regulation. The NPRM should support methods for combining use of LOINC and SNOMED that are consistent with current published cooperation agreements, such as the Cooperation Agreement July 2013 Between The International Health Terminology Standards Development Organisation (IHTSDO) and The Regenstrief Institute, Incorporated (RII). In general, the recommendation is to use LOINC for the question and SNOMED CT for the answers unless there is a good reason not to. More attention should be paid to the broader range of standards and requirements essential to learning health system objectives. Many HIT systems that support research and many clinical activities currently use other standards that might not transition or interoperate well. The certification program should allow for versioning of standardized terminologies without changes in regulation. It is preferable to specify the floor, rather than the ceiling. Specific codes should not be identified in regulation.

Mitra Rocca reported on the specific items assigned to the workgroup.

#### Pharmacogenomics Data – Standards p. 239

- The pharmacogenomics domain in the CDISC Study Data Tabulation Model (SDTM) standard should be considered.
- P. 237: Pharmacogenomics data is being included in an increasing number of FDA-approved drug labels. Recommend leveraging HL7 Structured Product Labeling (SPL) standard for inclusion of pharmacogenomics data.
- A natural area of focus for needed standards development should be in future versions of SPL
- Pharmacogenomics standards developed through CDISC for research and the Life Sciences Domain Analysis of the NCI should be considered as sources.

#### Common Clinical Data Set Definition - Vocabulary Standards p. 246

- The Common Clinical Data Set needs further vetting and harmonization, especially among federal agencies.
- The Common Data Set items should align with Clinical Data Acquisition Standards Harmonization (CDASH) as closely as possible.
- Specific versions of vocabulary standards specified may become obsolete or superseded and systems that are able to use later versions should be allowed to do so.
- Workgroup members would like to see source of truth on each item in the common clinical data set and its associated vocabulary (e.g., a table)
- An effort should be made to align the Common Clinical Data Set with the Core Common Dataset (~ 200 elements) that is recommended by FDA and paves the way to standards required by FDA and a learning health system

#### National Drug Codes for Administered Vaccinations p. 170

- Disagree with replacing CVX with NDC because CVX is specifically useful for coding instances and recommend augmenting records to include NDC with CVX for specific use cases. CVX is used for times when the precise manufacturer and package are not known and not needed as in shot records.
- Support the use of NDCs to augment CVX. CVX should not be replaced by NDC

#### § 170.315(f)(2) (Transmission to public health agencies – syndromic surveillance) p. 176

- Assuming that UCUM is not precluded based on our reading of the implementation guide we believe the proposed rule is acceptable

#### § 170.315(f)(3) (Transmission to public health agencies – reportable laboratory tests and values/results) p. 179

- Agree, as long as Unified Code for Units of Measures (UCUM) is not precluded.

#### Immunization History and Forecast p. 174

- CVX codes exist to support documentation of immunization when manufacturer, package, and lot number are not known or needed, such as in a shot record. We disagree with replacing CVX with NDC and support the ability to augment the CVX with the NDC when information is available and needed.

Eric Rose continued.

Work Information – Industry/Occupation Data pp. 90-92

- Use of SNOMED CT for encoding occupation should be given strong consideration -- SNOMED would facilitate easily identifying all patients who are healthcare professionals, (e.g. to make sure they have been vaccinated for hepatitis B or get annual screening for tuberculosis)
- Options -- Analyze SNOMED CT for gaps vis-à-vis other preferred lists like the CDC occupation list and propose addition of any cap concepts to SNOMED CT US Extension or cross-map SNOMED occupation codes with the CDC's occupation codes to allow analysis that combines data encoded in both
- More attention should be paid to the broader range of standards and requirements essential to learning health system objectives. Many HIT systems that support research and many clinical activities currently use other standards that might not transition or interoperate well.

§ 170.315(a)(14) Family health history p. 68

- §170.207(a)(4): The NPRM text should indicate that both SCT-International plus the US Extension are included in the US Edition of SNOMED CT distributed by the National Library of Medicine.
- The phrase “in accordance with” is ambiguous and should be clarified. In particular, it would be advisable to clarify that use of an interface terminology mapped to the referenced standard for recording data constitutes recording of the data “in accordance with” the standard.
- At this time it may be overreaching to require the HL7 Pedigree standard.

