HIT Standards Committee
DRAFT
Summary of the March 27, 2013 Web Meeting

ATTENDANCE

The following members attended the meeting:

- Jonathan Perlin
- John Halamka
- Dixie Baker
- Anne Castro
- John Derr
- Jeremy Delinsky
- Christopher Chute (term expired)
- Floyd Eisenberg
- Jamie Ferguson
- Lisa Gallagher
- C. Martin Harris
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Marc Overage (term expired)
- Wes Rishel
- Eric Rose
- Christopher Ross
- Walter Suarez (term expired)
- Sharon Terry
- Jim Walker (term expired)
- Andrew Wiesenthal
- Tim Cromwell
- Lorraine Doo
- Kevin Brady for Charles Romine

The following members were absent:

- Keith Figlioli
- Leslie Kelly Hall
- Nancy Orvis

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the Health Information Technology Standards Committee (HITSC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with an opportunity for public comment,

and that a transcript would be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Remarks

David Muntz, Principal Deputy National Coordinator, remarked on the recent HIMSS meeting in New Orleans, where interoperability was showcased. There were many conversations about how to optimize Stage 2. Analytics was a frequently discussed topic. He reported that the halfway mark on the distribution of incentives had been reached and noted the anniversary of the passage of the Affordable Care Act (ACA). Following an open call to fill expired terms, appointments to the HITSC were announced March 1st by HHS. Reappointed for another term were: Vice Chairperson John Halamka, Christopher Ross (chief information officer representative), Wes Rishel (HIT representative), James Ferguson (health plans representative), Charles H. Romine (NIST and director information technology laboratory), Lorraine Doo (CMS), and Nancy Orvis (DoD).

New members are: Jeremy Delinsky (small innovative provider representative), Keith J. Figlioli (purchaser and employer representative), Lisa Gallagher (HIT security representative), Taha A. Kass-Hout (CDC), Anne LeMaistre (chief medical information officer representative), Kim Nolen (pharmacy representative and medical outcomes specialist), Eric Rose (provider and HIT implementation representative), and Andrew Wiesenthal (provider and HIT implementation representative).

He thanked the retiring members, who will retain their roles as chairs, co-chairs, and members on the various HITPC and HITSC workgroups, subgroups, and tiger teams: Walter Suarez, Marc Overhage, James Walker, and Kevin Hutchison. Fourteen members will continue in their current terms.

Review of the Agenda

Jonathan Perlin, Chair, welcomed the new members and recognized the many achievements in health IT showcased at the HIMSS event. He noted that each of the agenda items represented an effort to thread together an HIT ecosystem. Perlin inquired about objections, corrections, modifications, improvements, amendments or additions to the meeting summary distributed with the meeting materials and, hearing none, announced the acceptance of the summary of the February 2013 meeting as distributed.

> **Action item #1: The summary of the February 2013 HITSC meeting was approved as circulated.**

He instructed members to identify themselves before speaking.

Comments

John Halamka, Vice Chairperson, spoke of his interest on behalf of his employer in obtaining the certification test scripts as soon as possible. In his several roles, he is being asked to incorporate patient-generated data in IT systems. Robustness of data is a concern. LTPAC coordination requires additional elements in the template for the summary of care. There is much work ahead to continue the progress in interoperability. Assignments for Stage 3 have been made to the workgroups.

Implementation Workgroup Update: Testing Scenario Presentation and Posted Test Scenario Materials

Liz Johnson, Co-Chair, introduced the topic. The purpose of scenario testing is to make testing clinically plausible, to ensure use of data stored in the EHR, and to increase the value, efficiency, and consistency of testing. Scott Purnell-Saunders, ONC, used his slides to describe the scenario testing. He began with the current unit-based testing, which requires independent tests and individual test data (input) and result(s) (output). Unit testing is required for 2011 and 2014 Edition testing and certification. Scenario-based testing is intended to ensure the ability to use data across systems and within a system, to reduce

