



HIT Policy Committee DRAFT Summary of the September 3, 2014 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 Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment (limited to 3 minutes per person), and that a transcript will be posted on the ONC website. After introductions, she instructed members to identify themselves for the transcript before speaking.

Remarks

National Coordinator and HITPC Chairperson Karen DeSalvo referred to the August 29 CMS flexibility rule, saying that there is an opportunity for discussion under the CMS report agenda item. The HITPC and the HITSC will meet jointly in October, at which time the latest version of the Interoperability Road Map will be introduced and feedback solicited. The wiki is still open at www.hit.gov and input on the Road Map is encouraged. In winter 2014, the Road Map will be published for public comment. She thanked everyone for the work on interoperability.

Review of Agenda

Vice Chairperson Paul Tang referred to each of the items on the agenda, which was distributed by e-mail prior to the meeting. No additions to the agenda were requested. He asked for and received a motion to approve the summary of the August meeting, saying that several corrections had been submitted to Consolazio. A motion was made and seconded to approve the summary report as corrected. The motion was approved unanimously by voice vote.

Action item #1: The summary of the August 2014 HITPC meeting was approved unanimously by voice vote.

Policy Update - FACA Work Plan

DeSalvo showed a slide that delineated a timeline for major activities. She repeated that the JASON Task Force and the Governance Subgroup were well underway as part of the work plan. They will eventually be merged into the new Interoperability Workgroup. A joint meeting of the HIT FACAs will convene October 15. ONC staff is refreshing the federal HIT Strategic Plan and the work on interoperability will flow back into the Strategic Plan. The FACAs will have opportunity to comment on the plan in December. She emphasized that the work on interoperability is a public private partnership. The slide is intended to show a partnership with the FACAs. Another slide projected dates for committee and workgroup deliverables. Members had no questions or comments.

JASON Report Draft Recommendations

The order of agenda items was changed because the data review presenters were late. HITPC-HITSC JASON Task Force (JTF) Co-chairperson Micky Tripathi showed slides to review the charge and process. Co-chairperson David McCallie summarized that the JASON report concludes that Stages 1 and 2 have not achieved meaningful interoperability “in any practical sense” for clinical care, research, or patient access due to the lack of a comprehensive nationwide architecture for health information exchange. The report points to the lack of an architecture supporting standardized APIs, as well as EHR vendor technology and business practices, as structural impediments to achieving interoperability. It recommends an urgent focus on creating a “unifying software architecture” to “migrate” data from these legacy systems to a new centrally orchestrated architecture to better serve clinical care, research, and patient uses. This architecture would be based on the use of “public” APIs for access to clinical documents and discrete data from EHRs, coupled with enablement of increased consumer control of how data are used. Tripathi pointed out that the JASON process does not allow engagement with JASON authors. He said that although the JTF tried to reasonably infer what is not clear, misinterpretations may have occurred. The JASON report covers more ground than listed in its specific recommendations. Likewise, the review covers some areas that are not necessarily listed in the report’s formal recommendations. Investigation for the report was conducted in early 2013, but much has changed in the industry in the last 18 months, such as market deployment of Direct-enabled functions, and beginning of Stage 2 attestations using CCDA. JASON explicitly focused on high-level technical architecture considerations. Other challenges to interoperability, such as legal, policy, federation, jurisdiction, and business models, were not in scope of the report. JASON recommended encryption of data and transactions as a critical security feature, but did not propose any new technologies or measures than are already in use today. JASON refers to the need for resolving patient identities across implementations as a key barrier to data aggregation. However, no new technologies or approaches were proposed. Preliminary JTF recommendations were presented on these topics: current state of HIE, architecture, core clinical and financial systems, APIs, consumer access and control of data, research and HIE, and accelerating interoperability.

The co-chairs presented slides stating background, preliminary recommendations, and rationale for each topic. The preliminary recommendations are as follows:

Current state

- ONC should take into account the current state of interoperability as well as current trends before incorporating JASON findings in any decisions on HIE plans, policies, and programs. We believe that JASON did not adequately characterize the progress made in interoperability, though we agree that there is considerable room for improvement as will be outlined in these recommendations.

