HIT Standards Committee
FINAL
Summary of the March 18, 2015 Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with an opportunity for public comment (3-minute limit), and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves.

Remarks and Review of Agenda

Acting Deputy National Coordinator and Chairperson P. Jon White talked about having attended a hearing on Capitol Hill on interoperability. He said that although there are several legislative proposals of interest to members, it is not appropriate for the HITSC to advise on pending legislation. Federal employees do not lobby. He asked them not to talk about these matters during the meeting. The proposals do not impact on-going HITSC efforts. He asked about revisions or corrections to the summaries of the January and February meetings. Hearing none, he asked for a motion for approval. A motion was made, seconded and passed unanimously.

> **Action item #1: The summaries of the January and February 2015 meetings were accepted as circulated in advance of the meeting.**

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

Security Risk Management

Ron Ross, National Institute of Standards and Technology (NIST), gave a slide presentation. He began by talking about understanding the cyber threat. A thorough criticality analysis of health IT organizational assets should be conducted. The complexity of health IT infrastructure should be reduced and health IT security requirements can be integrated into organizational processes. Organizations should invest in trustworthiness and resilience of health IT components and systems. He described the Federal Cyber Security Toolset, which consists of NIST special publications 800-39, 800-30, 800-37, 800-53, 800-53A and 800-160 (forthcoming). He pointed to and explained a depiction of a risk management framework. Agile defense and boundary protection are protection strategies. NIST's forthcoming publication will build on international standards to integrate the RMF and security concepts, principles, and best practices into IEEE/ISO/IEC 15288. He emphasized that security is a by-product of good design and development practices. The engagement of executive management is essential. He invited members to contact him personally with urgent questions.

Q and A

Arien Malec referred to 800-53 and the federal role. At DoD, the federal response to the cloud is to create enclaves. In health care the federal response has been to secure the health care enterprise. Cloud

providers should be certified. The federal response is counterproductive. He went on to make a long, technical statement proposing what the federal health care system should do in the cloud. Ross responded that federal agency officials are often risk adverse. In the federal system only 10% of systems are high impact. By classifying systems into low, medium and high risk, better decisions could be made regarding the cloud. He indicated agreement with Malec.

David McCallie asked about risk assessment across a suite of operations: What are the low hanging fruits? Ross talked about some architectural changed that can be done. Organizations can better educate their users and provide basic hygiene. Configuration management and control is important. Strong identification management is essential. For 8 years, the federal government has been moving to two-factor authentication, which can resolve many concerns. Organizations can also lock down to safe systems.

Eric Rose inquired what small practices with no IT-dedicated staff can do. Ross referred to NIST guidances and ISO 27000. Whichever set of standards is selected, an organization must determine the essential controls for its specific operations. There should be a contingency plan scaled to operations. They need to have scenarios and recommendations for different kinds of practices and operations. Industry must build safeguards into systems targeted to users.

Noting that EHR certification does not include security, Dixie Baker asked about advice to organizations on risk assessments with certified products. Ross said that consumers have to influence industry to meet their needs and then work on enterprise architecture and policies and procedures that enhance security.

Data Update

Dawn Heisey-Grove, ONC, reported on characteristics associated with meaningful use performance among eligible hospitals. She reminded them that providers must complete 2 years of stage 1 before progressing to stage 2. On average, stage 2 hospitals are sending electronic summaries of care for 36% of all transitions. Critical access hospitals (CAH) reported the highest summary of care rates. On average, 44% of transitions from CAHs received an electronic summary of care. Large hospitals (400+ beds) reported the lowest rate of providing electronic summaries of care. On average, 32% of transitions from large hospitals received an electronic summary of care. 15% of stage 2 hospitals' patients viewed, downloaded, or transmitted their electronic health information at least once. Hospitals that have been meaningful users since 2011 have the highest average rates (18%) of VDT. With an average of 17%, hospitals that attested in November had the highest rates of patients viewing, downloading, or transmitting their electronic health information at least once. On average, 70% of medications administered in stage 2 hospitals had all doses tracked through an electronic medication administration record (eMAR). Medium-size hospitals and hospitals that first attested to meaningful use in 2011 reported the highest average eMAR tracking rates. The e-prescribing measure is an optional measure in stage 2. On average, hospitals that selected this measure used e-prescribing for 56% of all permissible discharge medications. Of the hospitals that selected the measure, CAHs and other small hospitals reported the highest average discharge eRX rates at 64%. Of the hospitals that selected the measure, medium-size hospitals had the lowest average discharge eRx rates at 48%. Three public health measures are required reporting for stage 2; these were optional for stage 1. 72% of stage 2 hospitals reported, without exclusion, on all three public health measures. 5% of stage 1 hospitals reported, without exclusion, on all three public health measures.

Q and A

Jeremy Delinsky wondered about the CAH outperforming larger hospitals. Heisey-Grove hypothesized that smaller hospitals may have stronger relationships with their patients and partners. Also, the denominator is lower. Further analysis is underway.