Minimum Standards Code Sets p. 32

“If adopted, a newer version of a minimum standards code set would serve as the baseline for certification. As with all adopted minimum standards code sets, health IT can be certified to newer versions of the adopted baseline version minimum standards code sets for purposes of certification, unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and 77 FR 54268).”

§ 170.315(a)(5) Demographics p. 44

- It would be valuable if there was harmonization of demographic data across federal agencies.
- Since the prior requirement for CEHRT was to use the simpler OMB standard, adopting the CDC standard would require re-collection of data from all patients.
- The CDC race list\* is long, and may be confusing in use.  
\*<http://www.cdc.gov/nchs/data/dvs/RaceCodeList.pdf>
- Preamble proposes, “health IT developers and health care providers would work together to establish the appropriate implementation given the care setting.” This could result in user interfaces with poor usability, which in turn could affect the accuracy of data collection.
- Requirement that CEHRT be “able to aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity”
- If the CDC race code list is adopted, then transformation of the CDC-encoded race data to the OMB standard would more suitable for downstream analytical systems.

§ 170.315(a)(6) Vital signs, body mass index, and growth charts p. 49

Re: vital signs measurements that may be calculated based on other vital signs measurements – Should explicitly state that if a CEHRT provides the capability to calculate these values, it need not provide the ability to directly enter them (superfluous and introduce the possibility of error).

Re: The stipulation of specific LOINC codes — Avoid identifying specific LOINC codes for storage of vital signs (or any data).

- LOINC codes may be updated or deprecated by the publishers of LOINC
- Specific LOINC codes listed are unduly restrictive since other, more specific, LOINC codes exist that are pre-coordinated with relevant details
- Restricting specific LOINC codes to a more granular level could potentially discard critical clinical information
- Measurements are not semantically identical, and to promote admixture of instance data as if they are (which would be the effect of the regulation as written) would potentially be detrimental to patient care

§ 170.315(a)(12) Smoking status p.67

- Laudable to liberalize the use of SNOMED CT codes to represent smoking status beyond the 8 codes used for 2014 edition certification criteria
- Problem that only those 8 codes are permissible for representing smoking status in the Common Clinical Data Set and for electronic transmission in a summary care record.
- The premise that any other smoking status code could be mapped to one of those 8 (as stated in the preamble) is erroneous. Example: For instance, SNOMED 266920004, “trivial cigarette smoker (less than one cigarette/day)” is not a child, in the SNOMED hierarchy, of any of the 8 smoking-related codes required in the 2014 edition certification rule.
- Clarify that this refers to tobacco smoking status, rather than information on the smoking of other substances, since the intent of this criterion appears to be tobacco-specific.
- The Committee recommended a different and shorter (2 questions) measure for tobacco use and exposure than the one previously established as the standard for EHR certification. Shorter seems better, even if it requires making a change

§ 170.315(a)(21) Social, psychological, and behavioral data p.81

- Valuable to be able to capture psychosocial and behavioral data in EHRs in structured and coded form.
- The proposal to encode “answer” data should be rethought, generally not in the semantic scope of LOINC
- Regulation should not be based on any premises of action by entities outside the regulator’s control
- The ability to record gender identity separate from biological sex is important and its inclusion is laudable.
- Regarding sexual orientation - allow any SNOMED code describing sexual orientation to be used instead of limiting to 3 specific SNOMED coded
- The list of specific data required probably exceeds what is needed (e.g. increasing knowledge of, and reducing, health and health care disparities based on psychosocial parameters)
- Add dietary habits and use of psychoactive substances other than alcohol and nicotine

Work Information – Industry/Occupation Data pp. 90-92 — Use of SNOMED CT for encoding occupation should be given strong consideration

Rose concluded with slides and comments on military service and medication dosing

### ***Discussion***

McCallie inquired about harmonization of the clinical data base and implications for the Argonaut work and FHIR profiles: Are these far apart? Rose referred to comments on the Interoperability Roadmap that called for more vetting of the data set. Different profiles may be needed for research to enable a learning health system. Becky Kush emphasized the importance of harmonizing data sets across federal agencies. Halamka offered to send information on Argonaut harmonization to Kush for review. A debate ensued about the applicability of EHR data for research trials. Kush said that she has raised the issue at every HITSC committee over the past 5 years to no avail. Ferguson said that interagency harmonization is important.

