HIT Policy Committee and Standards Committee
DRAFT
Summary of the October 15, 2014 Joint Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the joint meeting of the Health Information Technology Policy Committee (HITPC) and Standards Committee (HITSC). 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 noted the significance of the joint meeting of the HIT FACAs. She thanked everyone for organizing the meeting to work toward interoperability.

Deputy National Coordinator and HITSC Chairperson Jacob Reider welcomed and thanked everyone. He acknowledged that although participants may not agree on everything, they all want to improve health. He told them to focus on being successful rather than being on the right path. He suggested that they listen and talk in the right proportion.

Review of Agenda

HITPC Vice Chairperson Paul Tang referred to the importance of the vision and the work plan. HITSC Vice Chairperson John Halamka reported that he is the recipient of many e-mails expressing his colleagues' disillusionment with technology. A roadmap is needed in order to build a learning health care system to be able to respond to the use cases of the future. He urged them to help identify the focus on the roadmap and to be part of a solution.

Tang mentioned 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 said that action on acceptance of the summaries of the previous meetings will be considered at a later time.

Interoperability Framing

Erica Galvez, ONC, read the updated IEEE definition of interoperability. She showed slides and talked about HIT adoption from 2001 through 2013, calling it a dramatic uptake and reminding the members that they had been presented with some of the information previously. In 2013, about one-third of physicians exchanged different types of data. In 2012, 50% received discharge summaries routinely, 25% electronically. 51% of hospitals were able to query patient health information electronically. Although their exchange increased from 2008 to 2013, only 36% exchanged with other hospitals outside their systems. She went on to describe community and state based exchange services. She noted the

expansion of the ecosystem from 2012 to 2013. The majority of state public health agencies are accepting immunization, lab and syndromic surveillance data. Transactions have increased. Various governance structures are in operation—DirectTrust, Commonwell, eHealth Exchange, NATE, and Care Quality. But no current approach can bridge these siloes. She cautioned against a sole focus on delivery.

Q and A

Thirteen members commented, frequently prefacing their comments with complements to Galvez. Comments are summarized as follows.

Quality measures of interoperability are needed. For instance, what proportion of these transactions actually matters? What percentage of providers exchange all of the types of data described on slide 4? E-prescribing should have been included. Administrative and financial aspects should be included. Claims forms data are used for many purposes. Health Insurance Exchange should be considered as part of the ecosystem. Use beyond minimum meaningful use requirements should be captured. Cost analysis and the value received from public expenditures should be included.

Categorization and breakdown of transactions by: within global and integrated systems, practice settings, geographical categories, destination, across vendors, and payment systems are needed. On the other hand, David Lansky urged that they think less about differences across settings and focus on the U.S. population as the denominator, returning to the goal of every person in the population having an EHR.

In response to a question about data on semantic interoperability, Galvez acknowledged the need for information on how standards perform and their interoperability in the real world. Surveys are being fielded to try to collect such data. Andy Wiesenthal observed that on-going consolidation across the delivery system affects the need for interoperability. Interoperability with educational and social services is of particular importance in pediatrics. According to Marc Probst, semantic interoperability is needed among committee members and in order to communicate with decision makers, such as board members. The data shown on the slides could be interpreted in different ways. He asked everyone to be clear and to use common definitions and vocabulary.

Although billions of transactions occur annually, providers using the same EHR system are not always able to access the records of mutual patients. Cross vendor interoperability needs work. As demonstrated by the index Ebola case in Dallas, exchange systems are not prepared for rapid detection and emergency responses. Patient level data and work flow integration cannot always be predefined; adapted systems must be considered. Use cases beyond minimum compliance with meaningful use should be anticipated. A standard strategy should support development that allows spontaneity. The desires of the customer must be considered. Patient interaction with the ecosystem and patient generated data must be considered. Market drivers should be acknowledged. Which trends meet the no special efforts criteria? The price charged by vendors for interfaces is an issue. No special effort is difficult to measure.