Floyd Eisenberg inquired about the usefulness of the summary of care record and a comparison of eMAR use pre-meaningful use. According to Heisey-Grove, meaningful use does not generate data to answer those questions. She assured Cris Ross that data on EPs will be analyzed after their deadline for reporting. She asked Leslie Kelly Hall to submit her request for information on patient engagement and educational materials through Consolazio.

S&I Framework - Electronic Long Term Support Services (eLTSS) Progress Update

Evelyn Gallego-Haag, Initiative Coordinator, described progress on the initiative with CMS. It is driven by the requirements of the CMS *Testing Experience and Functional Tools (TEFT) in Medicaid community-based long term services & supports (LTSS) Planning and Demonstration Grant Program.* In March 2014, CMS awarded demonstration grants to nine states to identify, evaluate and harmonize standards needed for the creation, exchange and re-use of: key domains and associated data elements of Community Based-Long Term Services and Support (CB-LTSS) person-centered planning, assessment and services; and accessible person-centered service plans that are interoperable and used by providers, beneficiaries, accountable entities and payers. The standard(s) identified are expected to support the creation of a person-centered electronic LTSS plan, one that supports the person, makes her central to the process, and recognizes the person as the expert on goals and needs. These standards will support interoperable exchange with various information systems to include:

- Community-based Information Systems
- Clinical Information Systems (e.g. EHRs)
- State Medicaid Systems and/or other Payer Systems
- Health Information Exchange Systems
- Personal Health Record Systems (PHRs)/ Digital Health Devices
- Other Information Systems (e.g. legal, justice, education, etc.)

The content or data elements of the eLTSS plan will be specific to the types of services rendered and information collected for CB-LTSS. Information collected may contain relevant clinical data needed to support the continuum of beneficiary care, support and services. The stakeholders are gathering functional and technical specifications for the eLTSS use case. Inputs include:

- CMS CARE Data Elements--2014 IMPACT Act Implementation and TEFT Care Functional Assessment
- CMS Balancing Incentive Program: No Wrong Door System Requirements
- IOM Recommendations for Social & Behavioral Domains and Measures for EHRs
- NQF HCBS Quality Measures
- ACL Aging and Disability Resources

In conclusion, she delineated these questions for the HITSC:

- What candidate standards exist that lend to this type of work?
- What SDOs should we consider engaging with?
- Do you have guidance for engaging with digital and mobile health innovators?
- What are we missing?

Q and A

Kelly Hall declared that she wants more work in semantics and taxonomy for patients in care planning. McCallie said that the eLTSS is an opportunity to test against the framework that he and Malec will present under another agenda item. He volunteered to explore the idea with Gallego-Haag. Moving access to a shared application would simplify the work.

Andrew Wiesenthal asked that they not invent new standards. Existing ones should be used. Care plans must live within the EHR. As a doctor, he assured everyone that he is interested in the patient beyond

clinical care. Everyone needs a care plan. Care plans are especially important for children with special health care needs who must interact with community providers.

Eric Rose reported that the UK NHS uses an app to coordinate care across informal networks. He urged Gallego-Haag to seek information on that app. Delinsky observed that the discussion seems to be at a pre-standards level. An application is not a standard. The solution must precede the standard.

Standards and Interoperability (S&I) Initiative Task Force Recommendations

Task Force Co-chairpersons Stan Huff and Arien Malec explained that the task force was charged with answering this question: Is there a continued need for the S&I Framework (or an equivalent process) to advance standards and implementation specification development? If yes, in what ways could the current S&I Framework be improved or enhanced to better address identified industry needs? If no, what alternatives should be considered to address the identified industry needs? The task force made 10 recommendations organized into four categories. In presenting the recommendations, accompanied by a draft transmittal letter, they prefaced each set of recommendations with findings and rationale.

Areas of focus for a convening function:

1. Recommendation: ONC should support a convening function that focuses on the following key enabling activities and associated recommendations:
2. Recommendation: Work with SDOs, coordinate across SDOs and perform additional activities to support identified national priorities:
    a. Define critical needs, desired outcomes, and evaluation criteria for projects and ensure they have traceability to National Priorities.
    b. Develop, identify, or refine use cases.
    c. Include front-end clinical and other requirements into the use case development.
    d. Support SDOs to identify gaps in existing standards/implementation guidance.
    e. Support SDOs to reduce optionality for existing standards/implementation guidance.
    f. Support SDOs to create easy to consume consolidated artifacts (e.g., consolidated implementation guides).
    g. When new standards and implementation guidance are needed, use a defined process for selecting which SDO(s) to work with.
3. Recommendation: Support production use of the above by:
    a. Facilitating (including by funding) pilots and effective production implementation and adoption.
    b. Feeding learnings back to SDOs (e.g., to further reduce optionality and clarify ambiguity).
    c. Evaluating success of standards and implementation guidance in achieving national priorities with respect to individual projects.
    d. Facilitating (including by funding) and supporting the development of widely available (e.g., open source) reference implementations.
    e. Facilitating, and seeking input of those with expertise in, development of testing tools in parallel with development of implementation guidance.
4. Recommendation: Facilitate effective federal participation in SDOs by working with ONC to coordinate involvement of relevant federal agencies in SDO processes
    a. Identify key representative(s) from each relevant agency.
    b. Ensure Federal role in SDOs and similar aligned with national priorities.
    c. Ensure active Federal participation in pilot, technology development, early production and national adoption of standards and implementation guidance.