the setup of testing, and to make testing consistent and replicable. As an alternative to unit-based testing, scenario-based testing means dependent tests for which the test data link unit tests with dependent inputs and outputs and the test data output of one test can be the input for another. Scenario-based testing will be optional for the 2014 Edition. Scenario-based test procedures will be clinically plausible, meaning that a scenario represents one possible clinical workflow that could link unit tests, but it does not represent the only way unit tests could be linked in a clinical workflow. Scenarios will test all of the capabilities of the criteria in the scenario. They do not imply any requirements about how eligible providers should use EHR technology to attest to meaningful use. Purnell-Saunders explained that in order to avoid redundant data entry, the test sequence assumes a sequence of unit tests, which is acceptable because the purpose of certification is different than that of quality testing. For certification, verification is that the expected outcome can occur, not that the code is bug free. He went on to show an example in which the post-test state of unit test 1 is used for setting the initial state of unit test 2. For each test after unit test 1, a testing analyst must determine which data flow through from previous tests and what incremental data must be entered during the test. The volume of flow-through data is compounded with each test in the scenario. The flow-through data include not just information that would be otherwise re-entered during subsequent tests. The data also include other data that might influence the quality of the unit test. There can be two testing scripts each for tests 2, 3, and 4. One instructs the tester to enter all of the data and the other instructs the tester only to enter the incremental data. Scenarios represent a suggested sequence for testing criteria. In a scenario, unit tests can be added, removed, or rearranged for various reasons, depending on the scenario. For instance, a scenario can be made clinical location-specific by adding or removing unit tests.

The first draft test scenario procedure is available on the ONC website. The draft Test Scenario Procedure: EHR Interoperability Intake includes the following criteria:

- (a) (4) Problem list
- (a) (5) Medication list
- (a) (6) Medication allergy list
- (b) (4) Clinical information reconciliation
- (b) (1) Transitions of care: receive, display, and incorporate

Discussion

Christopher Ross, Co-Chair, Implementation Workgroup, asked Purnell-Saunders about obtaining public comment on the scenario procedure. Purnell-Saunders replied that comments are being sought via the website. Staff is particularly interested in whether the scenario makes sense from a clinical perspective as well as how to improve the efficiency of presentation. The next step is to pilot the testing procedure with select vendors. Staff will continue to develop scenarios with data that can be used in numerous tests. Halamka reported that he had heard that the testing tools lack robustness and wondered about oversight tools. He also heard that Stage 2 certification includes silly stuff like manual data entry. With respect to the manual loading of data, Ross referred to slide 9, showing that the goals are to reuse data and to be plausible. This approach should make it easier for vendors. Regarding oversight tools, he explained that the Implementation Workgroup plans to gather information from the field via hearings. Halamka reported hearing that tools have improved. He encouraged the workgroup to ask about the need for observation of manual input. Johnson said that the next step is to look at the testing tools. She acknowledged that she and other workgroup members had heard the same complaints.

Wes Rishel commented that the workgroup (of which he is a member) addressed not reentering data entered in a previous step. Interdependence of data is not required for certification. The elimination of re-entering data should result in a substantial saving of time. There may be situations in which the user or the tester wants to use more than the minimal number of patients. It seems to be overkill to require witnessing the entry of patient data beyond the minimum. A local procedure without witness could be employed with

verification by spot check. Although it is important that the data are not known by the system prior to testing, witnessing is not necessarily required. In response to his request for clarification of the timeline, Purnell-Saunders said that once ONC gives final approval, each testing body will offer the scenario-based testing as an option for 2014. Staff is moving as quickly as possible.

Carol Bean, ONC, said that she is seeking comments on how to improve data loading. Staff has revised procedures in several areas to reduce loading time by allowing for the preloading of some data sets and the observation of subsets. Feedback indicates that these changes reduced the burden.

Judy Murphy, ONC, asked her colleagues what percent of testing uses automated test tools and prescribed test data, which she understood increased from Stage 1. Bean said that the tests increased from two to nine. She did not have other numbers at hand and said that she was searching to locate them.

Eric Rose reported on his experience with scenario-based testing seven years ago. It was difficult to develop scenarios that did not go beyond the actual required criteria. He asked whether they intended to ask vendors for their opinions about scenario testing going beyond the requirements. Ross repeated that the intent of the approach is to simplify. He asked Purnell-Saunders and Bean to call out this question for public comment. Johnson indicated testing during the piloting will include consideration of unintended consequences.

Rishel recommended that ONC ask the testing vendors for feedback in addition to the pilot entities. A structured mechanism should be used to obtain information on what is involved in a specific test. The forthcoming information would be used to improve testing but should not be published.

Perlin inquired about modular certification, saying that the interaction across modules may not be seamless. Ross responded that workgroup members and staff have been working on getting the nomenclature right, which was more difficult than anticipated. Now they can begin to look at more complex scenarios. They want vendor feedback before going further. Perlin said that providers need assurance of interoperability.

Bean reported that she had located the information requested. In Stage 1, 14 of the test procedures had test data supplied in the testing environment rather than having vendors bring or use their own data. The number doubled in Stage 2. Testing is now more rigorous, though perhaps more painful.