Architecture

- The industry should accelerate the current path of loosely coupled architecture based on iteratively proven, standards-based APIs and data model standards that support both document and discrete data access
- ONC should help to shape and accelerate this process by assisting with convening industry stakeholders to define the minimum components necessary to loosely couple market-based implementations
- ONC should not attempt to impose detailed architectures on the market
- ONC should help to shape and accelerate this process by aligning and leveraging federal infrastructure and programs to support rapid development and adoption of such minimal components, once they are defined

Core clinical and financial systems

- The industry should accelerate the parallel paths of improving current document-level encoding standards (CCDA) while introducing discrete data access APIs and associated data element standards in EHRs
- ONC should immediately seek guidance from the HITSC on: the maturity of development of standards to enable document- and data-level APIs; the foundational API requirements for document- and data-level access that can reasonably be included in 2017 Edition Certification to help to launch an ecosystem for more robust API development and implementation in the future. ONC certification should leverage standards-based APIs where possible to expand opportunities for modular certification

API

- ONC and the industry should support and pursue the JASON call for development and adoption of published, standards-based APIs and data models for documents and atomic data in a framework of legal, policy, and business rules of the road
- To this end, CCDA refinement (document-encoding standards) and FHIR (for data-level standards and standards-based APIs) should be targeted and accelerated through ONC contracting with existing initiatives and SDOs for development of tight specifications and implementation guides focused on high-value use cases and licensed for public use
- ONC should encourage rapid public/private experimentation and iterative improvement processes with these emerging APIs to ensure that they work as intended. These experiments should include uses targeting clinical care, research, and population data, as well as exposure to consumers via EHR portals.
- Standards development and certification should leverage existing industry and HITECH structures

Consumer access and control

- Patient-facing EHR functions should expose similar discrete-data APIs as discussed for clinical care and research needs. The Blue Button Plus (Pull) project offers a logical starting point by expanding the current use of FHIR and OAuth2 to include a richer set of APIs. Consider models that leverage the SMART Platform as an open specification for app developers to explore
- HHS (OCR) should help clarify the degree to which patients and consumers can control access and usage of their personal health data. Much confusion exists, even among HIT experts.

Research

- Standards-based, discrete data APIs to improve researchers' access to routine clinical data should be strongly supported through technical and policy development. Agree with JASON recommendation to convene the research community to identify use cases, technical requirements, alignment with existing data collection/analysis structures and processes, and legal/policy barriers and opportunities. Research community should participate in decisions about where structured APIs can best support research use cases. This should include representation from current initiatives where research is leveraging routine clinical data, such as Kaiser Permanente and i2b2
- Policy work to address the regulatory, governance, and business barriers to greater research access to routine clinical data should begin immediately, in parallel with API development
- Additional research and regulatory refinement will be necessary to balance the needs of the research community with the need to protect patient privacy.

Interoperability

- ONC and CMS should consider Stage 3 as one of many levers to promote advancement toward JASON goals, especially because the 2017 Edition Certification timetable does not appear to allow sufficient time for widespread adoption of the standards-based discrete data APIs at the core of the JASON architecture
- The federal government should align and leverage the many other means at its disposal to promote advancement of JASON goals.
- ONC should immediately assess and implement where possible streamlined approaches for incorporating new standards into federal certification. ONC should seek HITSC guidance on this topic.

Tripathi emphasized that the JTF has much remaining work. Following consideration of responses from the presentations to the HITPC and HITSC, the members will further specify the recommendations, and cross-reference them to the PCAST report and ONC Interoperability Road Map. Final action by the committees is scheduled for October 15.

Discussion

Many members prefaced their comments by saying that the presentation was exceptional in its clarity and comprehensiveness. Marc Probst said that he approved of the recommendations, but was skeptical of the industry's capability to carry them out. Industry's efforts over the past decades have not produced what needs to be done. How can the right level of industry efforts be obtained? What is the right role of government? He acknowledged that he believes in a strong role for government to drive change. Tripathi indicated that the JTF will try to consider that question. What is different now is the greater demand for interoperability, which has outstripped its availability. The role of government is to define loosely coupled architecture. McCallie reported that the JTF members talked about how to compensate if the bar is raised. It may be possible to change the time requirements. Industry representatives say that they cannot handle the JASON recommendations within the existing time frame. He referred to activity on FHIR and FHIR profiles, HL7 and the SMART platform. All of that work is industry driven and needs to be brought into focus and piloted. Rules on certification may need to be changed. Tripathi said that narrowing of the 2017 Edition may be possible. Probst cautioned against too much narrowing of the scope. Tang asked that precise recommendations for narrowing the scope of stage 3 be presented at the October meeting.