Interoperability Roadmap

Galvez emphasized that her slide presentation represented a very early draft. She emphasized that interoperability is about people. The 10-year road map envisions the following: leverage health IT to increase health care quality, lower health care costs and improve population health, support health, build incrementally from current technology, establish best minimum possible, create opportunities for innovation, and empower individuals. This is not just an HHS or federal government roadmap. It will be completed and released for public comment in January and published March 2015. A number of mechanisms have been and will be used to solicit input. The Interoperability and Health Information

Exchange Workgroup will review and provide feedback on the roadmap. Galvez declared that the meeting was an opportunity to solicit feedback on the early draft. She presented draft ecosystem goals in three categories—individual, provider, and population and public. Draft learning system requirements are:

- Ubiquitous, secure network infrastructure
- Consistent, secure transport technique(s)
- Consistent data formats
- Consistent semantics
- Standard, secure services
- Accurate identity matching
- Consistent representation of individual interests in sharing one's data
- Resource Location
- Verifiable identity and authentication of all participants
- Consistent representation of authorization to access data or services
- Shared governance and measurement of progress

Goals for 2024 are: longitudinal information, ubiquitous precision medicine, reduced time from evidence to practice, and virtuous learning cycle. She went on to describe the five building blocks for interoperability: clinical, cultural, business, and regulatory environments; rules of the road and governance; core technical standards and functions; certification; and privacy and security. For each building block, she summarized the feedback that is being taken into consideration and delineated sample actions for the period 2014-2017 by building block. For instance, for the first block, sample actions are: public and private payors incent or require the exchange and use of essential electronic health information that aligns with national standards in all value-based purchasing arrangements and; ONC and FTC monitor and coordinate activities to advance interoperability by promoting competition and innovation.

Q and A

Tang directed the members to comment on the first steps for the roadmap. Reider requested that comments focus on editorial changes and actionable steps for the committees and workgroups.

Eric Rose referred to slide 7 and 2017. He suggested making summary documents useful to the next doctor. Physicians want summary narratives that communicate meaningful information. According to Galvez, the goal is to have technology to enable rapid communication from producers of research findings to CDS. The mean 17 years from research to practice must be reduced. She agreed to clarify that having more patient data will not necessarily lead to the desired result.

Keith Figlioli requested that the nine guiding principles slide be moved to the front of the deck. Experience in the HITSC indicates that each member responds to issues through the lens of her own experience. Furthermore, innovation fostering is missing. The rapidity of change must be recognized. Galvez responded that flexibility is discussed in the vision paper.

Nancy Orvis referred to slide 9 and the comprehensive near term goals. She wondered about the inclusion of the ED visits. Short term notice is very important. Galvez responded that they were included in the inpatient category due to the importance of having short-term notice of those visits.

Christine Bechtel said that consumers want more than access to longitudinal data. Consumers want access to information that is organized and accurate. Galvez confirmed that the reference to consistent and shared data on the system requirements slide includes patients. Bechtel suggested that it be

expanded to engage and empower patients. Regarding the governance section, she asked that the slide be made consistent with Galvez's statement on making a significant presence.

Cris Ross pointed out a contradiction on slide 19 (feedback). Some feedback indicated that standards are over prescriptive. Regarding slide 20, the required steps from tested and mature standards to becoming a full-fledged ONC standard are not shown. He indicated that the Standards, Certification and Testing Workgroup is interested in working on this topic. McCallie interjected that the JASON Task Force recommendations will address slide 21.

Deven McGraw referred to slide 24 and privacy and security. She acknowledged that the statements were consistent with the feedback heard. She recommended that Galvez cull through previously made and accepted recommendations for inclusion. She expressed concern that the sample action listed on slide 25 focused on consent. Many transactions for treatment and care coordination do not require consent. Many needed transactions can assume consent. In the near term ONC may want to clarify the legal requirements for full use. She agreed with the encryption recommendation. ONC should work with OCR. Although the focus on consent is important, more clarity on authentication and authorization is needed. She was opposed to accepting the notion of a trade-off. Halamka added that Dixie Baker's group had worked on encryption on all data at rest. Encryption in a closed environment may be more harmful than the lack of encryption. According to Galvez, more work will be done to incorporate encryption best practices.

Referring to Bechtel's comment on slide 9, Tang said that the individual should be shifted to the left. Patients need access to their data in order to be activated. Use of data from home devices should occur much sooner than 2020.

Gayle Harrell pointed out the neglect of usability in the guiding principles. Governance must move forward more rapidly. Trust, patient perspective and state variation in laws must be taken into account. The federal government should establish a floor. Regarding the building block of culture and business, the providers' perspective must be considered as well. Galvez referred her to more detail in the reference documents.

Floyd Eisenberg talked about slide 8. Quality measures, public health and research should not be depicted in separate siloes. The slide should show the interrelationships. In slide 10, the provider roles, capabilities needed, and provenance of data should be captured.

Lisa Gallagher referred to slide 22 and identity management. She indicated that her organization is working on patient data and patient record matching in the near term. It is also looking at digital identity, multifactor, and multilevel of assurance identify as the national ecosystem develops. She requested better explanations for slides 53 and 61. The Transport and Security Standards Workgroup will work on digital identity.

