HIT Standards Committee
DRAFT
Summary of the January 16, 2013 Meeting

ATTENDANCE

The following members attended the meeting:

Dixie Baker
Anne Castro
Christopher Chute
Tim Cromwell
John Derr
Floyd Eisenberg
Jamie Ferguson
John Halamka
Leslie Kelly Hall
C. Martin Harris
Stanley Huff
Elizabeth Johnson
Rebecca Kush
David McCallie
J. Marc Overhage
Jonathan Perlin
Wes Rishel
Kamie Roberts for Charles Romine
Christopher Ross
Walter Suarez
James Walker

The following members were absent:

Lorraine Doo
Kevin Hutchinson
Arien Malec
Nancy Orvis
Sharon Terry

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 44th 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, talked about moving from meaningful use to the meaningful use of meaningful use through empowerment of consumers, interoperability and exchange. He remarked on the anxiety in the press over health care costs. Tactical approaches to the reduction of costs focus on shifting the costs of Medicare to beneficiaries and other payors, while strategic approaches examine more fundamental ways of bending the cost curve. He mentioned recent reports from Institute of Medicine (IOM) and the Commonwealth Fund. Considering changes in delivery and payment, there is the issue of whether HIT has delivered on its goal of reduction of costs. He talked about a recent editorial in *The Washington Post* and observed that evidence often mutates from scientific journals to the press. He went on to talk about a RAND report on the increase in health care costs that selected 2005 as the baseline. He said that had 2009 been used, the conclusion would be that the increase in costs was the lowest in 50 years. He declared that it is too soon to measure the effects of HIT. Stage 1 emphasized collection of data; Stage 2, sharing data; and Stage 3 will focus on outcomes. He observed that policy-based on attention deficit will not work. The RAND report identified things that will have to occur to maximize the benefits of HIT, such as a level of adoption comparable to that found in other countries, exchange, patient access to information and other Stage 2 objectives. HIT is a tool for improving care and lowering costs. He told members not to be distracted by press coverage.

Review of the Agenda

Jonathan Perlin, Chairperson, declared that the levels of EHR adoption are remarkable and a cause for celebration. A logical progression of adoption will increase performance. Standards are required to support this progress. He reminded members that they are charged to identify standards, not to rethink the HITPC's recommendations. Durable standards for the ecosystem are needed. Stage 3 is ambitious, as are the proposed workplans. He introduced Lauren Thompson, ONC, who works on the Federal Health Architecture. Perlin mentioned each of the items on the previously distributed agenda and recognized Chris Chute and Mayo's efforts on collaboration. Chute briefly described Mayo's efforts in valuing and using patient information to improve care. Perlin inquired about objections, corrections, improvements, amendments or additions to the meeting summary distributed with the meeting materials and, hearing none, announced the acceptance of the summary of the December 2012 meeting as distributed.

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

Comments

John Halamka, Vice Chairperson, talked about the confluence of the work of the HITPC, HITSC and the S&I Framework in the recommendation of standards for Stage 3.

2013 HITPC Preliminary Workplan

Jodi Daniel, OPP, ONC, acknowledged that the workplan did not reflect the discussion at the January 8, 2013, meeting of the HITPC at which it was first announced. Staff intends to revise the plan for discussion and approval at the February meeting and will update it quarterly. She described the plan as ambitious. She showed slides that outlined the key topics for 2013. Regarding meaningful use, recommendations for Stage 3 objectives and quality measures will be finalized. Preparations for Stage 4 will commence toward a learning health system. Consideration will be given to creating a shared health record, patient-generated data and shared decision making. She called out clinical documentation and an upcoming hearing. Safety-enhanced design of EHRs is another topic with a hearing scheduled for February 13. She moved to measuring clinical quality. Facilitating a supply of de novo quality "measures that matter" to leverage clinical data from EHRs and PHRs is important. Facilitating incorporation of flexible platforms for measuring and reporting quality measures in HIT systems is another area. The role

of data intermediaries and their sustainability must be discussed. "Near real-time" clinical quality dashboards for practitioners will be considered as well as connections to clinical decision support. The third major category of key topics is HIE. Subtopics include: the state of the field and best practices; the role of HIE in new payment models: facilitating greater exchange across organizational and geographic boundaries through policy and certification levers and standards development; governance models and principles to facilitate HIE; and ONC's EHR Safety Plan. Regarding the key topic of privacy, she delineated the following subjects: patient identities in cyberspace; consent and control of information in automated query/response exchanges; challenges of implementing minors' rights in cyberspace; personal representatives; cloud computing; and right of access in an electronic world. Another broad topic is consumer empowerment, which includes: Blue Button; combining and sharing data from multiple sources; data overload; reconciliation of data; protecting downloaded patient data; and shared decision making. She announced that the HITPC will also consider new models of care, such as accountable care, supporting population management, longitudinal data and shared care plans across the continuum, including wellness, supporting new payment models; and Medicare Shared Saving Program requirements.