Paul Egerman informed them that he had chaired a PCAST report group some time ago. Its report was approved by the HITPC. He suggested that the JTF review his group's report and subsequent discussion. He pointed out that JASON's reference to legacy systems is pejorative. However, legacy systems are operational. A theory is being compared with an operational system. The former always appears better because it has not been tested and its limitations are not known. Tripathi assured Egerman that he had read his report and will use it to cross map and finalize the recommendations. McCallie explained that the task force focused on how to move with existing systems to improve interoperability. Egerman wondered why the JASON authors were not listed and were unavailable to respond to questions, a situation very different from the PCAST experience. McCallie responded that JASON authors are protected by anonymity in order to be able to be completely free and frank in their opinions. He said that an AHRQ go-between had been able to clarify some points. The key author participated in a panel August 7 on HIT convened by RWJ. But her comments were prohibited from attribution. Egerman opined that it is irresponsible to put forward a theory calling for such broad-ranging changes without the authors being available for questioning. He said that it would be advisable to insist that the author(s) come to a meeting. Noting the time, Tang told the members to be brief.

David Kotz asked about protections for consumers after their PHI leaves HIPAA-protected environments and about patients uploading their data to providers. Tripathi responded that once the patient is in control of the data, there is no policy. APIs in principle are bidirectional. Devin McGraw concurred that patients are responsible for the PHI in their control. They must self-educate. The FTC has rules for patient-facing apps. She mentioned a new rule in California extending medical privacy to information gathered from patient apps and said that Apple recently announced that it will prohibit the sale of data generated from HealthKit. Kotz declared that he has no confidence that app developers and service providers will behave or consumers will sufficiently self-educate. McCallie responded that the JTF discussed the need for work on certifying and managing apps. Tripathi suggested that there is some precedence in the way EHR systems are authorized by Surecripts to handle lab data.

Terry Cullen talked about her concern that vendors do not self-regulate well. She asked the JTF to look at it again. She observed that many interdependencies are involved and asked about a pathway to acknowledge interdependencies. Tripathi agreed with her concern. McCallie, saying that he represents vendors, suggested that FHIR would be a potential candidate standard to reduce the need for proprietary work.

David Lansky declared that he too is skeptical of the industry. He suggested that slide 34 be expanded pertaining to non-meaningful use avenues. Noting that JASON did not include quality measurement as a use case, he requested that an architecture that facilitates quality measures reporting be considered. Perhaps other Stage 3 requirements could be dropped to focus on interoperability and standardized APIs. McCallie said that data element profiles for quality measures would require much work to gain agreement on standard APIs.

Christine Bechtel announced that patients perceive a lack of choice. The current technology enables choice and transparency. Consumers today are more privacy savvy than previously. They should be viewed as adults and equal partners.

Neal Patterson said that the problem of the lack of a national ID system must be solved. The core use case should be persons with complex medical conditions who see many different providers. Stage 3 is the final opportunity for incentives so every effort should be made to get as much done as possible.

Charles Kennedy commented in regard to Probst's point that the economic driver and interests are different now. The economics of sharing data and the use cases are in their infancy. There is much to learn about using interoperability to take advantage of new incentives. McCallie said that one difference today is that FHIR is a candidate standard generating much interest. Tripathi stated that JASON does recognize the importance of the physician's narrative.

