HIT Standards Committee
DRAFT
Summary of the September 10, 2014 Virtual 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. After calling the roll, she instructed members to identify themselves for the transcript before speaking.

Opening Remarks

Chairperson Jacob Reider, ONC, reminded everyone that the purview of the FACAs goes beyond meaningful use. The HITSC is charged to advise on standards and certification criteria for health information technology. He announced that ONC published in today's Federal Register the final rule for the second release of the 2014 standards and certification criteria. The final rule is flexible and represents gradual rulemaking as expressing future intent.

Remarks and Review of Agenda

HITSC Vice Chairperson John Halamka talked about each item on the agenda, saying that they were remarkably inter-related. Referring to Reider's point that this is not the meaningful use committee, he acknowledged that the challenge is doing what is right for interoperability while paying attention to the meaningful use timelines and trying to align the two. He noted that as of this morning the agenda was expanded to allow time for staff to brief the members on the content of the final rule announced by Reider. He asked whether there were corrections or amendments to the summary of the August meeting, which was distributed with the meeting materials. Hearing none, he declared the summary accepted.

Action item #1: The summary of the August 2014 HITSC meeting was accepted.

NwHIN Power Team – Query Recommendations

NwHIN Power Team Chairperson Dixie Baker began with a slide that stated the functional charge to the team: enable query functions within the context of HITECH EHR certification authority and building on market developments in directed and query exchange. She described the HITPC query recommendations and other background information pertaining to the charge. She described the query options considered for the 2017 Edition and the advantages and disadvantages of each: Data Access Framework (DAF) S&I Framework project, IHE Cross Community Access (XCA) Profile, Direct, and HL7 Fast Healthcare Interoperability Resources (FHIR). She explained that the need for certification criteria for the 2017 Edition is not well aligned with the long-range desire to move to HL7 FHIR as the standard for querying for documents and discrete data items. But assuming that query must be included in the 2017 Edition,

the team recommended a "least regret" approach to avoid compelling vendors to expend excessive time and effort on certification of a temporary approach. The specific recommendations were as follows:

- Recommend limiting scope of use cases for 2017 Edition to: query a named external health care organization (HCO) for a document containing a specific patient's data; respond to query with requested document, list of documents, or non-availability of document; and allow both synchronous and asynchronous queries
- For EHR Certification 2017 Edition, recommend including functional requirements as certification criteria, and allow vendors to provide documentation attesting to how their technology provides these functions. Focus primary efforts on "low regret" activities that are well aligned with moving the industry in the direction of broad use of RESTful, FHIR-based services, including services to support query for both documents and discrete data elements. Simple query of a known external entity for a document containing an identified patient's information could be achievable, for example, using existing EHR certification standards, emerging standards, or membership in a query network
- Certified EHR technology will have attested to having an automated capability that enables participation in the following query conversation, in either a requester or an external responder role: (Requester) generate and address to a trusted and known, external end point a query requesting a document containing clinical data for an identified patient; (External Responder) in response to a received query, return a list of available documents that contains the requested information; (External Responder) if the provider holds no information for the identified patient, return a response indicating that the requested data are unavailable; (Requester) From the list provided, select the identifier for the desired document; (External Responder) Return a structured, encoded document containing the requested clinical information.
- As high priority, low regret activity for the near term, recommend fast-tracking of improvements to Consolidated CDA Implementation Guide, as recommended by the Implementation Working Group and approved by the HITSC on August 20, 2014
    - Specific improvements are needed to facilitate query for, and selective retrieval of, a range of clinically useful CCDA documents, including but not limited to implementation specifications to support on demand retrieval of a simple current summary (problems, allergies/intolerances, current medications, recent labs, etc.), and specifications for a complete longitudinal summary, in addition to the current encounter-by-encounter documents
    - Recommend strong support of efforts to accelerate development of FHIR-based services and FHIR profiles, consistent with recommendations of the JASON Task Force

Discussion

Responding to a question about having something very specific FHIR-based in place for 2017, Baker said that the recommendations allow for FHIR, but do not require it. But insofar as the stage 3 NPRM is currently being written, there may not be sufficient time for a FHIR-based profile to meet the criteria for national standards readiness. NwHIN Power Team Co-chairperson David McCallie said that interchange occurs in the context not only of a particular standard at the edge but also in context of the networks that deal with governance, legal, contractual and licensing issues. Those issues are oftentimes just as complicated as the API issues. And to focus too excessively on a particular API detracts from the broader set of problems around the network activity.

