

**Health Information Technology Standards Committee
Final
Summary of the June 20, 2012 Virtual Meeting**

KEY TOPICS

1. Call to Order and Opening of the Meeting

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the meeting of the HIT Standards Committee (HITSC). She reminded participants that it was a Federal Advisory Committee (FACA) meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available on the ONC Website.

2. Opening Remarks

Judy Murphy, Deputy National Coordinator for Programs and Policy, ONC, announced that as of the end of May, 110,000 eligible professionals (EPs) had received meaningful use payments, which represents about 20% of the practicing professionals. She thanked the members for their work. Twenty-four thousand eligible hospitals (EHs), about 48% of hospitals, have received payment including critical access hospitals. \$5.7 billion have been paid. The regional extension centers have played a key role with the critical access hospitals, the rural hospitals and providers, and the small practice providers. As of May, the regional extension centers had worked with 133,000 primary care providers and 10,000 specialists. Information on their work is now available on HealthIT.gov under the professionals tab. She went on to announce that the committee meeting materials will also be migrated to that site where they can be more easily accessed. She talked about her excitement over accomplishments to date and invited them to bring forward their ideas for stage 3. Long-term and post-acute care (LTPAC) should be included in stage 3. All of the other different communities impacted by HIT should be considered—behavioral health, schools and the criminal justice system. The establishment of a more iterative process between the Standards Committee and the Policy Committee (HITPC) will be helpful. Interoperability in health data exchange is on the meeting agenda.

3. Review of the Agenda

Jonathan Perlin, Chairperson, noted the progress made in HIT as reflected by the agenda items for the 37th meeting of the committee. He thanked Dixie Baker for her work on the comments on the Governance Request for Information. The topic of LTPAC is an important one. Radiology must be addressed. He expressed his hope that the August meeting would be a virtual one and said that he looked forward to the presentation on the S&I framework. He referred to the minutes of the May 2012 meeting in the meeting materials and opened the floor for corrections, amendments, or modifications. Hearing none, he declared consensus on the approval.

Action item #1: The summary of the May 2012 meeting was declared approved.

4. Comments

John Halamka, Co-Chair, reported that many of the items before the committee were relevant to his work as a CIO. The state of Massachusetts will soon announce a series of procurements for a health information exchange (HIE) connecting all providers to each other. The procurement will involve Direct gateways, certificate management, provider directories, vocabularies and code sets, and a governance structure. He said that he told his colleagues the work on the Governance RFI can be used as guidance. Meaningful consent and patient-generated data around meaningful consent must be dealt with as well. Thus, the content of the meeting can be directly applied to his organization's response to procurement. He noted that funds for the S&I Framework end in 2013 and Doug Fridsma had asked for advice on new initiatives and priorities. He said that LTPAC is a national issue and the federal government should take action. It is the donut hole of meaningful use.

5. NwHIN Power Team Comments on Request for Information (RFI) on Governance for the Nationwide Health Information Network

Perlin reminded the members of the lengthy presentation and discussion on the topic at the May meeting and asked that they not comment on areas previously agreed to. Dixie Baker, Chair, showed slides, one of which recapped what the RFI proposed. The ONC will select a single accreditation body, and that accreditation body will accredit multiple validation bodies. The validation bodies will validate the Nationwide Health Information Network Validated Entity (NVE). Then the ONC will endorse and adopt a number of conditions for trusted exchange (CTE), which are sets of requirements that the validation bodies would use to validate the NVEs. The NVEs are the exchange nodes that enable providers to exchange health information. ONC will also administer a readiness classification process, which is the evaluation process that the NwHIN Power Team has been discussing. The RFI proposes three categories of conditions for trusted exchange—10 safeguard CTEs, 3 interoperability CTEs and 3 business practices CTEs. She went on to report that the RFI poses 66 questions, 22 of which were assigned to her team. She presented overarching recommendations:

- A core value of the NwHIN, and of the NVEs, is a trust fabric – preserving this core trust fabric is essential
 - Safeguards CTEs should be top-level trust principles that should persist over time – changes and additions to Safeguards CTEs should occur infrequently
- Interoperability CTEs will be influenced by market evolution to a greater extent than the Safeguard CTEs – innovation should be allowed to happen from the bottom up; top-to-bottom filtering should be avoided
- NwHIN Governance should be light-handed – establishing and preserving trust while enabling and fostering innovation in the market
- Even a voluntary process can have a profound impact on business if NVEs and their subscribers are denied “meaningful choice”
- ONC should establish core Safeguards CTEs, codified in federal regulations
- Interoperability CTEs should be established collaboratively by the Validation Bodies, with oversight from ONC and the accreditation body
- Governance over Business Practices should be achieved through
 - Transparency of business practices and of measured performance against agreed-upon service levels
- NVE oversight should seek to address any anti-competitive practices that inhibit free-flowing data exchange, without imposing absolute requirements through CTEs

Halamka asked whether the slide codified the discussion from the May meeting. Baker said that validation against the CTEs can take a number of forms; attestation may be one. The recommendation said that the only CTEs that should be in the regulation are those that are essential for establishing and maintaining the trust fabric. The interoperability CTEs should be managed and maintained by the validating bodies collaboratively among themselves. When they validate an NVE against those interoperability CTEs, they can use attestation or testing. The process of figuring out which standards and interoperability specifications need to be assessed, and even the assessment process of their readiness for national standards, would be overseen by the ONC and involve the FACAs.