She also presented a slide with the preliminary workplan that listed six workgroups and teams in rows with four quarterly columns and activities in the corresponding cells. Several hearings are planned for the Meaningful Use Workgroup. Data intermediaries is assigned to the Quality Measures Workgroup and the safety plan to the Certification and Adoption Workgroup. Nominations have been requested for the consumer empowerment workgroups, one for HITPC and one for HITSC. The nomination period will close January 14. Many activities have been designated for these workgroups. She announced that a new workgroup, Accountable Care, will be formed. Several emerging issues, such as quality improvement and big data, have yet to be assigned. Disparities will be incorporated as well. She assured the committee that policy staff and standards staff will coordinate all of these efforts.

Q&A

Once the decisions on Stage 3 have been made, work will continue on Stage 4 and beyond. HITPC reportedly wants to push on some areas, realizing that other areas require the development of capabilities.

In response to a question from John Derr about providers that are not included in HITECH and a report released July 2013, Daniel reported that providers, in addition to EPs and EHs, will be considered by the Accountable Care Workgroup. Derr requested that she show other providers in the workplan.

Dixie Baker observed that patient-generated data was assigned to both the Privacy and Security Tiger Team and the Consumer Empowerment Workgroup. How will the two groups coordinate? Daniels responded that ONC had contracted with NHIC to identify experts and best practices. A hearing with invited panelists will be convened. The initial focus will be on meaningful use and patient-generated data. Workgroups' activities will be coordinated by staff behind the scenes.

Jim Walker said that the initial phase of meaningful use was directed toward EPs and EHs. Now the entire care team including patients will be the focus. The HITPC needs to define the care team and plan for the integration of care team members in a time-phased approach.

HITSC Preliminary Workplan and Priority Area

Halamka announced that in 2012 the HITSC achieved everything planned except for images. He urged members to be proactive. He told them that he had used the Stage 3 RFC, the ONC and HITPC workplans, comments from committee members and the public to make a list of standards needed in five broad categories. He presented and talked about the items on the list:

Category 1 - Quality and Safety
Standards which support flexible platforms for measuring and reporting quality (QueryHealth, QRDA/HQMF)

Standards which support measurement of EHR usability
Standards which address current content gaps - HL7 version 2 lab orders, formulary downloads, cancel transaction needed for hospital discharge medication e-prescribing, representing genomic data in the EHR
Standards which support defect reporting to PSOs
Standards which support redundant data identification/reduction
Category 2 - Health Information Exchange
Standards which support query/response of provider and patient identity in directories
Standards which support Record Locator Services
Standards which support consent in a query/response architecture such as granular patient privacy preferences hosted in a managed service ("pull") and sent as part of the request for records ("push")
Improvements to the C-CDA standard to facilitate unambiguous parsing, longitudinal record sharing, and bulk record sharing
Standards to support image exchange
Category 3 - Consumer
Standards to support representation of patient generated data including consumer device data
Standards to support consumer friendly terminology
Standards to support transport of data to and from patients
Standards to record advanced directives/care preferences
Standards to record care plans/care team
Category 4 - ACO/Population Health/Care Management
Standards for clinical documentation supporting new payment models (includes ICD10, smart problem lists, computer assisted coding)
Standards needed for registry support including structured data capture and transmission to third party repositories
Standards to support closed loop referral workflow
Standards to support data comparability across entities including detailed clinical models
Standards for clinical decision support, both knowledge representation and application programming interfaces (APIs) for query/response to knowledge resources
Category 5- Privacy/Security
Standards for securing data at rest, especially genomic data and consumer downloads
Standards for application programming interfaces supporting modular application integration
Standards supporting data segmentation for privacy
Standards and certification criteria that anticipate broad NSTIC adoption
Standards supporting Digital signature

Discussion

Wes Rishel talked about an orderly evolution of standards in an environment in which not everyone can change systems at the same time as with ICD-10 adoption. A way must be found to gather advice that may help with Stage 3 beyond the standards. Halamka said that although he had received Rishel's message, he defined it as a process rather than a standard. He agreed to put the topic under implementation. Rishel went on to say that the HITSC is at the point of being asked for a standard that will change doctors' behaviors to capture more data. The pattern has been to make something possible and then make them do it. A simultaneous approach is needed.