David Coates referred to slide 10, saying that the technical scope goes beyond EHRs. There is a need to be flexible due to rapid changes. The amount of data wanted and used by patients will explode. Privacy preferences and consent for devices should be considered as well as the encryption of data in transit from apps.

Liz Johnson argued that practicality should be included in the guiding principles. There are numerous competing priorities and FY 2014 is gone. Galvez indicated that the 3-year time frame takes into account what is already in place.

Lansky talked about slides 7 and 9 and timing. Information on scale and scope should be included. Some organizations are already doing the things set out in the 10-year plan. Attention must be given to the

mechanisms for scaling and how all of this will play out in the market. Turning to slide 14 on business and culture, he wondered what instruments are available as drivers. He suggested strengthening the roadmap by describing the federal role, for example, its purchasing behavior, convening behavior, and tool making behavior. He went on to point out that having more health information moving is not an appropriate goal: the goal is to improve health care. The task is to make sure that a value payment strategy is supporting health improvement, which requires measurement. Moving to slide 32, he said that the definition of longitudinal measures must occur sooner. He recommended acceleration of the longitudinal measures in order to drive the rest of the building blocks.

Rebecca Kush reported that efforts are underway to shorten the 17 years from research to practice. In addition to EHR standards, research and public health standards and the IHE workflow should be used. The standards used by the NIH centers and AHRQ must be considered. CDEs are not necessarily standards. Many existing standards, such as for patient reported outcomes, diaries, and other documents, have yet to be considered. She anticipated that the Semantics Standards Workgroup will work on such topics.

Egerman complained about slide 10. Although it refers to being agnostic about the location of data, the guiding principles refer to building upon existing infrastructure and HIEs. He said that the existing structure may not be the correct one. Galvez talked about trade-offs, balance and practicality. She explained that she had looked at 10 years out and worked back. One must be agnostic regarding the edge system and the source of and recipients of data. They are not known. Egerman was concerned that the content of the slide was a code for preserving the current HIEs, which Galvez denied by saying that HIE is used more broadly than to indicate community and state HIEs. That being the case, Egerman asked her to just say build on existing technology. He declared his objection to keeping the existing intermediaries in place. Moving to another slide that stated new standards will not be adopted until they have been tested and are mature, he pointed out the importance of defining and operationalizing mature. The building blocks do not recognize test beds.

Malec suggested a change in the framework and talked about incremental from or incremental toward. Existing standards are not developed for today's opportunities. The environment is changing rapidly, making it challenging to plan to 2014. The cost for development, testing, certification, and implementation versus the cost for early test beds must be considered. Stage 2 did not allow time for mistakes. He advised keeping the 2015 certification requirements minimal to permit flexibility.

Baker approved of the privacy and security recommendations and suggested recognition of the roles of genomic data and big data analytics. Their impact will occur much sooner than realized. Various groups and FACA members are working on related projects. New models of consent are being devised. The adoption of standards that are not aligned with emerging and existing technologies and stifle innovation must be avoided. The roadmap should create opportunities for innovation. She asked that fostering innovation be added to the guiding principles.

Marc Probst expressed concern that the list on slides 7 and 9 would turn into meaningful use criteria. Regarding slide 7, standards should be developed first. Architecture and infrastructure must be defined. Pertaining to slide 11, sometimes one size will have to fit all. There will be winners and losers. On slide 16, calling for unprecedented collaboration is unrealistic. It is not enough to state it. The persistence of competition must be acknowledged. On slide 17, the definition of mature standards is missing. A roadmap should specify the steps toward mature standards.

According to Neal Patterson, the competitive use of data that affects lives is fundamentally immoral. The lack of a national health care identifier is a major problem. Since that lack cannot be openly acknowledged, an alternative is to make safety a guiding principle. It is not safe to exchange information

about a patient without assurance of her identity. He agreed with the suggestion that innovation be added to the guiding principles as well.

Kelly Hall pointed to slide 9 and said that outcomes that matter to patient should inform the system. She asked that patient values, goals, and directions be taken into account. Also on slide 9, Charles Kennedy said that the term use of data should be refined. Someone should figure out how to express information at the eighth grade reading level. Slide 11 does not mention anything about measures of success of interoperability, such as the truth and trust of data. The fidelity of the source and the trust of the user are important. In defining a population of interest, use of claims data, clinical indicators, or physicians' nomination will yield different results. According to Kennedy, physician nomination is the best approach. Interoperability should be consistent with the health and disease burden of the patient, who should be the frame of reference.