5. Recommendation: Identify needs for infrastructure and artifacts that may be developed outside of or across SDOs. For example:
    a. Value sets.
    b. Provider directory data sources (e.g., CMS NPPES modernization).
    c. Organizational identity assurance.

Prioritization of identified national priorities recommendations:

6. Recommendation: A convening function should ensure that its prioritized projects actively convened under the function meet all of the following criteria:
    a. Has high priority among the potential projects as determined by stakeholders including balanced representatives of beneficiaries and developers of interoperability (e.g., Federal, provider, developer, patient stakeholders) and should align with a strategy that has received broad public feedback, such as the Interoperability Roadmap. Priorities should not be determined by a single Federal Agency who wishes to address a need without respect to rank order prioritization across projects.
    b. If successful, projects or initiatives conducted through the convening function will lead to a measurable and meaningful real-world set of outcomes that will advance a given national priority (e.g., it will create healthcare value and/or equity).
    c. Has been screened through a consistent gating process to ensure projects (examples listed)

Standards and implementation guidance development lifecycle:

Recommendation: Coordinated lifecycle for standard-development

7. The ONC should actively encourage, and seek to avoid policies that may inadvertently discourage, market and mission-based work that leads to tight interplay between standards development, production implementation, and adoption. For example, avoid certification approaches that heavily load development roadmaps and implementation and adoption cycles: that would reduce time, energy and effort that could otherwise be used for mission and market-based standards development, implementation and adoption.
    a. When working with SDOs that have processes accommodative both of cycles of implementation and draft standards/implementation guidance feedback and of formal consolidation and balloting, the convening function should work within SDO processes
    b. When working with SDOs that do not have processes accommodative of such cycles, the convening function should encourage, where appropriate, cycles of feedback and implementation, and align such cycles with the SDO's formal balloting process.
    c. The ONC should not create certification criteria for standards and implementation guidance that lack adequate real-world piloting and production use.
    d. The ONC should ensure that certification criteria point to work aligned with OMB Circular A-119 (e.g., to formally balloted SDO standards and specifications).

Work Practice Recommendations:

8. Recommendation: Clear chartering driving towards real-world outcomes:
    a. Every project must be accompanied by a charter that lists expected real-world outcomes and interim deliverables/outcomes that lead up to the long-term goals.
    b. The combination of both process and outcomes measures must be continually evaluated.
    c. Each project must have a clear plan for how the outcome could be evaluated.
9. Recommendation: Clear roles for facilitation:
    a. The recognized stakeholders of the project should be the key, material participants in the initiative itself who should set the timeline for the project consistent with the

charter. ONC and other Federal agencies often use contractors to facilitate projects, but such facilitators must not drive outcomes or develop core content for deliverables.

b. Appropriate activities for facilitators include effective project management, note taking and editing, content management, and background research.
c. ONC or other Federal agencies should ensure clear roles for funded subject matter experts, who are expected to be material participants, and the Convening Function should ensure that such experts are peer and equal participants with other stakeholders, and thus do not disproportionately influence project outcomes.

10. Recommendation: Clear project management processes
    a. Consider narrowing scope of projects in order to target specific, achievable outcomes.
    b. Set time limits, project plans and processes to expedite the narrowly defined results.
        1. Process should be appropriate to allow the project to move forward expeditiously.
        2. Phases should be time-boxed.
        3. Ensure that roles and responsibilities for participation in project phases are well defined in order to allow participants with key needs (e.g., business, clinical, technical, etc.) to participate effectively.
    c. Define an oversight process for the convening function that includes:
        1. Well-defined checkpoints to evaluate the project against the timeline and desired real-world outcomes.
        2. If and when it is determined that the outcomes are unlikely to be achieved, there should be a process to end the activity rather than proceed.

Q and A

McCallie wondered about the role of business. Malec said that the preference is for processes driven by the market not regulation. The recommendation is that before projects are accepted the likelihood for success must be high, meaning vendors demonstrate interest in development. The recommendations are particular to a convening function and what should and should not be done. Sometimes something needs to happen and market forces are not lined up to produce it. McCallie talked about the role of a referee.