Perlin asked for consensus in approving the scenario-based testing. He asked whether members had any concerns about submitting approval to ONC. No objections were heard. He declared approval.

> **Action item #2: Members approved the 2014 edition test scenarios and materials as presented.**

Food and Drug Administration Unique Device Identifiers (UDI)

Terrie Reed, FDA, emphasized her interest in working with ONC and the HITSC on UDIs. She acknowledged the usefulness of the comments on the topic previously submitted by the HITSC. Section 201(h) of the FD&C Act states:

> "A medical device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Reed explained that there are many devices that do not have UDIs, such as an insulin syringe. In 2007 and 2012, legislation was enacted to address standard identification. Staff is working on the final regulations. She went on to describe in great detail the four steps involved in establishing a UDI system. The first step is to develop a standardized system to create the UDI that unambiguously identifies a specific device at its unit of use with an UDI code according to ISO 15459. The second step is to place the UDI in human readable and/or AutoID on a device, its label, or both. Next, the Global Unique Device Identification Database (GUDID) must be designed and maintained along with a Device Identifier (DI) look-up to associated device identification data attributes. For each DI, the following are available:

- Manufacturer, make/model, brand or trade name
- Clinically relevant size
- Contact information
- Sterility information
- Natural Rubber Information
- FDA premarket authorization (510k, PMA)
- FDA product code (procode)
- Marketing Status/date
- For single-use
- Higher levels of packaging
- Rx – OTC
- GMDN/SNOMED

The fourth step is implementation. GUDID is a device catalog, not a patient registry. It does not contain patient- or device-specific production information, such as lot or serial numbers. It is not for tracking or tracing or other similar purposes requiring the full UDI. GUDID contains only "static" identifying and product information. GUDID links to product information; it is not a replacement for FDA recalls and adverse event databases.

Reed reported on a proposal for adoption in EHRs. UDI will be the code used in HIT systems to link a patient with specific devices used as part of his or her care. Linking UDI of medical implants to a patient's EHR is a start with UDIs of other devices to follow. The UDI can be scanned at the point of care and stored with sufficient other data attributes (to be determined by expert groups) to maximize benefit to the patient, care providers, and other stakeholders. Certification and meaningful use criteria should facilitate the capability to search, exchange, and alert. Implementation would begin with implants, which are prevalent, high risk devices, not visible to the human eye, and persistent to the patient. Device data are currently captured for patient charging.

She went on to report on the thinking around possible EHR certification criteria in receipt and parsing, storage, look-up, and exchange, for example, the EHR capture of multiple UDIs per patient visit and per procedure within patient visit and storage of the UDI at the level of unit of use.

She noted the numerous benefits for clinical care of linking patients and their devices. Additionally, public health benefits are expected insofar as FDA will use information received to: improve decisions related to adverse event reports; better understand the risk profile of particular devices; mine population-based data sets to better understand the risks and benefits of device use within certain patient populations and indications; and better and more quickly address new concerns raised in premarket submission. She concluded by reading a list of questions directed to HITSC:

- How can I make the patient-device link use case more clear, more compelling, for including in EHR certification and meaningful use criteria?
- Are there other use cases to include in the preliminary stages of UDI being added to the EHR?
- What data attributes of the GUDID should be combined with the patient record to create a meaningful minimum dataset to support adding UDI to EHR Certification?

- Who are the best experts and what is the best mechanism for defining the minimal dataset and ensuring that they become the foundation for storage, exchange and access to patient-device data?
- What should I expect as next steps or outcomes of this presentation?
- What can FDA do to assist in moving forward? What can other stakeholders do?
- How can UDI assist with development of data standards for registries?
- Are there any considerations beyond those presented regarding collection, parsing, and exchange of data?

She requested that they respond to her questions.

Q&A

Halamka exclaimed that the questions will be assigned to workgroups for responses. He recalled that the HITSC's comments on the FDA NPRM included one that recommended iPhones and other applications used in PHRs be included in the scope of work. Reed responded that the scope is medical devices, using the definition cited in the law.

Andrew Wiesenthal reported that some GMDN harmonization was completed. Floyd Eisenberg commented that the UDI metadata may need to be carried over into the summary of care. He suggested that one of the workgroups consider what other metadata are required for provenance. He asked about a link between GMDN and RxNorm for devices that include components such as latex. Reed acknowledged that FDA has no plans for such a link. She suggested that Eisenberg comment to the effect of that need.

Jamie Ferguson recalled that the HITSC comments asked that no exceptions be made for OTCs. Regarding timely maintenance, he said that it is an issue when products are withdrawn from the market. Reed said that when she referred to market status, she was not referring to withdrawal.