McCallie praised the list. For most of the items on the list, standards exist. But they are not being used. The HITSC must consider the best standard and get them in use. The C-CDA is an example of a standard not sufficiently constrained. Health eDecisions is based on older HL7 standards that were never implemented with minimal, if any, vendor participation. Focus must be placed on how standards are

developed and what worked well in the S&I Framework. Halamka talked about his experience with an implementation guide for a provider directory.

Leslie Kelly Hall commented about identifying where standards have an overarching effect as new actors – patients – are being included. HL7 open notes is an example. Care team roles and responsibilities should be incorporated. She urged that the committee consisted standards for referential systems for persistence of data in a horizontal view.

Cris Ross noted that the topics appear to be additive while considerable work remains to be done on the core standards. He declared that the focus of the Implementation Workgroup will continue to be on maintenance of the core. The penetration of standards adoption must be sped up. He asked that the workplan reflect maintenance. Halamka said that Doug Fridsma will develop a quarterly workplan for consideration at the February meeting.

Walker described the need for a comprehensive, standardized patient profile with 40-50 data elements, each of which has standardized characterizations. Such a profile is doable and would benefit the care plan. Kelly Hall said that the profile should include patient generated data. Walker referred to the need for research on instruments for use by patients. He cautioned that consumer-friendly language must be tested before widespread use. Regarding dashboards, he expressed concern with micromanagement, saying that dashboards are not necessarily useful or relevant. He prefers a dashboard based on what patients need and want. Blue Button could be used to capture the patient's report of all places where he or she receives care, which would then be rationalized so that information could be send to those sites.

Dixie Baker agreed with Kelly Hall on the need for linkages that do not require downloading, which is a privacy and security issue. She also expressed agreement with McCallie on widely used standards. She reminded them of the NwHIN Power Team's recommendations on evaluation of standards.

Walter Suarez requested the addition of data provenance to the list of items on the workplan. An HL7 workgroup is discussing metadata in the C-CDA and there are new developments in other fields that can be considered. Halamka agreed.

Perlin announced a change in the order of agenda items due to the schedule not having been maintained. He called for public comment. Doug Fridsma, ONC, objected to skipping his scheduled presentation. Perlin requested that he compress his report. Fridsma then showed and talked about a series of slides that showed how each of the items delineated by Halamka was accompanied (or not) by ONC work. Some of the workplan items do not yet have activities; staff will prioritize. A few of the many ongoing projects described include: structured data capture, SI Initiative, lab order, eDOS (lab order compendium), PDMP, C-CDA, LTPAC shared care plans and HITSC review of imaging standards approaches. Staff will plan what to bring before the HITSC.

Discussion

Marc Overhage declared that the plan is overly broad and ambitious and, therefore, may not accomplish anything. He recommended calling out four or five priorities that demand answers now. Halamka responded that the plan is intended as a multiyear plan. Fridsma replied that staff will review ongoing activities in conjunction with priorities which can be completed this year. There are only two new items – data spigot and structured data capture.

McCallie repeated his earlier comment. The challenge is not developing a new standard but using a standard to scale. The right people must be recruited and engaged in any project. When the right people are not participating, it indicates a problem as per Health eDecisions. Vendors are not interested in participating in that project and probably will not use its output. Fridsma denied making the workplan priority list, saying that he used Halamka's list and then indicated related activities that were already underway.

Jamie Ferguson observed that the origin of the list was the HITSC's reaction to the HITPC wish list as delineated in the RFC. That wish list requires a multiyear work plan. Perlin exclaimed that although reworking the RFC is not within the purview of the HITSC, members have to be realistic in their consideration of the availability of standards to implement the Stage 3 proposals. The HITPC needs this feedback in order to do its job. The HITPC needs to know what can be done near term and long range to build a durable model. Core elements can be reiterated and refined.

Rishel noted that the entire discussion indicates some agreement that standards matter and that more than development and adoption are involved. It matters to each adopter what others are doing on adoption. The evolutionary development of standards must be recognized. Consumers' acceptance comes at around version 3. Marketing staff wants more and more features added. HL7 has draft standards for trial use (DSTU) based on an understanding of rapid movement to standards. The C-CDA is being rolled out as if it had gone through that process when, in fact, it has not. Many people are involved in its debugging. DSTU should be applied before a standard is encoded in a regulation. Most implementation of standards is done by vendors and vendors tend not to look to the next stage of meaningful use. The HITSC and HITPC should agree to identify the need for new standards in sufficient time to use DSTU.