Wes Rishel spoke in favor of slides with fewer words and bigger fonts. The one thing that rises to the top is the recommendation about implementations along the way to see if the standard works. Differences in a committee are often solved by ambiguity. Initiatives are driven by legislative mandates and election cycles. It will be difficult to establish national priorities and develop standards to support them within those drivers' time frames. The idea of policy-based prioritization does not allow for the opportunistic nature of things about which to operate. What we need and what we can do are always factors in prioritization. Private efforts must be recognized as well. The incremental development of standards through implementation is the most important recommendation. Malec referred to a flaw in legislation that separates policy development and standards development. As a result, policy is not constrained by what is achievable.

Baker referred to an item on slide 8, pointing out that an implementation guidance is usually use case-specific. SDOs typically do not develop implementation guides: so who would produce them? Huff responded that HL7 does implementation guides. Perhaps the term is an ambiguous one. Most work would continue in the SDOs rather than in the convening function. If implementation requires multiple standards, then the convener could take on the task. Work is also being done in other functions, people doing the work and being willing to share. Malec said that the term standard implementation guidance is used in HITECH. He wanted to conform to that language. Implementation guidances are often created ad hoc and refer back to existing standards.

Rose wondered why the S&I should be completely replaced, which appeared to him to be the conclusion of the task force. Why are the problems not fixable? Huff explained that they used the term convening function in order for the audience not to assume that the recommendation is for the S&I to continue in its current form. There is no assumption that the S&I must be rebuilt. A new name is used. The rationale for all 10 recommendations is explained in the slides. As presently constituted, the S&I Framework does not work well. As an example, the structured data capture project process did not accommodate the experts who were needed. As a result, the output was not representative.

Lorraine Doo spoke about the administrative side of standards. The primary issue is the length of time required for development and testing. Standards are often adopted prior to adequate testing. The OMB administrative procedures act governs the adoption of standards by federal agencies. Malec said that if agencies set clear expectations, vendors will meet them. Policy statements must allow sufficient time for the necessary standards development.

Delinsky recommended adoption of the task force's recommendations, particularly #5 about the infrastructure outside of standards needing to be identified. ONC should push key components where the market is not responding, for example, standards for provider directories and record locators.

Kelly Hall talked about the role of consumers in standards. ONC is a mechanism for consumers and others without a voice to be heard, for example, in imaging, for which the standards do not take into account discussions with consumers and shared decision making. There is a role for the convening function to act for consumer participation. Huff acknowledged that is a difficult issue. Consumers should contribute via SDOs. Kelly Hall said that the topic deserves more deliberation. Advance directives cannot be incorporated into records. Who will have that voice? Malec explained that the task force members did deliberate on that issue. Before a project is chartered, all key stakeholders should have a voice. The importance of consumer involvement may vary across projects. In reality the participants who show up and contribute will drive the process. He offered to amend a recommendation to incorporate consumer participation.

Nancy Orvis said that the S&I Framework could keep its name and declare that its focus is now a convening function and will assure appropriate key stakeholder involvement.

Ross declared his approval of a convening function. Regarding prioritization, what about standards maturity and the latency between the identification of a need for a standard and development time? Malec explained the proposed three tests for priorities, the third one being the high likelihood of success, such as the ability to produce a standard within the necessary time. With regard to maintaining a roadmap as a potential convening function, Malec opined that a roadmap is a HITPC function. Kelly Hall said that consumers are not always well represented in policy.

Wiesenthal commented on the timing and latency of standards development: Is there room for a national body to coordinate and manage the latency of health care standards (similar to a National Library of Medicine) and to offer a place to test implementation where no real damage can be done? Such a body would coordinate cycle releases. Huff said that regarding ISO, nations have different needs. He and Malec acknowledged that the task force did not consider such a function, although they agreed that some coordination at the national level is needed. Vice Chairperson John Halamka said that it may be something to work on in the future. Noting that the comments on the S&I recommendations were mostly positive, he asked whether there were objections to forwarding the transmittal letter and recommendations slides to ONC. Rishel asked about accommodating Wiesenthal's suggestion. Malec suggested a supplemental transmittal letter with that recommendation. Steve Posnack, ONC, asked them to amend the recommendations prior to forwarding the letter to ONC. Jamie Ferguson observed that Wiesenthal's concern is not a new problem; nothing in the recommendations would change that situation. He said that the Semantic Standards Workgroup will mention that concern in its response to the Roadmap. Posnack said that the concern could be highlighted in the cover letter. Huff opined that

although it may be an important function for ONC, it is not necessarily one for S&I. Malec suggested adding a request for ONC to coordinate standards calendars with international SDOs. Wiesenthal indicated that he was advocating for something more such as consensus positions. Malec said that he would accept a friendly amendment for Rishel and Wiesenthal to draft a recommendation to that effect. Halamka declared acceptance of the recommendations of the S&I Task Force.