David McCallie, interjected that the business practice CTEs could be thought of analogously to the interoperability CTEs in that subsets may evolve. Jodi Daniel, ONC, inquired about the meaning of oversight from ONC and the accreditation body and how validation would be aligned with meaningful use. Baker said that no one was suggesting a change of the meaningful use interoperability requirements. But interoperability CTEs should not be codified in regulation; they should be managed at a lower level. The recommendation is not different from what is proposed in the RFI. The high level principles regarding trust fabric would be codified in the CTE. They would not necessarily include principles on anti-competitive practices or inhibiting the free flow of data. McCallie pointed out that while protocols such as Direct and Exchange make sense today, other useful protocols will emerge in the future, perhaps with different business constraints. Flexibility should be preserved.

Leslie Kelly Hall said that at the previous discussion members indicated they wanted specifications of a floor technology. Baker responded that meaningful use establishes the floor. The primary function of the ONC should be to preserve the trust framework and not to manage exactly which protocols are used. Kelly Hall pointed out that meaningful use has an end date. Baker predicted that the momentum of the marketplace would sustain achievements.

Doug Fridsma, ONC, talked about the notion of the NwHIN technical specifications as a big tent; some things are ready for national roll-out. Others are regional or sub-national pilots. Things that were ready for national roll-out might show up in regulation, but there would be other ways to coordinate around those things not ready for roll-out. Baker responded that ONC might recommend that the readiness process look at certain specifications, but that it be done in collaboration with the validation bodies. Fridsma referred to the Health Information Technology Standards Panel (HITSP) and gradations of standards. Baker pointed out that not all standards come from the government. If the validation body collaboration decides on interoperability CTE, then it becomes part of the validation requirements.

James Walker commented that the process lacked agility. McCallie said that he understood that the proposed role of the accreditation body was decoupled and removed from what goes on in the real world. Therefore, the team attempted to push responsibility to the validation bodies, which are like trade organizations that would ensure interoperability and appropriate business practices. Walker pointed out the need for a governing structure for the validation bodies. Halamka observed that the American National Standards Institute (ANSI) has straightforward rules to evaluate certification bodies. But ANSI does not establish the certification criteria.

Cris Ross reported on his experience in other groups that commented on the RFI. He said that he appreciated the team's approach of creating a higher level context as opposed to addressing each question individually. But the nature of the thing being regulated is missing. Unlike EPs and EHRs and EHR vendors, an NVE is a brand new thing. He acknowledged being nervous about the assumption in the RFI that regulation is necessary in order to create an industry and that a high degree of regulation is required. The industry does not yet exist. Hopefully the Notice of Proposed Rule Making (NPRM) on Governance will not be the last word and will instead allow evolution.

Jamie Ferguson noted that the Technology Transfer Act requires all federal agencies to participate in voluntary private sector consensus standards bodies and also to use voluntary consensus standards, unless there is a good reason not to do so. The RFI appears to create new agents that are not private sector voluntary consensus bodies and would be in conflict with the law. Baker replied that the CTE standards would be developed by the validation bodies collaboratively and would be private sector consensus standards. The validation bodies would be private sector consensus standards organizations. Ferguson strongly disagreed, saying that the validation bodies would be an extension of a federal agency. McCallie observed that most of the standards would come from existing standards bodies, but the validation bodies would profile standards for health care use. Ferguson declared that the recommendation should say that the standards are not to be written by a federal validation body. Various opinions were expressed about what the RFI does or does not imply on the matter. Perlin said that he hoped the discussion would be helpful to ONC in identifying unanswered questions.

Anne Castro recommended that payers and other entities not yet studied by the committee not be covered. She told the group that officials of her organization, Blue Cross Blue Shield of South Carolina, were very uncomfortable with the blanket coverage of every organization that exchanges health information. She said that she was comfortable with the inclusion of EPs and EHRs and the NwHIN but not others.

Wes Rishel admitted that he had not heard the beginning of Baker's presentation. He observed that validation bodies would be organizations such as Certification Commission for Health Information Technology (CCHIT) and Drummond. Although CCHIT has its own program of establishing criteria for certification, it uses the criteria established by the National Institute of Standards and Technology (NIST) when it certifies for meaningful use. The reason for multiple certification bodies was to avoid control by a single institution. If a single body is allowed to make up the criteria, there is a race to the bottom in terms of the criteria. Therefore, the establishment of validation criteria needs to come through separate governance instead of the individual validation bodies. Baker responded that the RFI proposes exactly that; she suggested that Rishel wait for her to review the team's response to specific questions. She explained that the team recommended that any given CTE would be validated in exactly the same way by each validation body. Rishel continued to object, saying that it was confusing to say that although the validation bodies would set the criteria, they are not allowed to set different criteria. Baker explained that a collaboration among the validation bodies would establish the criteria. Rishel noted the absence of any standards to define collaboration. Baker acknowledged that the safeguard CTEs will also need standards and certification criteria and presumably those would come from the government, as well as the interoperability CTEs. She indicated that she would add that point to the comments.