Jim Walker proposed the use of the technology adoption model in prioritization. A felt need by intended users is necessary for adoption. Environmental scans should be conducted to identify and prioritize felt needs and demands.

Cris Ross announced that the Implementation Workgroup will host a hearing on balance and execution. He said that he welcomed ideas on how to organize the hearing. He hopes to get realistic testimony from vendors.

Halamka reminded members of a hearing on January 29.

McCallie suggested obtaining vendors' buy in prior to DSTU so that they will be ready to test.

Public Comment

Robin Raiford described her recent travails of multiple hospital admissions and rescues due to a missed diagnosis. She reported being told that there is no medical reason for her being alive today. She believes that she survived in order to help the committee to get this right. She urged priority setting based on what causes the most pain for patients. She volunteered to serve on the consumer workgroup.

Clinical Data Interchange Standards Consortium (CDISC)

Agenda item moved to end of day. See below.

Responses to HITPC Request for Comment (RFC)

Halamka said that it was not possible to discuss each question in the RFC. However, all workgroups' comments to the questions in the RFC were incorporated by staff into the comment grid. He asked each workgroup chairperson to give a "high-level overview."

Jim Walker, Chairperson, Clinical Quality Workgroup, reported that his group had reached consensus on most of the questions assigned to it. He recommended retiring attestation and reporting the use (not simply collection) of data. Standard content and terminologies for a care plan are needed. CQMs should focus on the support of efficient, evidence-based care processes and interdisciplinary, cross-venue care. The CQM data model and CQM authoring tools should be used. Wider input should be sought. Patient input needs standards development, beginning with symptoms and including adverse effects. Patient input occurs now through validated instruments, e.g., for depression. CQMs should be aligned with meaningful use objectives and suites of process and outcome measures should be used. Transitions of care are high priority. "Local" CQMs would require management and be hard to include in EHR certification. Population management platforms are not standard; they are ready for sharing best practices.

Dixie Baker, Chairperson, Privacy and Security Workgroup, noted that she had followed the instructions limiting each workgroup to one slide. As she went through the responses, she noted those points with which the NwHIN Power Team (NwHIN PT) agreed. IEWG102 – Directory standard: Inappropriate to externalize directory services by creating a separate certification criterion (NwHIN PT agrees). Embed standards instead. MU03 – IT safety risk assessment: Agree on need, especially since HIPAA security risk assessment addresses only risks to PHI; start with general measure; let standards and certification criteria evolve. MU04 – Patient consent for sharing categories of information with special legal protections: Need access control solutions for labeling and protecting special categories, and for coding, managing, and sharing patient consents across organizations (via push or pull); capitalize on security engineering approaches to MAC and DAC, foundational work of VHA; ultimate solution must enforce access rules based on both clinical labels and individual consents. Must support logical and intuitive workflows; must engender trust for both providers and consumers, and must be scalable at a national level (NwHIN PT agrees). PSTT01 – Reconciling EHR certification with NSTIC: The two are complimentary; start with multi-factor authentication for Stage 3, then accept NSTIC certificates when available; allow consumers' and providers' use of NSTIC certificates to develop independently. PSTT04 and 06 – Making specific HIPAA requirements meaningful use measures: No single HIPAA Security Rule standard or implementation specification should be called out as a measure.

Jamie Ferguson, Chairperson, Clinical Operations Workgroup, reported that his group had made three dozen comments. The workgroup agreed that a higher threshold for incorporation of lab results can be achieved using existing standards and formulary transmission can use existing NCPDP standards for formulary and benefits. He recommended clarifications to define "pertinent information" for an office visit, define "high priority conditions," and to define radiation dose in radiology report template instead of putting everything in one summary. He said that demographic data collection requirements should not be dropped. The workgroup determined that standards or processes are immature requiring a multi-year work plan beyond Stage 3 in the following areas: reconciliation of problem list and allergies from disparate data sources has multiple challenges; and requiring use of CDS rules from central CDS repository is not realistic at this time. Finally, the workgroup determined that complex filtering for clinical trials is applicable to very few patients (just link to clinicaltrials.gov) and that device data integration should be coordinated with FDA UDI final rule implementation May 2013. Halamka concluded that some of the HITPC recommendations cannot be implemented within the time frame and may have to be postponed to post-Stage 3.