> **Action #2: The recommendations of the S&I Task Force were accepted without stated opposition with an additional recommendation that Rishel and Wiesenthal will draft on coordination and management of health care standards.**

Public Comment: None

Interoperability Roadmap – Progress Update

Four workgroups had been assigned specific sections of the Roadmap. Each reported. The Implementation, Certification and Testing Workgroup Co-chairpersons Liz Johnson and Cris Ross reported initial findings on section I1 – Testing Tools:

- CCDA Simplification has occurred between Release 1 and Release 2. See additional detail in appendix slides.
- Practical, effective, industry-run tools are needed for post-certification testing in support of interoperability, and evolution of vocabularies, technologies and processes between regulatory cycles.
- Regular use of testing tools needs further definition
- Explore potential for deeming rather than certification for improved efficiency where services are already in place and widely used (e.g. ePrescribing)

They reported that the workgroup will also make recommendations on constraining the CCDA.

Content Standards Workgroup Chairperson Wiesenthal and Co-chairperson Rich Elmore presented a list of key concepts on section J:

- Need for consistency in data formats and semantics
- Use of SDOs to develop, curate and maintain standards and create implementation specifications and profiles; and need for ongoing collaboration among SDOs
- Improve consistency in the implementation of Consolidated CDA through further guidance or constraints
- Extension of standards to promote exchange across the care continuum, including new sources of patient generated health data, device/sensor, environmental and other big data
- Agreement on a core standardized common clinical data set that is extensible and consistently shared during care transitions
- Need for agreement on use cases that each vocabulary supports
- Need to exchange information in a more granular form, such as FHIR
- Many of the initiatives listed including FHIR, CIMI, DAF, SDC and others (full feedback on this next month).

They pointed out the need for greater specificity in defining goals and actions, in consideration of the constraints of policy, privacy and security. They asked that the Roadmap be specific on how the standards support prioritized use cases for each wave of interoperability. There must be laser focus on achieving national scale with selected standards including:

- Multi-year cycle time for standards to be absorbed nationally
- Broad group of stakeholders that need time to respond to changes
- Use all available levers to see it through nationally, encouraging aligned adoption of specific named standards

- Assure that all federal payers are aligned with common core of standards and incentivize commercial payers to follow

Regarding categories of standards, the conflation of concepts should be logically separated from the highest level down and should be reorganized as: semantics, content and context; vocabularies, dictionary and code sets; and format and structure. Finally, they explained the problem of incompatibilities with research standards.

In response to a question from Rishel, they assured him that the workgroup does not wish to stifle innovation; the members do want to stifle scattered, random efforts. They recognize that different agencies have different needs and will push specific standards.

Semantic Standards Workgroup Co-chairperson Jamie Ferguson presented 19 preliminary comments organized under four categories:

Additional focus areas needed:

1. Need a shared understanding of the importance of information models and terminology bindings
2. Need agreement on highly granular information models bound to terminologies for information exchange
3. Data standards e.g. for performance or quality measures should reflect the semantics actually implemented in EHR systems
4. Need attention to challenges of data aggregation , for example for resolving duplicates, when data is assembled from multiple sources
5. It is critically important for data provenance to be workable and practical for semantic interoperability.
6. Reject usefulness of National Information Exchange Model (NIEM) related to healthcare interoperability

Things missing or misconstrued:

7. Need to support semantic web standards including OWL and RDF
8. Recommend minimizing mapping between different standards because mapping is imprecise
9. Support the use of interface terminologies that allow accurate and precise use of target standards
10. Need to support semantic interoperability by at multiple mechanisms, including:
    a) Data exchange - standards for moving copies of data between entities
    b) Access to data at its source – need shared access to patient centered data sources
    c) Combinations of a and b

Clarifications needed:

12. Need a clear plan for achieving the objectives laid out in the Roadmap
13. Need clarity about how to achieve coordinated governance of semantic standards
14. The reference to “technical architecture” is too vague (p. 84, Table 10, J2)
15. The reference to “translation and adapter services” is unclear (p. 85, Table 10, J4)
16. Common data elements are not necessarily standards and a definition needs to be developed, preferable based upon a very efficient implementation of ISO 11179
17. The common clinical data set from the roadmap needs more specificity, needs to be vetted broadly, and to be harmonized with other common clinical data sets

ONC coordination with SDOs needed:

18. Need ONC to work more closely with (and within) accredited SDOs
19. Need closer coordination of US semantic standards with international standards organizations (e.g., via the Joint Initiative Council on SDO Global Health Informatics Standardization)

McCallie asked about discussing RDF off line.

Baker asked about slide #6 (11), wondering whether the workgroup had discussed sematic interoperability to support CDS. Ferguson indicated that it was discussed in that a common data model and API are important for CDS.

Kelly Hall asked about PGHD and the need for consumer taxonomy. Ferguson said that the need is covered in the interface recommendation. A consumer taxonomy in another hierarchy would not be helpful.

Nancy Orvis asked about interface terminologies. Given the difficulty of differentiating sematic and content standards, she requested examples. Ferguson responded with the example of NLM synonyms for SNOMED. Orvis said that it is difficult to label data when moving out of one system into another. Ferguson said that the workgroup agreed to avoid reference to one-to-one mapping. Data capturing terminology is a synonym for interface terminology. He agreed to add an explanation to the draft recommendations.