Posnack noted that although the social and psychological characteristics certification criteria are not applicable for meaningful use, staff wants to know whether they should be in or out. Rose said that structured data for social history should be in. Some elements may be superfluous and two should be added. Posnack called for balance. He observed some unintentional blending of terminology regarding the common data set. Policy on the common meaningful use data set was established 3 years ago. There are only a few minor changes. Is the issue the data or is it the code sets? Ferguson reiterated that the workgroup is saying the lack of harmonization across FDA and other agencies is the issue.

A member referred to vital signs and the recommendation for less specificity. Rose said that the certification regulations should be straightforward and less burdensome. The NPRM does not allow developers to take advantage of granularity in the terminology.

Nolan said that the Content Standards Workgroup also considered pharmacogenomic data and genomic information and drug interaction. More thought should be given to these relationships.

Malec wondered about having had sufficient EHR practice to justify the inclusion of social and psychological data. Regarding smoking status, what is the recommendation? Do the eight questions improve interoperability? Rose responded that there is an error in the slide. According to folklore, the eight SNOMED codes date back to a paper form used in the 1950s. The categories are very poorly defined. Ferguson interjected that the overarching comment is that the Rule should not be over specific on core values; rather it should point to a library of value sets. Malec went on. Regarding vital signs, some elements may not be routinely collected at all ambulatory visits. Rose explained how calculated measures work.

Halamka said that he sent Kush the implementation guides so that she can inform him of any gaps.

Huff talked about items in the common data set becoming wholly underspecified in order to get to interoperability. Real work experience with implementation is needed. He agreed that there should be no codes in regulations. Ferguson said that the Rule can point to a source of guidances.

Halamka announced that it was time to adjourn. The only potential reconciliation is pending Kush's response. He heard no objections for accepting the recommendations and comments for transmittal to ONC.

**Action item #6: The recommendations and comments of the Semantic Standards Workgroup were accepted for transmission to ONC.**

A virtual meeting is scheduled for June 11 to prioritize recommendations on the Certification NPRM. The goal is to enumerate the standards proposed in the NPRM as ready, not ready, or potentially ready.

White referred to more information on restructuring in June. Regarding a precision medicine workgroup, an invitation to participate is forthcoming. The new Standards Advisory Task Force is open for volunteers.

**Public Comment:** None

**SUMMARY OF ACTION ITEMS:**

**Action item #1: The recommendations made by the Architecture, Services, and APIs Workgroup were accepted for forwarding to ONC.**

**Action item #2: The summary of the April 2015 meeting was accepted as circulated.**

**Action item #3: The recommendations and comments of the Content Standards Workgroup were accepted for forwarding to ONC.**

**Action item #4: The recommendations and comments of the Transport and Security Standards Workgroup were accepted for transmission to ONC.**

**Action item #5: The recommendations and comments of the Implementation, Certification, and Testing Workgroup were accepted for transmission to ONC.**

**Action item #6: The recommendations and comments of the Semantic Standards Workgroup were accepted for transmission to ONC.**

**Meeting Materials:**

- Agenda
- Summary of April 2015 meeting
- Meeting presentation slides and reports

Meeting Attendance								
Name	05/20/15	04/22/15	03/18/15	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14
Andrew Wiesenthal	X	X	X	X	X		X	
Anne Castro	X		X	X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X	X	
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris		X	X	X	X	X		X
Charles H. Romine	X	X	X	X			X	
Christopher	X	X	X	X			X	X

Ross								
David McCallie, Jr.	X	X	X	X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson		X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X	X
Floyd Eisenberg	X		X	X	X	X	X	
James Ferguson	X	X	X	X	X		X	X
Jeremy Delinsky	X		X	X		X	X	
John Halamka	X	X	X	X	X	X	X	X
John F. Derr		X	X	X	X	X	X	X
Jon White	X	X	X	X	X			
Jonathan B. Perlin			X					
Keith J. Figlioli	X		X		X		X	X
Kim Nolen	X	X	X	X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X	X	X	X	X
Lorraine Doo		X	X	X	X	X		X
Nancy J. Orvis		X	X	X			X	X
Rebecca D. Kush	X			X		X	X	X
Sharon F. Terry		X					X	X
Stanley M. Huff	X		X	X	X	X	X	X
Steve Brown		X			X			X
Wes Rishel	X	X	X	X	X	X	X	

Total Attendees	21	22	26	25	22	20	25	22
-----------------	----	----	----	----	----	----	----	----