Dixie Baker, Chairperson, NwHIN Power Team, reported the team's comments. SGRP113 – Query of central repository for CDS rules: The business model for a CDS repository is not clear. The existence of such a repository is unknown. EHR vendors are likely to welcome the availability of repositories from which standard CDS data could be retrieved. Standards for CDS data (e.g., order sets) are more mature than standards for business logic. Further definition of a practical business model for CDS repositories, and standards for CDS data (defer standards for business logic) is recommended. SGRP209 – Query for clinical trials: Stage 2 HL7 Infobutton standard and certification criterion should support the function; recommend ONC (perhaps with CDISC) review criterion and test scripts to assure sufficient and appropriate data elements are included to enable query for relevant clinical trials. IEWG101 ability to query outside entity for patient information: The lack of reliable patient identifier is a significant challenge to care quality. The proposed measure is overly prescriptive, should let current efforts around "directed query" evolve. ONC should support development of new models for using voluntary or other high-quality identifiers and authentication methods (P&S WG agrees). IEWG103 – switching EHRs: create new standard C-CDA template for data export; start with transitions of care and add necessary elements. Canada Infoway and NHS work on transfer of records may be helpful (P&S WG agrees)

Liz Johnson, Co-Chairperson, Implementation Workgroup, emphasized the importance of a plan that recognizes a realistic timeline for new or modified measures. The steps required are: entry into the

Federal Register; modification and certification of vendor software; implementation into the provider care environment; collection of data; and submission for attestation. The Stage 3 requirements should balance ambition for change and ability of the industry to execute. The proposed expansions or additions of measures should align with the clinician workflow to allow for the most efficient use of resources and EHR product functionality. Innovation can be encouraged by recognizing when standards and the state of the industry are good enough to get started and then providing support for incremental innovation and iteration. Regarding images, summary reports are often used to reference important clinical information; the requirement that original data/image be always accessible could be burdensome. Provider workflow must be taken into account when increasing existing thresholds. At this point in the evolution of Stage 3 requirements, it is valuable to consider incremental steps to the compliance level.

Halamka reported on and stated agreement with Arien Malec's comment about three years being a minimum time for a standard to be applied. Perlin reiterated that standards are critically important to the iteration of cycles. Standards that support expansion of the data model should be applied.

Committee Discussion

Halamka said that questions and comments on the comments would be entertained in order of the workgroup presentations. He asked for comments on the Clinical Quality Workgroup's report.

Clinical Quality – Rishel wondered about the market driving the quality measures more than meaningful use. At some point pushing meaningful use will be in the way. Emphasis on methods for creating and sharing local measures are important. Halamka talked about how hospital reimbursement at his institution is partly based on quality measures. Measures that are part of revenue circle get attention.

McCallie referred to "evidence based documentation" and noted the shift in emphasis from documentation for payment to documentation for quality. This may be explored in an S&I workgroup. Data should be structured for easy capture. There is always a tension between losing the narrative in structured elements.

Kelly Hall said that patients want time for discussions with clinicians. Clinical competency is manifested in the narrative. Records become the narratives that the patients see and that contribute to their understanding. Structured data do not tell the story for a patient.

Walker acknowledged that both types of documentation are critical. For example, there are 16 critical questions to answer about low back pain as well as a narrative. The clinicians should ask only the questions that inform care. This is a world of have and have-not systems. One type of robust system operates at maximum cost efficiency and absorbs the turbulence created by new requirements. The other, larger group is made of systems that are not robust. Additional requirements make work in them unpleasant and unfeasible. The latter group is not represented on this committee.

Derr reported that clinicians come from different cultural backgrounds and languages and consumers may experiences difficulties in communicating with them.

Halamka moved to comments on the Privacy and Security Workgroup's report. Johnson asked about assessments. Baker responded that she was not really sure what the HITPC was asking. There are methods for software risk assessments, security risk assessments, privacy risk assessments and other types of assessments. Perhaps it would be good to start with an overall assessment. Halamka said that the director of the Office for Civil Rights (OCR) is looking at the measurement of the maturity of security systems. Internal policies and procedures as well as software are involved.

McCallie mentioned the IOM report on safety and ONC's response to that report. The highest risk software components in an EHR system should be identified and efforts can be stratified around the risk. Baker said that there are standards and methods for assessments based on work in the defense and aerospace industry.

Halamka called for comments on the Clinical Operations Workgroup's report. McCallie noted that the Clinical Operations Workgroup and the NwHIN Power Team reached the same conclusion on CDS. But some things may be ready for standardization, such as order sets. Vendors use similar approaches. Ferguson responded that this is not uniquely in the CDS arena, but he agreed on order set. The RFC talked about consistency of rules. McCallie said that he agreed the rules are not ready.