Rishel requested that the minutes show his objection, "There is no bright line between standards implementation guides and criteria for validating the operation..." He explained that learning takes too long when compared to the cycle of regulation. Regulation often includes requirements for which little is known about their implementation. He also asked that the diagram on the slide show the equivalent of the S&I Framework. Baker agreed to the change.

Perlin observed that the RFI is more of a schematic than an operating plan. Rishel referred back to the experience of CCHIT and multiple certification bodies and repeated his opinion that someone other than the validation bodies should make decisions about standards. Halamka said that the discussion indicated that members agreed in principle with the diagram and the separation between policies that change infrequently and those standards and technologies that change rapidly. But some members were concerned with the validation bodies defining the technical criteria. He suggested pushing the responsibilities back to the HITSC, ONC or some other place. He suggested a lightning round of no more than 30 second comments. Lightning responses are summarized below:

- Walker – schema does not identify a non-governmental executive body
- McCallie – there would be give and take across validation and standards bodies
- Kelly Hall – state that standards in Meaningful Use is the guide and show the entry points for new standards
- Marc Overhage – basic tension not yet resolved

Then the lightening rounds broke up into more back and forth among members. Halamka said that the framework was a good beginning. However, tension exists between the need for refinement at the operating level and the detail of a priori specifications. Kelly Hall noted the lack of role for patients and families or new non-covered entities.

Baker stated that she heard that a public/private entity in which the validation bodies and the government are represented should be depicted in the recommendations. She asked whether anyone on the team had any objections. McCallie said that ONC had been given that role by statute. Baker responded that the diagram reflected the description in the RFI. The HITSC may or may not be that body. Halamka asked whether members would accept a redrawing of the diagram showing that a public/private entity, which could be the Standards Committee, would provide a convening function to ensure the CTEs are developed for the validation bodies. Overhage spoke in favor of using the experience of hands-on people, not the HITSC. Rishel wanted to state that the depiction did not show the entities necessary to achieve the desired result. Baker stated once again that the diagram depicted the description in the RFI, not the team's recommendation. She reminded members that she had not yet been allowed to complete her presentation. Rishel repeated that a collaboration of the validation bodies lacks the necessary specificity. Halamka said that the operating capacity as opposed to the schematic overall should be considered. Cris Ross wanted to state that the team did not agree with the governance structure and proposed a different structure. Perlin told them that they could work on a diagram at the next meeting. Baker repeated again her appeal to be allowed to go through the team's responses to the 22 questions, which addressed the issues raised during the back and forth. She said that the only unique suggestion brought out in the discussion was to replace collaboration of validation bodies with a public/private entity (new or repurposed) that would come up with the criteria and standards. She referred the members again to the meeting materials and continued with the slides that delineated each question and response:

Electronic health information exchange will simply not occur without trust, and effective Governance is critical to establishing and maintaining the trustworthiness of the NwHIN.

The NPRM for Stage 2 of Meaningful Use put a great deal of emphasis on interoperability. Interoperability is important, but just because it is important does not mean it needs to be large, heavy handed, or obstructive. We believe that the key requirement for Governance is to establish and maintain the core trustworthiness of the NwHIN. We question the need for additional regulation beyond that needed to assure the trustworthiness of the NwHIN trust fabric. We do not see a need for regulated CTEs addressing interoperability and business practices other than those essential to preserve the trust fabric. We believe that service assurances such as competitive pricing, scope of services, and service performance levels are best left to transparency and market competition, with oversight from ONC.

Arien Malec apologized for not attending the recent meetings of the team and contributing to the recommendations under consideration. He inquired about the background discussion in the team. Did the team believe that trust is currently not being preserved in information exchange or that additional trust or clarity in trust would encourage or facilitate information exchange, each of which would require a different approach? McCallie explained that the current process for the establishment of trust is the right process, but it is difficult and incomplete. The team assumed that the trust framework would be good enough so that NVEs could interact with each other without requiring pair-wise business associate agreements.

Baker moved to slides on questions 4 and 8. She acknowledged that the language on the latter should be changed per the lengthy discussion on delegation to a public/private body. She went on to present the responses to questions 9, 10 and 11. Chris Chute interjected a question on #9. What are the implications for a body that wants to participate in health information exchange but opts not to adhere to those criteria? Baker responded that the exchange principals and stakeholders would decide. Chute predicted chaos would result from inconsistency in requirements. After additional back and forth, Mary Jo Deering, ONC, reported on the deliberations of the HITPC on the same topic. Since a potential NVE would have multiple lines of business, and may seek validation only for a particular stream of its activities, the HITPC recommended that ONC come up with a very public listing of validated NVEs. Perlin said that the answer needed to be modified to embrace the applicability modularity aspect and the impact of non-participation in the voluntary process. He announced that revised text would be circulated later.

Returning to the slides, Baker said that the question 11 response would be revised per the previous discussion. She directed attention to question 17, saying that the public/private entity concept would be added there as well. Walker pointed out that having agreed to that change in the first slide, it was not necessary to note the new language in every response.