Rishel talked about synonyms. Since physicians have difficulty communicating across specialties, the focus on synonyms must be carefully considered. McCallie said that it is important to preserve what the physician captured even if it is mapped to something else: preserve causality.

Transport and Security Standards Workgroup Chairperson Dixie Baker and Co-chairperson Lisa Gallagher reported on the assigned sections. Baker presented section E summary: cybersecurity 1a: What should the federal government (specifically) focus on first to move towards a uniform approach to enforcing cybersecurity in health care (keeping HIPAA and CEHRT Rules in mind and possible new cybersecurity legislation)? DRAFT Response:

- The Transport and Security Standards Workgroup (TSS WG) recommends that ONC partner with NIST, OCR, other federal agencies, and industry stakeholders in several ways to address a uniform approach to enforcing cybersecurity in health care.
- First, ONC should work to advance a consistent trust framework across the health IT ecosystem.
- Second, ONC should endorse a set of appropriate baseline security controls that are uniformly applied to all health IT technologies that enter the ecosystem.
- Third, ONC should work with industry to accommodate a diversity of emerging health IT technologies across infrastructures within the health IT ecosystem. Health IT infrastructures must be flexible, in that they should permit any certified health IT solution to operate within the ecosystem.
- Fourth, ONC should provide guidance on proper governance in cybersecurity, which is essential for building trust and security throughout the ecosystem. Finally, the ONC should bring together federal, state, and industry stakeholders to address the goal of reducing variations in cybersecurity enforcement.

Cybersecurity1b: Are there frameworks, methodologies, incentive programs, etc. that the health care industry has not, but should, consider? DRAFT Response:

- Trust is integral in building a secure health IT ecosystem. The National Strategy for Trusted Identities in Cyberspace (NSTIC) Trustmark, PCI, and ISO should be considered as possible frameworks for establishing electronic trust among healthcare organizations across the Internet.
- Cybersecurity needs to be considered for both enterprises and for interconnections among enterprises.
- The health care industry needs a minimum set of standards and metrics for measuring the strength of security protections. A number of minimum standard sets exist and can be drawn from. These include, but may not be limited to, OCR's minimum standards for control areas, the CAB-forum Baseline Requirements, and the questions asked by cybersecurity insurance companies and financial auditors.

- Additionally, the existing security control frameworks (including NIST's cybersecurity framework) should be considered for alignment and guidance when gaps occur.

Encryption: Are there other gaps (aside from lack of policies and guidance for implementing encryption) in technology and standards for encryption? DRAFT Response:

- ONC should work with OCR, other federal partners, and industry stakeholders to address the following three issues related to technology and standards for encryption.
- First, ONC should provide guidance on encryption key lifecycle management.
- Second, ONC should provide guidance on a method for encryption key escrow recovery.
- Finally, ONC should publish guidance on key oversight and authorization, addressing the people or entities that maintain access to encryption keys.
- ONC should also consider providing guidance on a minimum set of encryption requirements for health IT (i.e., medical devices, systems, and software) used to store and access protected health information.

Discussion

McCallie asked about a consistent trust framework across the ecosystem. Baker said that it refers to a baseline set of policies to share across nodes and the enforcement of baseline policy. Gallagher said that NSTIC Trust Mark and other frameworks are emerging. Baker pointed out that variation in state laws prevents a uniform system. In response to McCallie's opinion that to date NSTIC has produced nothing, Gallagher said that a pilot is underway. She expects the findings to be helpful. White asked whether ultra-large scale systems had been considered. Baker assured him that they had.

Rishel observed that a bunch of ideas can sound good until you have to think of them together. Regarding a trust framework and Malec's and Huff's recommendations on testing applications before standards become standards, he said that the requirements for federal agencies and HIPAA are so different that interoperability may be impossible. Baker agreed that trust agreements will be difficult. But a common way to communicate and the identification of the difficulties will make them less difficult.

Interoperability Roadmap – Framework Review

Halamka commented on the importance and brilliance of the up-coming presentation. Architecture, Services, and APIs Workgroup Co-chairpersons Arien Malec and David McCallie showed slides to remind members of the workgroup's charge to:

- Define architectural patterns sufficient for an ecosystem of nationwide scale information sharing and modular applications serving patients, providers, provider-organizations, and researchers
- In close coordination with sister groups from the HIT Policy Committee, explore technology policy to promote the adoption and use of enabling technology consistent with the architectural patterns
- Define and make recommendations on standards, implementation guidance and certification criteria consistent with architectural patterns
- Define and make recommendations on incremental progress towards proposed architectural patterns consistent with ONC roadmap and strategy

Malec showed slides that depicted the recommended architecture applied to the health care hourglass concept and described how it would work. McCallie went on to show more slides and give an orchestration example of pluggable apps. Malec explained that the workgroup deliberated on the proposed Interoperability Roadmap and concluded that the hourglass model provides a strong approach for rebalancing and a framework for an interoperability roadmap. Next, slides specific to the Roadmap recommendations were reviewed:

- To create greatest modularity, move towards parsimony of Transport and Security (HTTPS + OAuth2/OIDC), Content (Profiled FHIR), and Common Orchestrations
- Adopt a deliberate policy of "rebalancing" the standards portfolio towards parsimony Allow sufficient time to develop, adopt and use to allow for success during the rebalancing period
- (Avoid use of "SOA" and "REST"– too generic and confusing)

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- Create a glide-path to Core Composables and Orchestration Patterns by: Supporting SDO and public-private (e.g., Argonaut, DAF) work to define core composable API services and profiles ("Core") Support SDO and public-private work to define orchestrations and related security components for SMART/mHealth Apps
- Support future work to define other key high value orchestrations and security components (e.g., Peer to Peer record access, Remote CDS, Pub Sub)
- Support priority use-cases work (e.g., CDS, PDMP, SDC, etc.) to be implemented in terms of Core + Orchestration Patterns
- Reduce friction and distraction to adopters and implementers by minimizing certification requirements overall to allow ample time to pilot, adopt and refine Core and Orchestrations*; e*nsuring that government incentives can be met using the newer approaches, even if not formally adopted into Certified HIT; continuing to support production adopted standards not based on Core (e.g. C-CDA, XCA/XCPD, etc.) while minimizing changes and new uses*; and a*voiding endorsing new standards that are not based on Core, and seek alternatives that are based on Core (e.g., HPD+, CSD, HIEM)

2018-2020

- Refine and extend core composable services, profiles, and orchestration patterns
- Expand the number of piloted use-cases based on core
- Address needs for national-scale services such as MPI, RLS, Directories, etc.
- As Data Sharing Networks emerge, address needs for network-bridging services
- Consider mature APIs, orchestrations, and use-cases as candidates for addition to Certified HIT
- Begin transition from non-Core/Orchestration standards and APIs

2021-2024

- Continue as above
- Address complex data profiles that require more robust data models (CIMI) as may be needed for the Learning Healthcare System
- Contemplate transition to new Core/Orchestrations

The presentation concluded with a slide on examples.

Discussion

Halamka said that the presentation would have been informative to congress, some of whose members have said some peculiar things recently about the Roadmap. These are actionable steps. White noted the progress in the year since the release of the JASON Report. Rishel joined others in commenting on the brilliance of the recommendations, which contain specificity unprecedented in FACA work. He was pleased to hear that Josh Mandel was a major contributor. This is a much better model for integration of consumer applications into a national network.

Baker said that OAuth2 and Open ID Connect profile do not address authentication, auditing and accounting of disclosures. Ross talked about private sector actions. He noted that the three largest vendors were represented on the workgroup. There is speculation about vendors putting up barriers to interoperating: How would your companies receive this? Is it congruent with a competitive environment? Malec acknowledged that in the beginning more interests were represented, but some members dropped out. Those who continued to participate said that this makes sense and we shall do

it. It solves many business problems. Vendors want to do it regardless of ONC. McCallie said that it is an example of competitive forces benefiting all. "We want to do something that works well."

Ross commented that to be able to purchase and implement such architecture would be powerful. Halamka said that he hopes this can be overlaid with the forthcoming certification NPRM, which hopefully will not be overly prescriptive.

Anne Castro talked about the consumer standpoint run against long term care. McCallie said these patterns will work for consumer apps. Malec mentioned projects that include consumer access to records.

Kelly Hall referred to computable consent and wondered about acceleration of a privacy consent framework that could work. Jodi Daniel said that Lucia Savage, ONC's chief privacy officer, is in charge of that project. Malec said that consumers are familiar with such a framework per Facebook permissions. Kelly Hall said that policy recommendations could help to move it forward. Daniel said that it is fortunate that policy and standards are developing in tandem. Halamka called for the press to note this accomplishment.