In response to a question from Derr, Ferguson clarified that the comments did not address individual level formularies. Kelly Hall announced her agreement with the additional demographic data collection. She said that formulary as a source outside EHRs allows more flexibility. Formulary does not have to be within the EHR. Regarding demographic data, Johnson reported that her workgroup questioned the addition of sexual orientation and disability status and made detailed comments on the grid. Ferguson's workgroup also recommended not requiring data on sexual orientation; no appropriate standards are in use. Additionally, there may be privacy and security concerns. The metadata and standards do not exist. Halamka recalled that Clem McDonald argued for retaining the Stage 1 demographics to reward providers for their work. Johnson emphasized that the workgroups had different perspective and presented different recommendations on this issue.

Discussion moved to the NwHIN Power Team report. Ferguson offered his agreement on the importance of standards for longitudinal representation but he said that the existing C-CDA is inappropriate for that purpose. Halamka concurred with the need for standards for longitudinal representation.

Baker asked about the next steps. Halamka asked Robertson, who responded that the combined comment document will be forwarded to the HITPC for division among the workgroups. In addition, Halamka will make a presentation to the February meeting of the HITPC. Halamka observed that comments across workgroups are consistent to a high degree. He noted that a number of RFC items assigned to the HITSC were not delegated to workgroups and several assigned questions remain without responses. He told the members that he would read the remaining questions in order to formulate committee responses.

Returning to the previous item, McCallie asked Ferguson about the C-CDA being the starting point for bulk exports. Ferguson replied that although it may be a good starting point, it requires rethinking since the C-CDA is a snapshot. McCallie and Baker agreed.

SGRP120 – Johnson opined that it should continue as menu. Members agreed. SGRP127 and related questions on the same page – Johnson reported that the Implementation Workgroup members were concerned with fill and dispense data. Where do the data come from and what is to be done with the data by whom? Ferguson pointed out that the use of external data raises issues of validity and integrity before standards have been developed. 401A – Immunization: Members denied knowledge of standards for counter-indications.

204D – There are no standards for patient online recorded addendums, according to several members. Baker said that there are standards for Stage 2; the item is proposed as a measure for Stage 3. Walker interjected that if safety is a priority, a set of standards to capture allergies, adverse effects and counter-indications is essential. It is unbelievable that no progress had been made on this issue. His comment initiated a long discussion. Johnson added that severity must be included. Perlin urged support for the aspirations of the HITPC and the evolution to increased capacity in Stage 3. Halamka indicated that the recommendation is to support development of standards. He reminded members that the HITSC will make recommendations to the HITPC, not to ONC directly. Someone noted that a workgroup had recommended deferral. Halamka ruled that rather than referral, standards development is the recommendation. Rishel declared that the identification of the use case is critical. The use case extends beyond a standard for communication; the clinician needs to know why a patient has not complied with prescribed medications. Walker said that someone needs to commission standards. Kush informed them that standards do exist in research. Kelly Hall wanted to capture the patient's voice. McCallie recommended using the C-CDA to nail down something for Stage 3 even though a full vocabulary is not

available at this time. Stan Huff agreed that existing research model standards can accommodate the use cases even though these standards have not been balloted. The information on the standard can be brought forward for education and use.

404, 406 and 408 (registries) – Kush informed them that research standards were available. Johnson expressed concern about menu becoming core at later time. Additionally, "or non-mandated" becomes an issue with certification. Rishel argued that there is a way to give people most of the standard for a register, such as a skeleton use case for certification. Johnson asked about the compliance threshold. Rishel pointed out that a menu item would not be selected unless the EP reported to a registry. Baker indicated that the criterion could be accommodated via the same standards as sending records to a third party. She reported that she had looked at the Stage 2 criteria and that there are standards for appending to the record. In this case, the standard preceded the measure.

Walker asked for the definition of mandated. Is it legally mandated? Halamka noted that throughout the RFC, undefined terms are used. He said that Ferguson so commented.

Returning to the NwHIN Power Team's comments on consent, Rishel said that standards are available but operational vocabularies may be unique to institutions; the standards must be nationally scalable. Baker concurred, saying that scalability is called out in the NwHIN Power Team's recommendation on standards approved by the HITSC.

Halamka asked for questions on the Implementation Workgroup's comments. Rishel said that although economists say all standards inhibit innovations, sometimes standards narrow the focus and actually encourage innovation. To spur innovation, areas should be carved out and labeled as no standards. The HITSC and the HITPC should work together on such a carve-out.