Reider indicated that the recommendations were clear on what ONC should not do; he wondered about a recommendation for what ONC should do. Baker explained that the team had to assume a 2017 Edition requirement for query, given its charge. Without the HITPC's directive, the team might have recommended against a query requirement. So given the assumption that there must be a query requirement in the 2017 Edition, the recommendations are to focus on making FHIR ready as quickly as

possible. In the interim, given that assumption, the requirement should be functional rather than forcing vendors to implement something they must later tear out or redo.

Cris Ross referred to slide 11 and wondered about batch queries for population health or cohort management. McCallie said that the charge was specific to targeted patient query. The recommendations would not preclude supporting more powerful capabilities, such as query for multiple patients but not a population. The DAF includes queries to support population health, but that was beyond scope.

Stan Huff declared that he liked the recommendations. The development of FHIR profiles should be coordinated so that the results are interoperable. Competing FHIR profiles from different sources would not be helpful. FHIR could be ready by 2017 if work were concentrated where standards are most advanced. Baker said that FHIR must not be forced prematurely. McCallie referred to trade-offs to obtain nimbleness, agility, and flexibility.

Jamie Ferguson announced that he agreed with the recommendations except for slide 6, which said that XCA is complex and not well received by providers. Approximately 30% of U.S. hospitals and over 10,000 physician medical groups are currently using XCA for query-based exchange. XCA should be reconsidered as a supported option until a better transition plan can be made. Transition to FHIR is likely to take more time and be more costly than expected. Alignment with the DAF would be highly desirable. Baker clarified that the recommendations do not exclude XCA. Most likely, the vendors that currently use XCA for query could meet this functional requirement using XCA. The recommendations do not exclude it but they do not require it either. The recommendations support a number of the capabilities that the DAF is implementing. The recommendations say that DAF is addressing a broader scope than should be targeted for 2017. McCallie added that the team assumed the vast majority of vendors would meet the attestation requirement by using XCA. It is possible to deploy XCA in a way that is not cumbersome, contrary to its current interpretation. New templates may be needed.

Arien Malec, a member of the power team, said that the team was asked a very specific question relative to certification for 2017. Fairly rigorous standards readiness criteria are used for universal certification criteria. Therefore, the team was very conservative in its recommendations for standards. There is a single vendor network that is well-established that uses XCA as underlying technology. But most of the vendors did not support XCA. They did support XDS, but required additional development work to get to XCA. If one asks a different question, such as how to enable innovation over a longer time horizon, the constraints would need to be relaxed.

A member said that the HITSC should push FHIR forward and wondered about the right timetable for doing so. McCallie asked to defer the question until the discussion of the JASON Report. Baker said that previously adopted criteria for standards readiness should be applied to FHIR.

Leslie Kelly Hall inquired about alignment of PGHD and expressed concern about the timing of ripping out and redoing regarding FHIR. McCallie said that the JASON recommendations address the consumer facing exposure of the services. Many old standards are still in place, accepted by all, and serve their intended purpose well. FHIR separates the core part of the standard from the profile of the data that are being sent over the standard. The framework of FHIR can be in place and then the profiles can evolve. It is easier than starting over, which is one of the reasons that FHIR is appealing. Regarding rip out, Baker talked about avoiding forcing vendors to implement something incompatible with the current trajectory.

In response to a question from Halamka, Reider talked about gradual rulemaking as an attempt to be less onerous from a complexity and payload perspective and yet take advantage of a trajectory. He told them not to assume annual rule making. Halamka said that taking certain guidelines such as FHIR as the trajectory, XCA and other possibilities along the way would be allowed until there is sufficient maturity and a FHIR specification. Although the trajectory is not here today, its principles can be enumerated.

Reider said that the HITSC has the potential to give ONC very clear recommendations for both what and when a standard is ready. There is no need to assume an explicit timeline. McCallie talked about reaching consensus among stakeholders for which one avenue is SDOs. But that process is a slow one. The S & I Framework has worked well in some instances but has not worked well at all in others. He opined that S & I Framework's success is a function of who shows up to the meetings. The right process has yet to be designed. Halamka said that the recommendations can say that ONC has and will enumerate certain principles that will allow the committee to further consider timing and trajectory. Then the HITSC can use the recommendations to continue to proceed toward FHIR at a reasonable pace while not constraining other possibilities.