Rishel commented on recognizing conflicts. Regarding measures of success, one should go beyond fidelity to the usefulness of the information in the processes of the next provider. Clinical summaries do not constitute useful information. APIs are the buzz word of the year. The process by which information can be made useful must be considered. The single common standard for everybody's use case has failed. The transport mechanisms associated with it likewise are not the transport mechanisms needed in going forward. Forcing the adoption of standards that are appropriate for a few things but do not address the future should be avoided. Regarding a realistic time frame, some organizations, such as the one that employs Probst, will be consistently ahead of the curve. What they do can be seen as pre-standards work and free demonstration of the business value of the standards.

Jamie Ferguson referred to privacy and security and the last three pages of the document. The breath of data is increasing rapidly far beyond HIPAA-covered entities. There is regulation by different agencies with different definitions of data and different risk frameworks that are used for analysis. Safe and secure data handling has to be consistent and predictable. Therefore, he suggested adding to the roadmap the idea of more interagency coordination on a common taxonomy or set of definitions for data, data uses, and risk frameworks.

Another member reminded Galvez that a roadmap or plan is required to be more specific and detailed about actions, and who is responsible for what, when than was evident in her presentation. The expected output should be delineated. The work will be difficult and must be approached in an organized manner. Halamka interjected that the HITSC workgroups will provide much of the detail.

Sharon Terry announced that she worked on a PCORI.net committee. Responding to McGraw's comment, she said that while the door should be left open for various kinds of research and clinical care, there are other ways to engage consumers. Fair information practice principles are important. Rather than an old transactional model of consent, a relational model that has yet to be built must be considered. Better engagement of communities in both care and research is required for a learning health care system.

Chris Lehmann repeated the idea that exchange per se should not be the objective. The objective is the meaningful exchange of useful information—information that can be used in the care of the patient. The exchange of information of no or little use can be damaging. Research and better tools on how to extract what is valuable for the care of one patient is needed. Tang said that recipient reported outcomes may be one measure of success. He declared the report and the discussion outstanding.

Public Comment

Carol Bickford, American Nurses Association, invited the committees to focus on all health care providers and other community entities. EPs are more than physicians.

Rebecca Hancock, American Academy of Ophthalmology (AAO), reported that her organization had submitted written comments on the roadmap. The roadmap must go beyond EHRs. Specialty societies and registries have the capability to assist with the goals of the roadmap. The AAO recently launched its eye care registry, which allows users to track quality of treatments and get feedback on performance. ONC should recognize the role of clinical registries in a learning heath system.

Gary Dickinson, CentriHealth, submitted written comments in advance of the meeting. During the meeting, he repeated that interoperability achievement is measured by whether the information is fit for primary use. It is a qualitative measure of truth and trust. Interoperability is end-to-end throughout the life span and life cycle within the span of information; there is too much focus on point-to-point.

Shawn Mitchell, Jefferson County Public Health Department (Colorado), noted the absence of any reference to ethical guidelines to build patients' trust.

Eric Heflin, Texas HIE, commented about use cases. Not taking into account use cases is a high risk approach. The best practice is to create targets, then the high value use cases, followed by the architecture and clinical requirements. The government should not try to regulate high speed activities. Rather, the government should convene stakeholders. Stability and innovation should be considered. He recommended a focus on high value use cases.

Tom Leary, HIMSS, commented on 2015 reporting requirements. He urged CMS to move to a 90-day reporting period. He supported the ONC vision and referred to work on patient matching He submitted a 30-page document on the five building blocks on behalf of HIMSS. ONC should continue to convene stakeholders. He urged engagement with the entire health care ecosystem. He said that he looks forward to a response to the 30-page document.

Governance Recommendations

Interoperability and HIE Workgroup Governance Subgroup Co-chairpersons Carol Robinson and Chris Lehmann presented recommendations in response to two questions posed by ONC staff.

> Will continuing with the current governance approach ONC has taken ensure the community can fully achieve the three year goal of providers and patients being able to send, find, receive and use a basic set of essential health information across the health care continuum?
>
> Subgroup members felt ONC's current approach to governance has been helpful in advancing progress, citing successes borne from the Exemplar HIE Governance grants, the State Health Policy Consortium program, and other examples. The Subgroup feels additional work by ONC is required to enable all communities to reach the three year goal. However, Subgroup members had differing perspectives on the types and amount of additional interventions required to reach the three year goal. Some felt ONC needs to take a more active role in governance to achieve the goal. Others felt ONC could reach the goal by continuing its current approach to governance with a few additional targeted initiatives. Supporters of the current approach felt the current velocity of change would allow the industry to reach the 3-year goal with some additional targeted initiatives. They see a variety of interoperable networks and approaches growing across the industry. Stakeholders are coming together via the current approach and solving some of the key problems. Government has an important role to play and has struck the right balance between action and inaction. Many of the current challenges in the field that need to be overcome are implementation issues that require a nimble and agile approach to address that is not conducive to a significantly larger government role. Supporters of a more active role for ONC felt the velocity of change is not sufficient and that without additional government action the industry is highly unlikely solve the key governance problems needed to achieve the

3-year goal. Industry is currently implementing standards in a variety of ways and taking varying policy approaches to key governance questions. These divergent approaches are not likely be solved without additional government involvement to drive consensus.