Gayle Harrell talked about privacy. PCAST was very detailed regarding metadata and privacy and putting the patient in control. JTF needs to deal with privacy. She said that she is concerned with governance and controlling bad players. Everyone needs to know where responsibility rests and who sets the consequences. How is exchange authorized? The HITPC must address these issues. A great investment of taxpayers' money is involved with interoperability being the main benefit. McCallie responded that although JASON calls for metadata tagging, the report is silent on who would pay for it. The report does not address what tags are or what they would do. The first edition of the report stated that consumers own their data; the statement was later retracted in favor of a statement on shared ownership. Clarity is needed. Tang said that although incentive payments end in Stage 3, penalties then kick in.

DeSalvo noted that both business drivers and consumer preferences have changed to drive greater demand for interoperability. There are much data that should be shared. Open APIs and more potential trading partners change the game and open up more privacy and security issues. This is an exciting time. Tang noted that the length of the discussion made it necessary to reduce the time allocated for lunch.

Data Review

Elise Anthony, ONC, and Elizabeth Myers, CMS, showed slides outlining the monthly CMS status report. Through July, active registrations total 487,866 and \$24,873,262,183 has been paid in incentives. Over 92% of EHRs have received an EHR incentive payment for either meaningful use or AIU. 90% of EPs have registered for the Medicare or Medicaid EHR Incentive Programs. 75% of Medicare and Medicaid EPs have made a financial commitment to implementing an EHR. Over 400,000 Medicare and Medicaid EPs have received an EHR incentive payment. 8024 EPs attested for the 2014 reporting year of which 1479 are new participants and 3152 attested to Stage 2. 436 EHRs have attested for the 2014 reporting year. 136 are new participants and 143 attested to Stage 2.

The final rule for CEHRT Flexibility Options in 2014 was published August 29, 2014, reflecting adoption of the ANPRM issued May 23 without modification. For providers scheduled to attest to Stage 1 in 2014, there are three options. The 2011 CEHRT consists of the 2013 definition Stage 1 objectives and 2013 CQMs. The combined 2011 and 2014 CEHRT option is 2013 definition Stage 1 objectives and 2013 CQMs; **or** 2014 definition Stage 1 objectives and 2014 CQMs. The third option is use of 2014 CEHRT which consists of 2014 definition Stage 1 objectives and 2014 CQMs. Providers scheduled to attest to Stage 2 in 2014 also have three options. The first option is the 2011 CEHRT with the 2013 definition Stage 1 objectives and 2013 CQMs. The second option is combined 2011 and 2014 CEHRT with 2013 definition Stage 1 objectives and 2013 CQMs; **or** 2014 definition Stage 1 objectives and 2014 CQMs; **or** 2014 definition Stage 2 objectives and 2014 CQMs. The third option is 2014 CEHRT, consisting of 2014 definition Stage 2 objectives and 2014 CQMs; **or** 2014 definition Stage 1 objectives and 2014 CQMs. The final rule delineates the steps for attestation, which Myers described. CMS is designing resources for users in determining which option to select. She said that the most frequently voiced comment was based on misunderstandings concerned the time of attestation. A provider can attest anytime from the end of the selected reporting period through the end of the open attestation period for the year. There is not a requirement that if a provider selects the first quarter, the provider must attest within 60 days of the close of the first quarter. A provider can choose the first quarter and attest up through February 2015.

Q and A

Responding to a question about anticipated impact, Myers said that she expects more providers will be able to attest because they will have the technology in time to attest. The rule will affect providers that otherwise would not have the opportunity to participate. The attestation numbers will be better. She declined to quantify her expectation. In response to a comment that other potential changes in the rule would have a greater impact; Anthony explained that the change gives providers the opportunity to stay on track. Myers said that the rule effectively means that if a provider has certified technology, the provider can attest to meaningful.

Cullen asked about unintended consequences, a quantified goal, and the impact on Stage 3. Staff responded that they do not expect an impact on providers that were progressing on target. Although they attempted to make some preliminary estimates, they concluded that it was not reasonable to benchmark. The pathway to Stage 3 is still in place although possibly 3 months to 2015 could be lost.

Public Comment

Mari Savickis, AMA, reported that she has been crunching numbers from these reports all summer and although she could not recall exactly the numbers from May or June, she questioned the accuracy of some of the CMS data. According to her calculations, 50% of EPs are at risk of dropping out or not participating. There are many questions and contingencies that need to be factored in. It is all rather

confusing. Hardship exemptions should also be taken into account. She offered to discuss her conclusions off-line.