Baker explained comments to question 56:

We think that the regulatory CTEs should be limited to those necessary to establish and preserve the trust fabric, and that CTEs that address interoperability and business practices other than those necessary to preserve the trustworthiness of the NwHIN should be in the purview of the validating bodies, with oversight from ONC.

Comments on specific CTEs:

- [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IHI may be exchanged by the NVE.
- “Meaningful choice” needs to be defined.
- [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.
- Suggest changing to “Digital certificates must be used to authenticate the identity of organizations on the NwHIN.”
- [I-3]: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.
- This Interoperability CTE will not apply to all NVEs
- [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.
- The oversight of the NVE should seek to address any anti-competitive practices that inhibit free-flowing data exchange, but without imposing an absolute requirement that no fees be involved.
- [BP-2]: An NVE must provide open access to the directory services it provides to enable planned electronic exchange.
- This CTE is protocol specific and is not appropriate as a top-level interoperability CTE.
- [BP-3]: An NVE must report on users and transaction volume for validated services.
- Actual performance should be transparent, but minimal levels should be left up to the market.
 - The validating bodies should collaboratively determine what performance measures are reportable.

Jamie Ferguson questioned whether amending or rewriting the HIPAA security rule was necessary to establish and preserve that trust fabric. Baker reviewed that S-1 says that the HIPAA Security Rule has a number of implementation specifications that are labeled addressable, meaning they can be implemented in different ways. S-1 says that an NVE must treat those addressables as required. She reported that she would cover the issue with her presentation on behalf of the Privacy and Security Workgroup, the next agenda item. Ferguson said that S-1 went beyond its scope of authority. Perlin noted that the meeting was running far behind schedule. He requested focus. Walker opined that from a standards perspective, one HIPAA standard is preferred. Rishel talked about colleagues striving for emotional impact, saying that he concurred with the recommendation. Baker said that the RFI does not propose to change HIPAA. It proposes a CTE that addressables must be interpreted as required. Ferguson insisted that the characterization would change HIPAA. Rishel continued to argue against Ferguson's interpretation. Malec said that a floor is not a ceiling; HIPAA sets a floor and organizations can set requirements that go beyond the floor. McCallie recalled that during the team's deliberations, ONC staff, in particular Joy Pritts, requested that they comment on whether it made sense for a voluntary certification attainment to set higher standards than HIPAA. Baker accepted Walker's suggestion to revise the recommendation to make each addressable implementation spec a separate CTE, and to delete the reference to HIPAA. Halamka declared that members agreed.

Baker moved to the comments on business processes. Members made no comments. She proceeded to the items on policy and process for selecting national standards and for adopting or modifying CTEs:

Top-level CTEs should focus on policy and should not change often. Lower-level CTEs should specify standards and criteria for certifying an NVE against a top-level CTE. We recognize that market needs may encourage an NVE to provide services, and to support standards, other than those endorsed by the CTEs against which the NVE was validated. We suggest that an approach modeled after the HIPAA "hybrid entity" approach might allow for an entity to be regulated as an NVE for certain activities and to operate outside its NVE validation for other services. Transparency will be important here. We recommend that ONC consider a set of core CTEs, required by Federal Regulation, and allow for NVE governing bodies to add optional CTEs by industry consensus in order to balance the need for a trust fabric with the need for industry innovation. We assume that NVEs would need to conform to some CTEs regardless of the specific electronic health information exchange service(s) or activities provided. We believe this approach could create a core trust baseline for all NVEs and that such commonality could strengthen the public's trust of NVEs, and NVEs' trust of each other. Finally, we assume that some NVEs could perform services or activities unrelated to adopted CTEs. In such cases, we believe it would be necessary for there to be a clear differentiation between those services an NVE performs in accordance with NwHIN governance covered by its validation and those services or activities it supports outside its validation. We also believe that the certification process should allow for bilateral version skew for those standards that continue to evolve, such that an NVE would not sacrifice its validated trust or interoperability during a rolling upgrade to a new version of a certified standard.

Castro commented that the more she heard, the more she was convinced that voluntary was problematic for everybody involved because of the need to construct different information exchange requirements with every entity. She asked that the record show her opposition due to the huge impact on information exchange entities. Although the requirements may be appropriate for hospital and physician exchange, they are not necessarily appropriate for payers and other entities that have yet to emerge. She emphasized that she represented payers and that the proposals in the RFI would create problems for her constituency. Responding to additional suggestions about what the team should have recommended, Baker stated that she heard that some members wished to go further and say that trust fabric requirements must be in place prior to the exchange of information.

Perlin reinstated the lightning round:

- McCallie – to require certification for exchange would be disruptive – start voluntary and let it evolve
- Kelly Hall – fill the gap
- Rishel – NPRM (sic) is not replacing or changing HIPAA - not prohibiting entities that want to exchange from establishing a bilateral agreement – restricting use of trademark only
- Castro – concerned with Accountable Care Organization planning and payment methods determination

The lightning round halted for a discussion between Rishel and Castro. Perlin eventually summarized that the payer community's interests need to be recognized and variability introduces complexity. The recommendations are not intended to supplant existing secure exchange. Ross talked about requirements on procurement contracts rendering the voluntary concept meaningless. Therefore, rules are needed. Baker proposed mentioning that it may be problematic for payers and payers should be considered. The pilots should include payers.