Rishel referred to slide 7 and the issuing agencies' processes by which a device is registered and comes to market. Who does what and when? Can the device be shipped before it has a number? Can the same device have different type codes issued by different agencies? UDIs do not always allow comparison of the same items. Reed replied that registration is required before coming to market. ISO 94519 outlines a process to maintain the unique ID through these issuing agencies. The uniqueness should be assured. GUDID business rules prevent the same IDs coming in. There is a primary device identifier as well as a secondary device identifier. They are all in the same record and they are linked. She acknowledged that she did not know who owns the codes that are issued. She offered to find the answer and to report back.

Reed said that many comments had been received on OTCs and are being reviewed. Arien Malec requested that the FDA consider voluntary registration and identification for those devices for which registration is not required. Halamka announced that Reed's questions will be assigned to the Clinical Operations Workgroup.

Long-Term Care Coordination Update

Bill Russell, Seasons Hospice and Palliative Care, referred to the limitations of current and proposed standards to support meaningful use transitions of care (ToC) and care plans. He described Stage 2 ToC and care plan exchange requirements, including the contents of a summary care record and a care plan. The HITPC's RFC for Stage 3 resulted in responses, as summarized by ONC staff, of strong support for the intent of the objectives. Although ToC standards are available, their adoption remains low. There is currently no standardized definition for ToC (exchange of patient information from one entity to non-affiliated entity) and care plan. More work is needed to expand consolidated CDA (C-CDA) to enable interoperable exchange of care plans across care teams. Thus, three major standards gaps were identified for Stage 3: availability of standardized care plan terminology and definitions; availability of C-CDA document types to meet the needs and responsibilities of EPs and EHs as senders and receivers of information during transitions of care; and the maturity and adoptability of candidate standards. He went

on to enumerate these in detail. The concept of care plan and its component parts are ambiguously defined and thereby affect the capability for interoperable exchange. Current standards do not support the requirement to exchange a longitudinal care plan. The C-CDA focuses on problem-specific goals, instructions, and care team members. Other components, such as health concern, interventions, patients' overarching goals, nutrition assessment and diet orders, are omitted. There are no standards for: codifying all of the longitudinal care team members; conveying when and how each section was last reconciled for a given patient; or conveying the many-to-many relationships among the care plan components. Regarding the gap between EP and EH information needs and responsibilities for ToC, Russell noted, first of all, that although meaningful use has a tremendous effect on LTPAC providers, they are ineligible for incentives.

Larry Garber, Reliant Medical Group, reported on his ONC-supported IMPACT grant, which he indicated may solve some of the standards deficits described by Russell. Project staff surveyed workers in 46 organizations to identify the perceived data needs of receivers of ToC. Their responses, along with additional input from representatives of select state and federal agencies, associations, workgroups, and providers, were used to design a data set. 483 data elements were perceived to be required for longitudinal coordination of care, 175 of which are CCD data elements. IMPACT staff used 325 data elements to construct five transition datasets:

- Report from outpatient testing, treatment, or procedure
- Referral to outpatient testing, treatment, or procedure (including for transport)
- Shared care encounter summary (office visit, consultation summary, return from the ED to the referring facility)
- Consultation request clinical summary (referral to a consultant or the ED)
- Permanent or long-term ToC to a different facility or care team or home health agency

IMPACT piloted the full dataset on paper with two hospitals, two large group practices, two home health agencies, and eight skilled nursing facilities involving several hundred patient transfers. Ninety-three percent of respondents reported they were able to send all IMPACT data elements. Testing in an electronic environment will commence June 2013. The project contracted with Lantana to coordinate HL7 balloting and other tasks. Many vendors have participated to date and will be involved in piloting. Vendors and facilities are very interested in using the results. Balloting will occur in August and September.

Summarizing, Garber said that adoption will be facilitated since the standards extend the existing C-CDA documents (e.g. CCD) and will be incorporated into C-CDA during next C-CDA ballot. These are open source documents (implementation guides) and sample .xml documents that are displayable using the standard CDA .xsl style sheet. They support bilateral asynchronous cut-over and include an open source SEE tool to edit and generate new documents.

Q&A

John Derr expressed his desire for LTPAC providers to be allowed to participate in Stage 3. The work of the S&I Framework has been instrumental for coordination with LTPAC.

David McCallie asked about any confusion between disease-specific and multi-disease templates. Garber replied that Lantana is working on templates with rule constraints. Definitions are contained in the implementation guides. Existing templates can be re-used.