Halamka left the meeting. Perlin summarized that the discussion had covered many technical points. Semantically, the evolution of standards and the need for clarity and precision of use cases and words were called out. He asked for objections to the sense of the HITSC to transmit the comments and the results of the subsequent discussion to the HITPC. Hearing no objections, he declared that the comments were approved.

> **Action item #2: The HITSC workgroups' comments on the Stage 3 RFC, along with subsequent discussion, were approved for forwarding to the HITPC.**

ONC Updates

Doug Fridsma commended Lauren Thompson's work on the Federal Health Architecture. He showed slides and gave an overview of the S&I Framework and the current status of various projects. Balloting on Health eDecisions is underway. PHRI use cases have been developed and will be evaluated per public health priorities. Staff is working with NIST on test scenarios. In the coming months, staff will begin to transition the portfolio from development to maintenance. ONC has contracted for advice on how best to maintain the products, which will involve coordinating with SDOs. Eventually he expects that products will be packaged and the artifacts made available to the public. Only a few new projects are projecting for the current year. It is possible that certified products will not be able to interact, so ONC may need to address that problem by triaging and selection of best tools. He referred to several challenges in the use of pilot demonstration projects to validate standards for national deployment.

Testing of standards occurs for the first time during pilot demonstration
Testing of standards occurs much too late in the process to influence standards development
Changes to standards made during pilots ("Learning") don't get back into improving standards in a timely manner
Implementing untested standards introduces business risk to pilot organizations

In addition to S&I Framework initiatives, staff will work with other ONC components on activities such as:

NIEM Health Domain
Formalize an approach to align with CEDD/FHIM
Generate a robust patient data set for use across initiatives and testing
Support quality measures work with OCMIO

Much is being accomplished in the Federal Health Architecture in terms of interoperability architecture, including a FHA public-facing portal, standards harmonization and demonstration of exchange methods beyond Direct and SOA – RHEx pilots. Innovations include CONNECT Open Source and RESTful Health Exchange.

Q&A

McCallie repeated his comment about the engagement of vendors. When they understand the use and business cases, they will be ready to participate upfront. Some new standards are driven by vendors rather than SDOs. The lack of participation of vendors in Health eDecisions had resulted in a disconnect and moving standards forward when they are not ready. Fridsma pointed out that the vendor community is heterogeneous. He assured the members that he wants to involve vendors.

Rishel noted that vendors who do not participate early will not be inhibited in criticizing the standards. Consideration must be given to what can be done to create standards that meet community needs and vendors can help with that via work with their customers. No DSTU project should be launched without at least two vendors and two implementers. Those who participate from the beginning get to make the rules.

Baker pointed out that NwHIN can work on ways to get vendors involved at an early stage. Fridsma thanked her.

Program Achievements in 2012

Jodi Daniels reviewed 2012 activities. According to CMS reports, 2012 goals have been meet. The most recently available data show that 84% of EHs have registered. 64% of eligible EPs have registered. Nearly 65% of all eligible hospitals have received an EHR incentive payment for either MU or AIU. Nearly 65% have made a financial commitment to put an EHR in place. As of November 30, active registrants totaled 340,090. 96,426 EPs have received Medicare incentive payments. 65,625 unique Medicaid EPs have received incentive payments. Regarding the regional extension program, which she declared was hugely successful in helping EPs, a GAO study found that 47% of providers who received AIU payments had been helped by RECs. Also, 94% of pharmacies are actively e-prescribing and 43 states and territories have directed exchange with 60,359 clinical and administrative staff nationwide having access to directed exchange. During the third quarter of 2012, 79,957,695 directed messages were exchanged. Twenty states have statewide query-based exchange. She noted several successes of the Beacon Community including: all 17 communities have at least two measures trending positively; and the launch of new exchange capabilities in communities like New Orleans and San Diego. The collaboration has enabled 51 primary care practice locations representing 432 providers and 447,000 patients to exchange a consistent patient summary care document to better manage transitions of care and to populate community data repositories or registries.