6. Report and Recommendation from the Vocabulary Task Force

Due to the discussion of the RFI having greatly extended the time allocated it, Perlin skipped to item 8 on the agenda, which was originally scheduled for that time slot. Jamie Ferguson, Chair, showed slides on the status of recommendations made by the HITSC in April 2010. He declared that the plans of the National Library of Medicine (NLM) aligned almost perfectly with those recommendations. He noted that members had detailed information in their meeting materials. The NLM value set authority center will be able to support the need for value sets for Meaningful Use as well as the need for those value sets to be used and supported by the measure developers in particular. He proceeded to the slide stating a new recommendation:

Recommended HITSC Guidance To Measure Developers For The Use Of Vocabulary Standards:

- Developers of eMeasures should rely on existing medical record documentation and coding in the standards instead of requiring new or different documentation and coding, except where a policy process determines a need to use measures as a deliberate forcing function to induce new behaviors.
- Developers of eMeasures should first use existing standard vocabulary concepts the use of which has been demonstrated in certified electronic health record systems.
- NLM as part of the Value Set Authority Center should provide to eMeasure developers data from cooperating EHR systems on the frequency of use of vocabulary concepts, in convenience subsets of standard vocabularies, or reference sets, for specific purposes such as primary care.
- NLM should support and promote consulting assistance from terminology experts so that eMeasure developers may better use resources provided by the Value Set Authority Center.

He went on to talk about convergent medical terminology in SNOMED CT, noting the donation of his organization:

- What it is: Open source donation from Kaiser Permanente, scheduled by clinical domain from February 2011. Content is reviewed by IHTSDO and NLM for applicability and for adherence to editorial guidelines – some is accepted by IHTSDO into SNOMED CT international release; some is accepted by NLM into US Extension of SNOMED CT; some stays in Kaiser Permanente namespace. Excel spreadsheets and IHTSDO Release Format 1 problem list subsets include concepts used by over 20,000 clinicians with: concept fully specified names; descriptions that are used as clinician preferred display names; patient preferred display names; cross-maps to ICD-9, ICD-10, Laboratory LOINC and medication terminologies as applicable; multiple identifiers and parent concepts as applicable.
- Clinical domain coverage and schedule for content review
 - CMT files downloadable now: Over 18,250 concepts including Top 2500 problems; also Cardiovascular; Mental Health; Neurology; Musculoskeletal; Ophthalmology; Oncology; Hematology; Endocrinology; Urology; Nephrology
 - July – September 2012: Common lab procedures; Common lab results; Ear, Nose, Throat, Infectious Diseases, and GI
 - October 2012 – May 2013: Skin; Respiratory; Orthopedics; Non-fracture Injuries
 - Now in process as a high priority, date not finalized: Primary Care including Internal Medicine, Family Practice, Pediatrics, OB and Gyn

McCallie asked about extensions to SNOMED to allow for pre-coordinated matches to make translation to ICD-10 easier. Ferguson indicated the extensions were included in the recommendation. SNOMED pre-coordinated terms match the ICD-10 CM terms. That is part of both SNOMED International and a US extension in the NLM. In other words, measure developers should not make stuff up. Floyd Eisenberg asked about making the resource available to measure developers not under government contract. Betsy Humphreys, Co-Chair, Vocabulary Task Force, confirmed that the focus would be on assisting with stage 2.

Stan Huff inquired about the meaning of “except where a policy process”. Ferguson asked Fridsma to respond. Fridsma acknowledged that he had no answer. The answer may come through the establishment of government standards for clinical care.

Someone talked about a distinction between algorithmic determinations or calculated value determinations and vocabulary elements. For implementation, it is important to distinguish between assigning a vocabulary notion to these things and understanding how people and providers in the field are actually going to generate this information.

Perlin asked about a general consensus of enthusiastic support for the recommendation. No opposition was noted.

Action item #2: The recommendation of the Vocabulary Task Force was accepted.

7. Report from Hearings on Clinical Quality and Patient-Generated Data

Marjorie Rallins, Clinical Quality Workgroup, reported on the June 7 hearing on clinical quality. She showed slides and talked about the hearing objectives and described the panels and the questions they were told to address. Her slides gave a concise summary of the assessment of roles for federal policy:

- CQM
 - Several layers for intervention and action
 - CQM for MU,
 - Consider state and private measures, QI measurement at enterprise level
- Coordination/Harmonization/Dramatic Acceleration in areas of progress, e.g.
 - CDSS toolkit to drive improvement against measure; does fed policy have a role? How, and where?
 - Value set repository
 - Data dictionaries
- Facilitate real time interoperability
- Facilitate and/or incent “first movers” related to standards, e.g. value sets, use of structured data or newer quality measures such as functional status, care coordination
- Leveraging the role of the patient,
- Governance and transparency of information

Leslie Kelly Hall, Chair, Patient Engagement Power Team, reported on the June 20 hearing on patient-generated health data (PGHD). She showed and talked through nine overview slides and then drew conclusions. PGHD should be able to be accepted into the EHR. Other considerations are: standardized data, interoperability, accommodation of multiple respondents, inclusion of patient facing systems, shared decision making, inclusion of expert systems outside the EHR, quality, and legacy systems. PGHD has improved quality and patient confidence. PGHD for values, intolerances, advanced directives, and preferences may fit well within Computerized Physician Order Entry (CPOE). Workflow, structured data, and expectations should be well defined and understood. New technologies like mobile health and new data sources may overwhelm providers who have not initiated structured PGHD efforts.