Eric Rose pointed out that a vendor might comply with the proposed requirements by instituting query functionality that does not conform to any published standard and only works for communication among its own software applications. He suggested including that if something other than a published standard is used for the query functionality, the technical specifications be made public so that any entity that wants to maintain a system that can receive and respond to a query is able to do so. McCallie responded that one must consider the difference between certification around published standards versus incentives for system use. Incentives could be given for open ended interchange. The providers will then lead the vendors. He said that the notion of public APIs to be discussed under the JASON Report agenda item would reduce the frequency of such an issue.

(The HITSC did not act on the recommendations.)

Standards and Technology Updates

Steve Posnack, ONC, showed slides and described the data provenance project. Provenance standards are needed because providers need confidence in the authenticity and integrity of the health data they review, access and receive. There is a trend from documents to atomizing data. The variability in how HIEs, EHRs, and PHRs currently capture, retain, and display provenance is problematic for the interoperable exchange, integration, and interpretation of health data. Jonathon Coleman, ONC, reported that Phase 1 will tackle the following:

- When health care data are first created, what is the provenance information that should be created and persisted?
- Can a receiving system understand and trust that provenance information?
- Do we need to know who touched it along the way?
- When the receiving system combines this information with data received from a third party, how do we persist the provenance from multiple sources?
- When multi-sourced data are assembled and sent to another system, how do we convey the provenance of the multiple data sources as well as for the system doing the assembly? Is this considered new data? What if the assembling system cherry picks from multiple sources, or adds some new health information of its own?

Coleman reviewed a series of slides that depicted the application of these questions to a use case. He reported that a tiger team has been convened. Consensus on a charter was obtained and the team is working on use cases. The project was proposed in HL7 (HL7 Implementation Guide for CDA® Release 2: Data Provenance, Release 1). Vocabulary harmonization with other HL7 workgroups is underway.

Q & A

McCallie cautioned staff on the complicity of the project. Being a candidate standard is not the same as a good standard. The wrong result would be harmful to everyone. Referring to the number of candidate standards, Coleman said that the group is still identifying the use case and specifying actual optional requirements. While candidate standards are being proposed to the community, data are being put in a list in a parking lot until such time as standard evaluation criteria can be applied to specific use cases.

Functional requirements have yet to be developed. He offered to talk to McCallie offline regarding evaluation of standards. Halamka said that the problem has yet to be defined.

McCallie declared that the HITSC should be involved early in the process to define the problem. Posnack told him that was the purpose of the presentation. He welcomed input from the members and assured them that they will be subject to frequent reports on the topic. Halamka said that coupling the S & I Framework and the committee more closely would be beneficial to both. Lisa Gallagher suggested that the HITSC Steering Committee examine ways to maximize workgroup and committee input into the provenance standards and other projects. Halamka agreed to follow through.

Kelly Hall told them that as the patient starts to enter the ecosystem, provenance will become even more important. A good housekeeping seal that keeps the documents tamperproof as it moves throughout the ecosystem is needed. She wondered why the data system of origin and not the person or role of the originator was cited. Eventually, provenance is not a system level attribute but rather is one attached to the person who created that document or captured the data in question. Coleman assured her that PGHD is absolutely a topic of conversation within the community. Many participants are putting forward suggestions for scenarios that include PGHD. Participants are discussing how individual attestations can be carried forward so that the provenance is not lost. The gap between technical actors and human actors must be spanned. Kelly Hall referred to versioning in care plans. Coleman indicated that care plans will likely be a topic of future discussions.

Stan Huff talked about a unique instance identifier for data elements. It can be difficult to recognize a piece of data as the same piece of data previously received. Failures in operation were experienced and his organization found that the only solution was to require that any system that originates or creates data assign a unique instant identifier that stays the same through the life of the data elements. Any time that data element is present it has the same identifier.

Nancy Orvis commented on the importance of capturing information about the provider's originating system. She inquired about the timeframe for the project. Coleman speculated 12 to 18 months or more; the use cases will be defined soon.

2014 Edition Release 2 EHR Certification Criteria Final Rule

Posnack explained that ONC proposed a Voluntary Proposed Edition of certification criteria on February 26, 2014. The goals were to provide regulatory flexibilities, clarify policy, improve interoperability, and make administrative changes to the ONC HIT certification program. Stakeholders complained that the full set of proposals in the Voluntary Proposed Edition was too expansive. Support for incremental rule-making was mixed. The previous editions of EHR certification criteria were named for the first year of expected compliance to support the EHR incentive programs. But feedback on the February NPRM indicated that this naming approach created unrealistic expectations that certified products will be available by the edition year. Therefore, staff determined that editions should not have any additional implied meaning. Editions of certification criteria will now be named by the year in which the final rule is released. Other rulemakings like the 2014 Edition Release 2 final rule would be added to the most current edition of certification criteria (e.g., 201X Edition Release 2).