Draft Governance Framework

Tang said that the Governance Subgroup and the JTF should coordinate their work since there are several overlapping topics. Interoperability and HIE Workgroup Governance Subgroup Co-chairperson Carol Robinson showed slides. She emphasized that much work remains. The subgroup is charged to identify the substance, scope, and process ONC should use to implement an approach to establish the rules of the road necessary for information to flow efficiently across networks. This approach should address the key problems that slow trust and exchange across diverse entities and networks that provide exchange services including: misaligned or inconsistent security policies and practices; privacy policies and practices and operations and business; and inconsistent policies and technical agendas of governance bodies at the local, state and regional levels. Another slide detailed the ONC Ten Year Interoperability Plan's vision at three intervals. Robinson described the process that the subgroup used to arrive at its output, in particular the results of two invited listening sessions. The subgroup focused on identifying the appropriate processes and approaches that ONC should advance to establish the rules of the road: set goals and principles for a governance structure; agree on set of problems to solve and the process needed to solve problems; and map the structure and process recommendations to the Interoperability Road Map (which is being written) to create recommendations for incremental development of governance content. Governance problems that impede interoperability were delineated as follows:

- Misaligned and inconsistent security policies and practices—encryption, Level of Assurance for ID proofing, methods for authentication, authorization, etc.
- Misaligned and inconsistent privacy policies and practices— consent, meaningful choice, data use and query response policies, etc.
- Misaligned and inconsistent operational/business policies and practices— variation of user fees, patient matching methods, duplicate records resolution, multiple trust bundles, variation in accreditation costs and rigor, disclosure audit requirements, etc.
- Multiple governance bodies at local, state and regional levels with incompatible and/or inconsistent policy and technical agendas
- Questions about liability when information moves from one system to another
- Multiple technical standards development efforts and deeming organizations are operating without an industry portfolio approach

Robinson went on. She described discussion points for three use cases: query, directed and consumer mediated. Again acknowledging that the subgroup has considerable work to do before presenting recommendations for action by the HITPC and HITSC on October 15, she referred to a process of identification of topics and questions, prioritization and selection of topics and questions, and development of guidance for the selected topics. To date, sample questions are:

- Should HIE governance be segmented by use cases, by transport standards, or by something else?
- Are there aspects of HIE governance that should be centralized at a national level?
- Are there aspects of HIE governance that should be left to States?
- Are there aspects of HIE that would be set back by a system or systems of governance?
- What is the appropriate private/public mix for each system of governance?
- What should ONC do (and/or not do)?
- How should the recommendations for a Governance Framework map to existing efforts?
- Is this the right time for a Governance Framework to be adopted?

She closed with a reference to elephant architecture and repeated that much work is yet to be done.

Discussion

Bechtel referred to the overlap between the Governance Subgroup and JTF and told Robinson to be very clear about the definition of governance. Troy Seagondollar pointed out that the banking industry has applications that allow consumers to access and use many other sources of information and wondered whether the subgroup had examined the applicability of those applications. Robinson reminded him that a representative of NACHA had reported at a listening session. Debit and credit transaction are relatively constrained. To go deeper is out of scope for the subgroup, but could be the next step for some other body.

Harrell said that state privacy and security requirements vary. She wants recommendations to establish similar levels of assurance across states. Technical standards as well as governance requirements must be considered. The two groups should meet jointly to delineate boundaries. With true interoperability, the need to establish responsibility increases. Which federal agency bears responsibility? What are the basics to project PHI that people cannot do for themselves? Authentication is the main concern. Robinson said that pollination between the two groups may contribute to a richer environment for the next steps.

Tang said that the demand for interoperability has increased and there are both technical and non-technical gaps. Regarding the data model and the data element model and the need for information to flow across entities, there may be policy components that various types of entities can use. It may not be possible to design a governance model to apply to every entity. There may be rules of engagement (problems, use cases) and rules of the road that work together. He asked Robinson for more concrete and substantive recommendations, saying that principles of governance had been delineated previously. Robinson said that she is optimistic the subgroup can produce recommendations.