Q, A and Comments

Liz Johnson spoke about the need to go beyond Meaningful Use stage 2, which is download and view. She suggested selecting two or three populations for which to build standards.

Rebecca Kush suggests that research tools, such as electronic diaries and interactive voice response, with audit trails and regulated requirements could be leveraged.

McCallie asked how PGHD differed from the usual process of patients bringing data to their providers. Kelly responded that the former is patient-generated and basically accepted electronically; the latter is interpreted and entered by an intake process and could include messaging. After the expression of different opinion on what defines PGHC, Perlin requested a formal definition, which Kelly Hall offered to submit one from the white paper presented in conjunction with the hearing.

Eisenberg reported the example given by the patient panelist. The patient experienced a number of adverse events related to a peripherally inserted central catheter (PICC) line insertion. He wanted the information in his record so as to prevent a repeat of the event. However, the information was not placed in the record; he found himself in the OR again with a PICC line. Patients want to enter the data themselves and have the source known because interpretation by physicians may miss the point. McCallie argued that in Eisenberg's example the clinician failed, not the IT systems. Perlin declared that they needed a definition of PGHD, saying it is one thing to upload blood glucose from glucometers and another to enter self-assessed functional data. Eisenberg observed that standards must be in place to address this cultural change.

Marty Harris related Cleveland Clinic's experience with PGHC. Patients want to enter information but then they assume someone is acting on it, whatever that means to them. The clinician may be getting data that allows her to improve outcomes in the long run, and maybe some short term clinical decision making as well. That gap must be bridged.

Marc Overhage inquired about the cost of patient measures such as PAM, which he indicated is expensive. Kelly Hall responded that cost was not discussed. Panelists said that when patients participated with their own data, they were more confident in the providers' care and more confident in their ability to self-care.

Daniels reminded the members that the definition and the white paper referred to earlier (as well as the panelists' testimonies) were easily available as a part of the public record. She read the definition:

PGHD are health-related data including health history, symptoms, biometric data, treatment history, lifestyle choices and other information created, recorded, gathered or inferred by or from patients or their designees, to help address a health concern. PGHD are distinct from data generated in the clinical setting and through encounters with providers in two important ways. First, patients, not providers, are primarily responsible for capturing or recording these data. Second, patients direct the sharing or distributing of these data to health care providers and other stakeholders. In these ways, PGHD health data compliment provider-directed capture and flow of health related data across the health care system.

Kelly Hall declared that standards need to be made available to organizations.

8. NwHIN Power Team Comments on Request for Information (RFI) on Governance for the Nationwide Health Information Network

Baker resumed with questions 63 and 64. Members had no objections to what was shown on the slide. Baker noted that she would make the agreed-upon change to private-public entity and add something about actors and the evolution of roles. She moved quickly through question 39, 45 and 46. Walker asked how the sender and receiver would not be known when the exchange occurs at the patient's direction. Various examples were given back and forth. Baker agreed to add a comment about the lack of clarity in the language. She continued, saying that questions 45 - 47 were at a much more granular level than was appropriate for a governance regulation. Regarding question 48, Baker said that the team determined that the question was one of policy and forwarded it to the Privacy and Security Tiger Team.

Baker referred to the slides with questions 49, 50 and 51, which related to condition I-3. Johnson said that insofar as a specific level of matching algorithms is not required, how would the consumer obtain information? Baker said that according to the recommendation, availability level and matching accuracy level, as well as the method of measurement, would be published. Johnson suggested adding something to the effect that people need to read the description of the product.

Eisenberg asked about communicating to customers whether the matching process included a human intermediary who validated and refined the match. Baker said that such information would be included in the method of calculation. Eisenberg continued to press the point, saying that a lower quality match may be acceptable when a human intermediary can confirm or disconfirm the match. McCallie reported that the recommendations were made with the assumption that such details belonged within the purview of the validating bodies. Ross questioned the presumption that every NVE will engage in patient matching. Baker said that the comment stated that the CTE should only apply to those NVEs that need to match a specific patient. Ross said that the preface materials should say that NVEs may come in different forms and styles with different missions.

Baker said in conclusion that the review of the Governance RFI was a diversion from the team's core task of developing recommendations for criteria and metrics for assessing the readiness of standards and implementation specs to become national standards. She appealed to team members to attend meetings and participate in the work. Final recommendations on evaluation of readiness will be presented to the HITSC in August.