Mike Lipinski, ONC, showed slides and gave an overview of release 2, which includes 10 optional and 2 revised certification criteria, a few changes to the certification program, and administrative updates. The 2014 Edition computerized provider order entry (COPE) criterion was split into three optional certification criteria based on capabilities (medications, laboratory, and diagnostic imaging). These three options would allow an EHR to provide adaptations, such as mobile apps, for a specific capability (e.g., medications) and not have to be certified to the other two capabilities.

Lipinski continued. The content portion of the 2014 Edition transitions of care (ToC) criterion was decoupled from the transport capabilities, and a new set of optional transport criteria was adopted. This

decoupling allows health information service providers (HISPs) and other health IT developers to provide either content or transport capabilities without having to be certified to both. Also adopted is the Edge Protocols Implementation Guide (IG) v1.1 for the optional ToC criterion to promote an EHR's ability to reliably connect to a HISP. A revised view, download, and transmit to third party (VDT) criterion that offers the same revisions made to the optional ToC criterion as optional for testing and certification (e.g., Edge Protocols IG v1.1) was also adopted. As part of decoupling content and transport for ToC and VDT, three optional certification criteria for transmission methods were adopted: Direct, Direct and XDR/XDM for Direct Messaging, and SOAP RTM and XDR/XDM for Direct Messaging. An optional clinical information reconciliation and incorporation (CIRI) certification criterion that moves incorporation from the ToC certification criterion was also adopted. Regarding syndromic surveillance, ONC adopted an optional certification criterion that permits any electronic method of creating syndromic surveillance information for exchange in non-urgent care ambulatory settings. The SED criterion was revised to include the optional three CPOE criteria and optional CIRI criterion. The gap certification policy allows the use of test results from a previous certification for certification to functionalities that have not changed, subject to the ONC-Accredited Certification Body's (ONC-ACB) discretion. Seven Release 2 criteria are eligible for gap certification if EHRs were certified to the 2014 Edition versions of these functionalities: three optional CPOE criteria, optional syndromic surveillance criterion, and three optional transmission criteria. ONC will discontinue the Complete EHR definition and Complete EHR certification beginning with the next adopted edition of certification criteria. This does not affect prior or future 2014 Edition certification. The ONC Certified HIT certification and design mark for required use by ONC-ACBs was adopted. An updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs was adopted. The proposal to remove 2011 Edition-specific EHR certification criteria and related standards, terms, and requirements from the Code of Federal Regulations (CFR) will be effective March 1, 2015. The temporary certification program regulations will be removed from the CFR on the effective date of this final rule. ONC will publish a proposed rule for the next edition of EHR certification criteria jointly with the next CMS EHR Incentive Programs proposed rule by the end of 2014.

As he summarized each of these changes, he specified the rationale, which most frequently was to increase flexibility or regulatory clarity.

Q & A

Malec asked about the optional designation, which was presumably included to provide additional flexibility for a complete EHR, saying it is difficult to determine what is required for a certified EHR technology that is adopted for meaningful use. He asked about ToC and requiring the edge protocol. Lipinski said that the optional designation can lead to confusion. It does have a dual meaning. Developers are not required to certify to any of these optional criteria. Once a choice is made to certify to a criterion such as ToC, anything not listed as required is optional. Malec suggested finding a way to make this clearer. Posnack interjected that the purpose of adopting these criteria was to make them available for certification. They can be built into the regulatory modification as an alternative to the originally adopted 2014 Edition. Currently, for ToC, when using the 2014 Edition, the developer can choose to get certified to the ToC content or use a separately certified HISP as the new transport capability. There is no requirement to upgrade; it an option that could provide more flexibility and more opportunity for exchange. He declined to comment on how this would impact any future ONC proposals.

Kim Nolan reported that regarding CPOE when someone enters medication data into the CPOE section instead of the prescribing module, the information may not flow to the medication or the same place into the EHR. This occurs in both in- and out-patient settings although more frequently in the former. Better linkage of the CPOE and prescribing modules would provide better quality data for research and management. Lipinski indicated that although the link was not explicit for certification, he is interested in having more information on the topic.