Regarding workforce development, as of November 30, 21,917 students have been enrolled in community college training with an attrition rate of 29.5%. Nine hundred and eighty-one students have graduated from university-based programs. More internships and hands-on experience opportunities are needed to improve these programs. Eighty-eight million U.S. consumers have access to Blue Button, resulting in 1.4 million Blue Button downloads. Four hundred and fifty organizations joined the Blue Button Pledge Program. Among many other activities, ONC sponsored a pilot to evaluate the role of patients in

improving accuracy of information in their medical records. Information on 29,110 certified projects is available on the CHPL. Daniels also described a number of e-CQM developer and implementer tools. The strategic plan is being updated. Regarding policy, final rules for Stage 2 and the 2014 Edition of Standards and Certification Criteria were issued. The Stage 3 Meaningful Use RFC and the Health IT Patient Safety Action and Surveillance Plan were released. A non-regulatory framework was developed for the nationwide health information exchange. Seven waves of draft test procedures, test data and test tools were released for public review and input September – November 2012. Tim Cromwell added an item: ONC, American Nurses Association, Veterans Affairs and Kaiser Permanente announced a competition for design of a mobile app for pressure risk assessment.

Public Comment

Darrell Roberts, American Nurses Association, referred to Tim Cromwell's prize and thanked Judy Murphy for her efforts. Regarding Walker's comments on the capture of patients' data on allergies and other negative outcomes pertaining to drugs, he said that there are ways to capture this information as well as patient preferences and changes in their preferences. These data are critical in the reduction of medical errors.

Lindsey Hoggle, Academy of Nutrition and Dietetics, reported that an HL7 ballot on allergies and intolerances is underway.

Clinical Data Interchange Standards Consortium (CDISC)

Becky Kush, CDISC, said that the 15 minutes originally allocated to her presentation had been reduced to seven minutes. (Perlin later noted that her presentation had actually extended to 20 minutes.) She told the members that two representatives from the FDA had remained at the meeting all day to hear comments on her presentation. She described the state of standards in the research arena. Available standards and enablers consist of the following:

Suite of global consensus-based standards to support common data from protocol representation through data collection, analysis and reporting (i.e. regulatory submissions or study reports for publication)
A model to harmonize all of the research standards and provide a link to healthcare standards
Controlled terminology for the research standards
Documentation for using EHRs and eDiaries for regulated research
Integration profiles developed (and tested) with quality, research and public health experts to facilitate workflow for clinicians using EHRs to provide high quality data for numerous secondary use cases

She described that standards have been harmonized through the BRIDG Model Controlled Terminology (NCI-EVS) Semantics/Glossary and said that standards for allergies are available. CDISC, FDA and many other terminology subsets are published as open source subsets of NCI Thesaurus (NCIt). This builds on EVS collaborations across multiple NIH ICs, FDA and other agencies, SDOs and many other research and clinical care consortia. EVS also provides integration of biomedical data standards from 76 national and international sources into one database through the NCI Metathesaurus (NCIm), a mapped overlap and inter-relation of current versions of CDISC CT, NCIt and other research and clinical required terminologies including the ICDs, MedDRA, SNOMED, LOINC, drug and gene nomenclatures.
She went on to describe the eSource Data Interchange (eSDI) Initiative, a FDA initiative to facilitate the use of electronic technology in the context of existing regulations for the collection of eSource data in clinical research (available at www.cdisc.org/eSDIdocument).

Q&A

Kelly Hall talked about a natural nexus point between the patient entering care and research. She urged the members to look at the work on consent as well as the need for common data elements. Patients are active participants in research.

Chris Chute described his concern about silos. The quality measurement community reinvented tools and processes that had been in place for decades in research. The same reinvention is now happening with analytics, thereby duplicating resources and creating confusion. He pleaded with the members not to invent yet another set of standards. He disclosed that he served for three years on the CDISC board of directors. He cautioned against more fragmentation and discordant standards.

Baker asked about standards for using the C-CDA to send data to registries and to other third parties. Kush referred to something around the BRIDG model that could be used. Also Outcomes Sciences' testimony at a hearing can be reviewed. One can start with a set of core elements as with adverse events and add elements.

McCallie talked about common data elements and the difficulty of harmonization. Clinicians have different needs for levels of granularity. When providers are asked to capture more granularity than they use, the results are poor. Kush declared granularity a good topic for future discussion.

Someone referred to data salvage rather than collection for observational studies. Comparability and consistency in recovery is important. Both structured data and narrative are required.

Perlin said that all of this information will be useful for Stage 4 and the development of a learning health system. Members need to be informed about all available resources. There are differences in philosophy and use cases are not value neutral. Patient preferences intersect around several topics. The agenda for this year will emphasize increasing clarity and reducing ambiguity.

SUMMARY OF ACTION ITEMS:

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

Action item #2: The HITSC workgroups' comments on the stage 3 RFC, along with subsequent discussion, were approved for forwarding to the HITPC.

Meeting Materials

Agenda
Summary of December 2012 meeting
Presentations and reports slides