Quality Improvement Standards Evolution

Julia Skapik, ONC, said that all 93 eCQMs are to be published in HQMF R2.1. The current measure authoring tool release packages include HQMF R2.1 file validation. The value sets are updated to include the latest 2014-2015 code systems and corrections to incorporate feedback from users and changes to other standards. All measures were pre-tested using BONNIE testing tool, which creates QRDA libraries. HQMF R2.1 is much more tractable than HQMF R1. The intent is to enable automated machine importing. Regarding QI standards mismatch, within the Clinical Quality Framework, CDS and eCQM are closely related, share many common requirements, and both support improving health care quality. CDS recommends actions and eCQM measures impact or outcomes. The standards used for the electronic representation of CDS and eCQM were not developed in consideration of each other, and use different approaches to patient data and computable expression logic. Adhering to different standards places an additional implementation burden on vendors and providers with homegrown systems to build product-specific decision support to support quality measures. It is currently difficult to share logic between eCQMs and CDS rules. Shared standards will allow harmonization. She described several ballots. One was introduced in February 2015. Metadata is used to classify an information artifact to enable that artifact to be retrieved, used, or quantified. Prior to this approach, the Clinical Quality Improvement domain included several information models with a total of 18 different HL7 standards with metadata requirements. The Clinical Quality Metadata Conceptual Model brings together the requirements for many CQI standards and models and harmonizes them into a single conceptual model. A DSTU balloted January 2015 (awaiting publication) builds on functional requirements defined in the Harmonization of Health Quality Artifact Reasoning and Expression Logic. It leverages Computability achieved by HeD and measure author understanding (QDM Heritage). The focus of the high-level syntax is on authoring while providing a clear and automatic path to computable logic. Authors use CQL to produce libraries containing human readable yet precise logic. ELM XML documents contain machine-friendly rendering of the CQL logic. This is the intended mechanism for distribution of libraries. Implementation environments will either directly execute the ELM, or perform translation from ELM to their target environment language. She went on to describe other ballots. CQL-based HQMF Implementation Guide Ballot is in submission for May 2015. She talked about its pros and cons. An S&I coordination effort led to realization of an opportunity for common FHIR profiles across CQF and DAF. Discussion with the CIMI-HSPC team revealed further interest in coordination. The current approach is QI Core = common FHIR content for all three use cases with modifications or further constraints. Another ballot in submission for May 2015 builds upon an intermediate approach for CQL-based HQMF implementation guide. Other

work is underway such as pros QUICK and Quality FHIR profiles. QUICK is a UML-based logical model. QUICK and Quality FHIR profiles are to be balloted for DSTU in 2015.

Discussion

Eisenberg asked about coordination across value sets. Referring to slide #15, he observed that sexually active is interpreted in different ways. Understanding the phrase in addition to the word is important. He noted that the search function is difficult to navigate, and BONNIE needs conventions.

McCallie observed that this may not translate well to something vendors want to do. Although there may be standards, they were not much deployed. It is not meaningful to base something on existing standards if those standards were never used. Successful deployment experience is important. Regarding CDS and CQM, doctors do not want to be reminded of quality measures. To constrain their choices is better than an alert. It is better to push data to a place where rules can be executed. Skapik said that the goal is to have the functionality not necessarily the specific standards. Rules are not intended to be the only use of standards. The intent is to create building blocks so that eventually CDS can fire at non-physicians. Regarding knowledge and data, ONC and CMS have not committed to these tools. The concept is an editing and testing environment for community members. According to McCallie, the rule is usually the trivial part.

White said that there is interest and pressure to move knowledge into practice. McCallie said that his and Malec's architecture would do that.

Huff declared that it is good to bring groups together for a solution. The first step is a way to unambiguously define the data for rules. One hypothesized way is to share data in other languages. Logic can execute in the cloud. Let people do it in different ways and then standardize the better approaches. McCallie said that the approval of information models by the respective medical societies is key. First, get the data. Decouple the data and the rules.

Public Comment: None

SUMMARY OF ACTION ITEMS:

Action item #1: The summaries of the January and February 2015 meetings were accepted as circulated.

Action #2: The recommendations of the S&I Task Force were accepted without stated opposition with an additional recommendation that Rishel and Wiesenthal will draft on coordination and management of health care standards.

Meeting Materials:

- Agenda
- Summary of January 2015 meeting
- Summary of February 2015 meeting
- Meeting presentation slides and reports
- S & I draft transmittal letter

Meeting Attendance							
Name	03/18/15	01/27/15	12/10/14	11/18/14	10/15/14	09/10/14	08/20/14
Andrew Wiesenthal	X	X	X				X
Anne Castro	X	X	X	X		X	

Anne LeMaistre	X	X	X	X			X
Arien Malec	X	X	X	X		X	X
C. Martin Harris	X	X	X	X		X	
Charles H. Romine	X	X					
Christopher Ross	X	X				X	X
David McCallie, Jr.	X	X	X	X		X	X
Dixie B. Baker	X	X	X	X		X	X
Elizabeth Johnson	X	X	X	X		X	X
Eric Rose	X	X	X	X		X	X
Floyd Eisenberg	X	X	X	X			
James Ferguson	X	X	X			X	X
Jeremy Delinsky	X	X		X			
John Halamka	X	X	X	X		X	X
John F. Derr	X	X	X	X		X	X
Jon White	X	X	X				
Jonathan B. Perlin	X						X
Keith J. Figlioli	X		X			X	
Kim Nolen	X	X	X	X		X	X
Leslie Kelly Hall	X	X	X	X		X	X
Lisa Gallagher	X	X	X	X		X	X
Lorraine Doo	X	X	X	X		X	X
Nancy J. Orvis	X	X				X	
Rebecca D. Kush		X		X		X	X
Sharon F. Terry						X	X
Stanley M. Huff	X	X	X	X		X	X
Steve Brown			X			X	
Wes Rishel	X	X	X	X			X
Total Attendees	**26**	**25**	**22**	**20**	**1**	**22**	**21**