Halamka said that the scope of the rule seems appropriate. He applauded the separation of transport and content and enabling health information exchanges to certify a module for transport using Direct. Lipinski said that there will be updates to test procedures along with a period for public comment.

NCPDP Real Time Benefit Check Analysis Task Group

Margaret Weiker, Bruce Wilkinson and Roger Pinsonneault represented the National Council for Prescription Drug Programs (NCDPD). NCPDP is a not-for-profit, American National Standards Institute (ANSI)-accredited SDO with over 1,500 members representing virtually every sector of the pharmacy services industry. NCPDP's standards have been named in various laws, such as the Health Insurance Portability and Accountability Act (HIPAA), Medicare Modernization Act (MMA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. Task groups work on specific issues within a work group and membership is not required to participate. This task group was formed to define what constitutes the prescription benefit as reported by actors of the use case. It work is focused on defining the use cases and business requirements of an RTBC solution without being limited by current implementations. The task group's scope is not to select a standards base or define a solution, although these documents will help guide NCPDP in recommending a solution and standard. The first meeting was June 2014. Questions to be answered are:

- What is the patient's financial responsibility for a proposed medication?
- Is the pharmacy a preferred (lower cost) pharmacy?
- Are there any coverage restrictions that may prevent the proposed medication from being covered?
- Are there any drugs in the same therapeutic class that are less expensive?
- What is the patient's remaining deductible?
- What is the health plan's financial responsibility for a proposed medication?
- What if the health plan/PBM has a need to communicate with the prescriber?
- How (much) longer is the patient covered by the health plan? Is the health plan the primary insurer?
- What is the patient's financial responsibility for a proposed medication?
- Is the pharmacy a preferred (lower cost) pharmacy?
- Are there any coverage restrictions that may prevent the proposed medication from being covered?
- Are there any drugs in the same therapeutic class that are less expensive?
- What is the patient's remaining deductible?
- What is the health plan's financial responsibility for a proposed medication?
- What if the health plan/PBM has a need to communicate with the prescriber?
- How (much) longer is the patient covered by the health plan? Is the health plan the primary insurer?

Slides that described the Surescripts RTBC pilot and the CPDP Telecommunication Standard Demonstration Project were shown. The Real-Time Benefit Checking ASC X12 270/271 – Health Care Eligibility Benefit Inquiry and Response is HIPAA mandated for dental, professional, and institutional providers in order to inquire and response to obtain any information about a benefit plan for an enrollee. The 2*013 U.S. Healthcare Efficiency Index* estimated the 3 billion eligibility and benefit verifications occur in a year and 1.98 billion used the ASC X12 270/271 transaction, which is used by all health care industry sectors for ePrescribing, formulary and benefit pointers and medication history. The task force wishes the HITSC to help obtain greater participation from providers and vendors and to identify the success criteria for incorporation into the recommendations.

Q & A

Halamka asked the members to think about next steps for the committee. McCallie encouraged the task group to focus on the simple use case of cost to the patient. Responding to a question about the telecom standard, Weiker said that no standard is being recommended at this time. The goal is to develop the use cases, the business requirements and the data elements. Pilots are underway using different standards. McCallie suggested that the service perhaps could be delivered to the EHR vendors by an app. He offered to explain offline how to do this.

Nolan noted that the pharmacy has one source of information and the providers have a different source. It would be helpful if both had the same information from the same source. Regarding the first five questions, she said that they appear to be in scope. The sixth question may not be in scope. Acknowledging her membership in NCPDP and her understanding of the seventh question, she said that messaging should be related to benefit verification for medication. She asked about clinical messaging and benefit messaging. There should be standards about the type of communication permitted to ensure that it is truly a benefit verification and not for commercial interest. She asked additional questions about the Surescripts pilot.

Wilkinson said that every one of the proposals for RTBC is out-sourced with the pharmacy benefit manager. The source of truth comes from the same adjudicator. Nolan repeated that the provider gets different information and in a different format from pharmacies. Wilkinson said that the difference is due to timing and specificity, but the source is the same. Halamka gave a personal example of the provider and pharmacy having different information for an EpiPen prescription. McCallie said that the formulary is generic and real time transactions should take into account the particular patient's current limitations, location, and co-pays. Pinsonneault said that the goal of using the telecom standard out of the physician's EMR is to match that price to the penny so that it perfectly replicates the pharmacy's charge. Weiker reported that she captured Nolan's concern for addition to the use case.