Cullen opined that the scope should be constrained to the governance necessary to meet the 3-year goal. Some of the topics listed overlap with work done by other groups. The scope was unintentionally expanded due to the presentations at the listening sessions. Robinson responded that there is already a definition of governance. It may be broader than what can currently be achieved. The subgroup members are interested in what is causing the many pain points. She indicated that she wants to avoid scoping too narrowly.

Egerman talked about a need to better understand what governance is: What about enforcement? Governance cannot be viewed independently from technical concerns. If the rules of the road were more like guidelines without an enforcement entity, that approach should impact on the technical approach. So the JASON recommendations need to be viewed through a lens of understanding what governance will be applied.

Probst referred to data standards and the need to address who will develop and set standards over the next few years. Robinson talked about the federal highway act that standardized construction of federal highways, but did not regulate state and county roads. Safety, security and standards are a part of governance. She acknowledged that scope is the greatest challenge for the subgroup.

Jodi Daniel reported that ONC's concept of governance is the establishment of oversight of a common set of behaviors, policies and standards that enable exchange of electronic health information among a set of participants. ONC has the statutory authority to establish a governance mechanism. The mechanisms could include processes and determining participants. What are the overarching rules of engagement? How do we get consent for some of these things? What is the role of the federal government? She said that she realized the subgroup will not solve all of the problems in exchange.

Seagondollar talked about the lack of a national universal ID being a fundamental issue for authorization and authentication. The JTF has determined that there are no governance guidelines on the technical aspects and the Governance Subgroup members are saying they do not know where to turn for guidance. He asked CMS where the guidance is. Who makes the regulation? Daniel said that ONC does have the authority to regulate. She is seeking recommendations on whether and how to use that authority.

Harrell referred to a tipping point for interoperability. The public is waiting to hear about responsibility. Bad things generate laws. There must be consequences for violating rules of the road. If ONC has the authority, it should use it. Robinson said that some states are attacking governance strongly. She predicted that the tipping pain point will become more acute with new payment models, meaningful use penalties and Medicaid transformation at the state level. State legislatures will begin to pass laws thereby contributing to a patchwork of regulation. Harrell said that law making will hamper rather than promote interoperability.

Public Comment

Holt Anderson, NCHICA and Convener of the Governance and Policy Framework Task Force of the Learning Health Community for the Learning Health System, said that he had been involved with the development of the health exchange. He reported that his group has scheduled its first meeting for October 27. Everyone is beginning to embrace the concept of a learning health system. Stakeholders need to learn how to coordinate these governance efforts into a unified effort in order to move toward a learning health system.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the August 2014 HITPC meeting was approved unanimously with submitted corrections by voice vote.

Meeting Materials

- Agenda
- Summary of August 2014 meeting
- Presentations and reports slides

Meeting Attendance								
Name	09/03/14	08/06/14	07/08/14	06/10/14	05/08/14	05/07/14	05/06/14	04/09/14
Alicia Staley		X	X				X	X
Aury Nagy	X							
Charles Kennedy	X	X	X				X	X
Chesley Richards	X	X					X	
Christine Bechtel	X	X	X	X			X	X
Christoph U. Lehmann		X		X				
David Kotz	X	X		X			X	X

Name	09/03/14	08/06/14	07/08/14	06/10/14	05/08/14	05/07/14	05/06/14	04/09/14
David Lansky	X	X	X	X			X	X
David W Bates			X	X			X	
Deven McGraw	X	X		X			X	X
Devin Mann			X				X	
Gayle B. Harrell	X	X	X	X			X	
Joshua M. Sharfstein		X					X	X
Karen Desalvo	X	X	X	X			X	X
Kim Schofield	X	X	X	X				
Madhulika Agarwal		X					X	X
Marc Probst	X	X	X	X		X	X	X
Neal Patterson	X	X	X	X				
Patrick Conway								
Paul Egerman	X	X	X	X	X	X	X	X
Paul Tang	X	X	X	X	X	X	X	X
Scott Gottlieb			X	X				X
Thomas W. Greig	X	X	X	X			X	X
Troy Seagondollar	X	X	X				X	X
Total Attendees	16	19	16	15	2	3	19	17