Perlin observed that the time limits for the agenda items were not being adhered to and urged that any questions be briefly stated. He said that there will be opportunities to consider these gaps and evolving standards over the next year and assured them that no action was expected today.

Dixie Baker observed that the ToC data elements are extensive and asked about the identification of a minimum necessary set. Garber responded that the survey yielded data on which elements are required for

specific types of transitions. Refinement will be done to identify a minimum set and to define vocabulary constraints.

Stan Huff reported that although he was convinced of the need for enhancements, he was concerned about the lack of real world experience that, if the standards were implemented, the results would be as intended. To date, existing standards for care plans have not been implemented by organizations. He advocated a recommendation for additional testing rather than for a Stage 3 requirement. Russell said that implementation challenge grants are in process. Some preliminary results are available and the findings can be used. Huff indicated that he was primarily concerned about care plans. Garber stated that this would not be the first time something was implemented without complete evidence. The work is incomplete.

Perlin announced that he will work with ONC staff to identify what further action may be required on the topic.

ONC Updates

Judy Murphy reported. The Food and Drug Administration Safety and Innovation Act (FDASIA) Workgroup is being formed under the auspices of the HITPC with Paul Tang appointed as chairperson. A governance forum will be convened by NeHC under a cooperative agreement and charged to identify key issues and common problems in the governance of HIE and the best ways to address them. The first meeting is scheduled for April 12. Input will be solicited from HITPC and HITSC workgroups. ONC co-sponsored an e-health equity summit on February 21. Proceedings will be made publicly available in April. ONC, SAMHSA, CDC, and ONDCP are collaborating on prescription drug monitoring programs (PDMP). Pilots were conducted at six sites to integrate existing technologies to connect to state PDMPs in order to make data available to physicians at the point of care as part of their normal workflow. Evaluation reports are available at http://www.healthit.gov/PDMP. CMS and ONC have issued a RFI on ways to accelerate electronic exchange. Comments are due April 21. (For information, go to http://www.ofr.gov/OFRUpload/OFRData/2013-05266_PI.pdf.) Two new data briefs (ONC Data Brief 9 and 10) on hospital adoption based on responses from the 2012 AHA survey were recently released. Murphy noted that hospital EHR use has tripled since 2010. Forty-five percent of hospitals now use EHRs. Also released were *Health IT in Long-term and Post Acute Care Issue Brief, 3-15-13* and *Building Better Consumer eHealth: Summary Report of Consumer eHealth Unintended Consequences Work Group, 3-21-13*. Interactive training on the interoperability basics is available at the ONC website. Over the coming weeks, four additional modules that cover Stage 2 interoperability data exchange criteria will be released.

Baker referred to the Stage 2 requirement for view, download, and transmit via patient portal, saying that some vendors are reportedly charging high fees for this function. Does ONC have any way to affect pricing? Murphy responded that ONC unfortunately cannot directly affect pricing. There is, however, a price transparency requirement that vendors must inform their customers of additional add-on fees.

Rishel declared that the presentations represented excellent staff work.

Doug Fridsma, ONC, reported. He is looking to HITSC for priorities for long -term care coordination. Regarding the UDI NPRM, three standards are recognized – GS1, HIBC, and ICCFA. Each has a slightly different syntactical approach to representation of the UDI, which raises issues around implementation. He indicated that he will ask for input on how many standards are necessary. Which standards are legacy and which are linked to particular domains? The UDI does not include a product ID. Responsibilities for a patient ID registry have yet to be determined. He suggested that the members think about use cases per responsibilities.

Fridsma reported on the announcement of the US-EU MOU on HIT and the publication of a road map. An upcoming call will consider workforce training, identification of a subset of most commonly used

vocabularies for 80 percent of all diagnoses, drugs, or laboratory test for international recognition, identification of a ToC subset for international use, and provider to provider exchange across national boundaries. No questions were entertained.

Public Comment

Robertson announced the three-minute limit on comments and reminded members that there was no need to respond to comments.

Ben Moscovitch read a statement of The Pew Charitable Trust's position on UDI, repeating many of the benefits delineated in the FDA presentation. He encouraged ONC and CMS to require the incorporation of UDIs into EHRs and urged the HITSC to recommend standards for certification to facilitate that requirement. Technical specs for UDI incorporation will contribute to the objectives on reporting to registries.

Conclusion

The next meeting is scheduled for April 17. Perlin thanked the retiring and current members, and staff.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the February 2013 HITSC meeting was approved as circulated.

Action item #2: Members approved the 2014 edition test scenarios and materials as presented.

Meeting Materials

Agenda
Summary of February 2013 meeting
Presentations and reports slides