Halamka concluded that the HITSC Steering Committee will look at the items on the list and determine on which the HITSC should deliberate. There is overwhelming support for doctors and pharmacists getting the same timely data and ensuring patients will have the benefit of consistency as they navigate the system. Reider agreed, adding that prescribers in addition to physicians are included, and asked Consolazio to take note of the item for the Steering Committee.

Halamka concluded the Q and A since the meeting was 30 minutes behind schedule. Kelly Hall and Rose were asked to e-mail their questions to Consolazio.

JASON Report Draft Recommendations

HITPC-HITSC JASON Task Force (JTF) Co-chairperson David McCallie showed slides to review the charge and process. He 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 "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. He 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. 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.

McCallie 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 use 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 and analysis structures and processes, and legal and policy barriers and opportunities. The 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.

McCallie 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 the ONC Interoperability Road Map. Final action by the committees is scheduled for October 15.

Halamka noted that the NwHIN Power Team and the JASON Task Force recommendations are well aligned. Consolazio clarified that the HITSC was not to act on the draft recommendations today.

Discussion
In response to a question about what architecture JASON actually suggests, McCallie reminded the members that JASON does not allow discussion with or questions to the authors. The critical insight is a recommendation for loosely coupled APIs to enhance data flow. The task force will have more to say about this in its final draft recommendations.

Sharon Terry urged coordination with PCOR-Net, saying that she and several other FACA members are participants. McCallie reported that a representative from that organization had been invited to and participated in a listening session. The research community must be included in making decisions about architecture. Regarding privacy bundles, he agreed that much of the ongoing work is interesting. The issue will be to what degree the consumer has control and how to maximize the interesting choices available to consumers.

Halamka asked about a path to reduce optionality with FHIR. McCallie replied that it can be done if there is sufficient will. Currently, there is no consensus among vendors as to whether it should be done.

Public Comment

Marianne Yeager, HealtheWay, commented on the Jason Report. The report did not recognize the extent to which query based exchange has been adopted and used. 30% of U.S. hospitals participate in eHealth Exchange. Radical, forced changes do not have good outcomes. She acknowledged the widespread interest in FHIR, but said that national policy should not be based on an untested approach. Emerging approaches should be vetted and time must be allocated to migrate to any new system. Technology should be a tool to policy, not policy itself.

Scott Brown, MyDirective, acknowledged that the NwHIN Power Team's recommendations supported the capability to query external systems and to be able to delegate representative authority. He wanted the recommendations to include the capability to query for advance directives. Many systems are integrating MyDirective. Also, opportunities for consumer preferences for services such as hospice care should be incorporated. The advance directive standards should be upgraded.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the August 2014 HITSC meeting was accepted.

Meeting Materials:

- Agenda
- Summary of August 2014 meeting
- Meeting presentation slides and reports
- http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations.
- **O**NC Fact Sheet: 2014 Edition Release 2 EHR Certification Criteria Final Rule
- CFR scheduled for publication September 11, 2014 45 CFR Part 170 RIN 0991-AB92 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange

Meeting Attendance								
Name	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14	02/18/14
Andrew Wiesenthal		X	X		X	X	X	X
Anne Castro	X	X		X	X	X	X	X
Anne LeMaistre		X	X	X	X		X	
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris	X		X	X			X	
Charles H. Romine			X				X	X
Christopher Ross	X	X	X	X		X		X
David McCallie, Jr.	X	X	X	X		X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson	X	X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X	X
Floyd Eisenberg		X	X	X	X	X	X	X
Jacob Reider	X	X	X	X	X			
James Ferguson	X	X	X	X	X	X	X	
Jeremy Delinsky						X	X	X
John Halamka	X	X	X	X	X	X	X	X
John F. Derr	X		X	X	X	X	X	X
Jonathan B. Perlin		X		X	X	X	X	X

Meeting Attendance, continued

Name	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14	02/18/14
Keith J. Figlioli	X				X		X	
Kim Nolen	X	X	X	X	X	X		X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X		X	X	X
Lorraine Doo	X	X	X	X		X		X
Nancy J. Orvis	X	X		X			X	
Rebecca D. Kush	X	X	X	X	X	X		X
Sharon F. Terry	X	X		X	X	X	X	X
Stanley M. Huff	X	X	X	X	X	X	X	X
Steve Brown	X				X	X	X	X
Wes Rishel		X	X	X	X	X	X	X
Total Attendees	**22**	**23**	**22**	**24**	**21**	**23**	**24**	**23**