9. Privacy and Security Workgroup Comments on RFI

Perlin reminded the members that the preliminary recommendations had been presented and discussed at the May meeting. He directed them to focus on the highlighted red material, which indicated changes made based on that discussion. Baker reported that the workgroup commented on the six assigned questions plus an additional question in which the workgroup members had a high interest. She declared that the workgroup's comments were completely consistent with the comments made by the NwHIN Power Team. She directed members to read the comments on the validation approach. Since no questions were asked, she moved quickly to the questions pertaining to S-1. She announced that insofar as the recommendation had been discussed in her earlier presentation, she would include the statement that instead of referencing HIPAA, the addressable implementation specifications should be explicitly required in a CTE. Members had no comments on the responses to questions 45 or 47. Regarding the questions on which CTEs should be revised or deleted (or added), she reported that the workgroup recommended the elimination of duplicate requirements.

Moving to S-2, she noted its importance. Electronic health information exchange should be facilitated only for authenticated parties, consistent with the Federal Identity Credential and Access Management (FICAM) trust framework at assurance level 2 or higher, and must implement an appropriate certificate policy that accounts for identity proofing and level of assurance. Baker informed the members that assurance level 2 is just above 1, which is no assurance. McCallie interrupted to say that although (as a member of that workgroup) he had forgotten about the recommendation, the Privacy and Security Tiger Team had debated the inconsistency with the current FICAM rules that are not group focused. He asked that the comment be softened to say consistent with FICAM approaches. Baker agreed that the organizational certificate element should be captured. Rishel asked for more explicit language. Baker agreed to add an explanatory sentence saying not all of FICAM applied.

Ferguson interjected a comment on S-3 although Baker pointed out that it had been agreed on at the May meeting. He said that there were a number of potential conflicts with existing law in the area of HIPAA and Federal Drug Administration regulation of research of human subjects in particular. He gave examples. Baker agreed to add something about being examined with respect to conflicts with existing law. Ferguson went on to talk about intermediaries that do not have a relationship with a patient. Some intermediaries may have repositories. Baker agreed to add "and a direct relationship with the consumer".

Baker moved to S-4 and S-5. She observed that although the RFI describes the difference between what an NVE would be required to disclose versus a HIPAA notice of privacy practices, reading the CTE alone does not capture the necessary nuances. Therefore, the workgroup recommended that the content of the notice be detailed.

Castro observed that the requirements for disclosure constitute a big burden. Baker informed her that the requirement was the publication of the privacy policy, not that each consumer be individually notified.

Walker observed that a consumer relationship is different than a patient relationship. More thought should be given to the variety of relationships. Kelly Hall said that commercial purposes should be defined. Baker said that she would add something about the need for clarity on aggregation services.

Baker referred to the slide on S-7, saying that the recommendation was consistent with the one presented on behalf of the NwHIN Power Team. On Safeguard 10, Ferguson said that query response is used for many purposes other than treatment of the patient. In the NwHIN Exchange, the largest numbers of exchanges are with the Social Security Administration for disability determinations. If the recommendation were implemented, those exchanges would not be allowed. He suggested replacing the word treatment with permitted purposes. Perlin suggested established or establishing relationship with patient. He declared that the discussion had been completed and said that he hoped the discussion had provided useful feedback to ONC staff.

Baker announced a public hearing on identity management scheduled on July 11. McCallie observed that if recommendations to the RFI were implemented, very little would change. Halamka reported that officials in Massachusetts are hoping to eliminate bilateral **Data Use and Reciprocal Support Agreements (DURSA)** and go to cloud-based trust fabric. Although policy may not change, operations would change. A conversation between McCallie and Halamka ensued. Perlin moved the agenda.

10. Update on S&I Initiatives and Plans for Coordinated Structure

Halamka announced that because of substantial reductions in funding, Doug Fridsma, ONC, had been asked to tell the committee how it can have better input. Fridsma began by apologizing to his team members, who had made a considerable effort to compile information on their activities only to find that their projects would not be described because the agenda time allocations had not been adhered to. He referred the members to the handout and began to talk through his slides. ONC's commitment to enabling rapid standards development has not diminished with the end of funds. The HITECH gave ONC authority to identify the standards, implementation guides and the certification criteria to enable health information exchange. That authority is not tied to American Recovery and Reinvestment Act funding. Regarding standards development, several approaches can be used. If an incremental approach is available in combination with a high degree of consensus, public comment through a rule making process may work. Or a HITSC workgroup can give feedback. Other circumstances may call for help from standards development organizations or community driven pilots. Areas characterized by a moderate-to-high degree of incrementalism and a moderate-to-low degree of consensus are the areas in which ONC can provide the greatest value. He gave examples and then described various projects. Several S&I initiatives are underway. The Direct project is in evaluation and implementation and is part of the NPRM. Transitions of care pilots are underway. Three new initiatives: are Primary Care Online Resources and Education (PCORE) to support patient centered outcomes research; a blue button project; and Health eDecisions, which is about clinical decision support. Also, in response to the recommendations of the NwHIN Power Team, additional work is being done on RESTful interfaces as a way of transport. The S&I framework is a public platform where the community can build consensus around solutions to a standards gap that must be addressed to support health information exchange. He went on to funding, saying that the criteria for successful S&I initiatives must be made explicit. He talked about the role of the HITSC within the S&I framework governance. He said that he wanted the committee to look at the artifacts and "tell us whether we hit the mark or not" The committee can help set priorities. The committee can ask for information to help with its recommendations.

Discussion

John Halamka asked staff to put discussion of the S&I on the agenda of the next meeting. He informed members that blue button is not the unstructured text scattered in random formats for various purposes. It is a brand that refers to patient enabled transfers of structured data like the consolidated CDA. Regarding the importance of a RESTful standard, the problem is how to take OAuth or OpenID, which are application layer authentication mechanisms, and incorporate them into a RESTful architecture so that the whole package is something that can be certified. Adoption of standards by EHR users is the primary criterion of success. Fridsma talked about crowd sourcing and government as a platform around implementation as areas of focus.

Ferguson asked about balancing competing interests in the process of standards development, something in his opinion that had been missing in S&I. Fridsma responded that the HITSC is expected to provide balance of interests. Ferguson pointed out that by the time issues were brought to the committee there were done deals. Halamka indicated that at the next meeting potential projects will be reviewed and prioritized. Kelly Hall requested more detailed information about funding by project. Patients and families should be included in new projects.

McCallie talked about ideas for criteria such as which efforts are tied to a regulatory requirement, such as meaningful use. Another issue is the availability of a sufficient number of stakeholders to do the work. With MicroData, there were not enough experts to do the work.

11. Updates on Long-Term and Post-Acute Care (LTPAC) Initiatives

ONC LTPAC Initiatives (S&I Project and Roundtable)

Other LTPAC Activities

John Derr said that he was not asking for decisions. He said that he wanted to be in stage 3. He described LTPAC. He distributed a handout. He showed slides describing the Long Term Post-Acute Care HIT Collaborative, which is person centric. HIT plays a role in being proactive and preventing re-hospitalizations. Quality of life is important. He described the different kinds of care and facilities involved in the collaborative. The collaborative works with the National Quality Forum. Some vendors are already certified under CCHIT. He described the S&I framework and the four challenge HIE grants.

John Feikema, ONC, showed slides. He said that for S&I the LTPAC is between the limited and the strategic support models. The ratio of volunteers to support staff is significantly higher than in other initiatives. Helping community members get comfortable with a standards development process takes work. That the demand for LTPAC is growing with the aging of boomers is well known. ONC convened a roundtable May 3 at which the following priorities for ONC were identified:

- Federally required patient assessments
- Dynamic care plan
- Transitions of care criteria (create, transmit and incorporate)

He reported that the Longitudinal Coordination of Care (LCC) Sub Workgroup is working on a white paper to define the long term vision and requirements for LTPAC to include all the care settings within the long term care spectrum. The primary goal of this work is to drive the prioritization of additional use cases and it should include a timeline and priorities for inclusion into stage 3.

Deer said that the S&I LCC Workgroup has three-near term deliverables, all of which support Meaningful Use: expand the data sets for clinical summaries and transitions of care to make them more meaningful for LTPAC settings; exchange of home health plan of care for skilled home care to set the foundation for ongoing work to define care plan requirements; and availability of standardized, federally required patient assessment summaries.

Halamka referred to the description of the Massachusetts activities, saying that they illustrate the kind of standards needed. In long term care (sic) an EHR certified for Direct is not always available. He said that his next challenge grant will build two software components. LAND is a local application for network distribution for use with a non-certified EHR. SEA is a surrogate EHR and web-based application that allows consolidated CDA documents to be edited, sent and received. Derr reported that Geisinger has a useful product.

Ferguson informed the members that he supported getting these standards into Meaningful Use certification requirements. He spoke about his participation in a symposium at the Hilltop Institute, University of Maryland, on long term services and support. He learned that many duplicative efforts are creating new data silos for long term services and supports. He gave examples. A patchwork is rapidly developing.

Rishel said that the individual efforts are probably the most important activity that is going on. To show economic benefit, many unanticipated problems would probably have to be solved. But these individual efforts create the wellspring of support that gets problems addressed at a national level. Those programs should not delay their efforts until a common specification is ready.

McCallie suggested that much post-acute care is not associated with long term facilities. A dynamic care plan would be very difficult. He wondered whether efforts should include a broader perspective than long term care facilities.

12. Public Comment

None

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the May 2012 meeting was declared approved.

Action item #2: The following recommendation of the Vocabulary Task Force was accepted.

Recommended HITSC Guidance To Measure Developers For The Use Of Vocabulary Standards:

- Developers of eMeasures should rely on existing medical record documentation and coding in the standards instead of requiring new or different documentation and coding, except where a policy process determines a need to use measures as a deliberate forcing function to induce new behaviors.
- Developers of eMeasures should first use existing standard vocabulary concepts the use of which has been demonstrated in certified electronic health record systems.
- NLM as part of the Value Set Authority Center should provide to eMeasure developers data from cooperating EHR systems on the frequency of use of vocabulary concepts, in convenience subsets of standard vocabularies, or reference sets, for specific purposes such as primary care.
- NLM should support and promote consulting assistance from terminology experts so that eMeasure developers may better use resources provided by the Value Set Authority Center.

Meeting Materials:

- Agenda
- Summary of May meeting
- Presentation slides
- Other handouts