Which governance-focused actions should the government take in order to best protect the public interest, including improving health care, improving the health of the public, and reducing costs in immediate future?

ONC should continue its current approaches to governance and expand and build upon them through potential mechanisms including, but not limited to the following:

- Legal and business framework: Building on the Governance Framework for Trusted Electronic Health Information Exchange ONC could develop a formal set of governance principles. To address implementation issues, ONC could issue guidance on important national interoperability issues to support alignment and convergence in the marketplace (e.g., Direct: Implementation Guidelines to Assure Security and Interoperability).
- Align federal activities: ONC could align federal activities with guidance they issue to encourage consistent marketplace adoption and use.
- Regulation: Any regulation, if utilized, should be undertaken carefully and with a light touch to remove impediments, to create an environment for opportunity, and to provide for national goals.
- Public-private collaborative consortium: ONC could begin the process to establish or identify a public-private collaborative consortium with designated governance authorities (refined, for example, through by-laws and/or Rule). The consortium should be modeled from a best practices review of other nonprofit, government-deemed organizations*. The role of the consortium could include the evaluation of issues (technical, operational, financial and policy) impeding interoperability and/or threatening the security of protected health information in electronic health information exchange, and apply governance levers where needed, coordinating across the multiple industry consortia, Standard Development Organizations (SDOs), and state, federal, and private sector initiatives. The appropriate structure, criteria and balance of members in the consortium needs to be carefully considered and curated to ensure the appropriate representation/balance of stakeholder interests including the perspective of patients, where possible. Striking the right balance of government involvement in the consortium will be important to its success and stakeholder buy-in. If a public-private collaborative consortium is undertaken, ONC should consider these important design principles for the consortium: The Consortium's work and priorities should consider market based use cases, which will evolve over time. The Consortium should consider partnering with relevant organizations to solve specific problems. ONC should review the experience of the National eHealth Collaborative and other governance initiatives to draw lessons learned in designing the operating and governance principles for this consortium.
- Education: ONC could undertake an education campaign to encourage providers, vendors, payers and patients to adopt and use health information exchange for clinical and administrative use cases. As part of this campaign, ONC could publish studies regarding the benefits of health information exchange (e.g., case studies, ROI studies, etc.)
- Measure and report HIE progress: As part of the Interoperability Roadmap, ONC could develop and deploy a national measurement and reporting plan to track and measure progress in HIE (verb) adoption and use that: establishes and defines a core set of standardized national HIE measures for vendors, payers and providers to track and report;

articulate and prioritize use cases of high value and measure progress toward adoption; establishes the current benchmark state of HIE between disparate EHRs, between unaffiliated organizations across HIE networks, and with other geographic and organizational data, wherever possible; establishes a timeline with realistic milestones considering the maturity of implementation and use of health IT in various use cases and in different care settings.

Finally, potential levers were delineated. Lehmann emphasized that the list was not intended to be exhaustive:

- Federal benefits purchaser requirements (FEHB)
- Federal agency requirements / incentives / penalties as provider, purchaser, grantor, regulator, researcher
- FDASIA
- Registries (CDC etc.)
- Regulatory requirements through Federal Rule or Acts of Congress (e.g., payment reform)
- Federally-developed non-regulatory tools (FAQs, best practice toolkits, implementation guides, testing suites, etc.)
- Market convener (FACAs, S&I Framework, Exemplar HIE Governance grants, etc.)
- Communications, outreach, education
- Examine existing regulations and other levers in place today to see if they incentivize (or disincentivize) desired exchange behaviors/approaches
- Align incentives and levers with market based Use Cases

Discussion

Jodi Daniels, ONC, said that ONC has been working on governance over the past decade. Several entities stepped in but there is nothing nationwide. She wants to leverage the authority in HITECH. The governance recommendations will now be handed off to the Interoperability and HIE Workgroup. Governance is one of the building blocks for the roadmap. ONC has contracted with MITRE to consider long term governance issues. Halamka added that not all governance questions will be answered today.

Rishel asked whether HIE refers to state HIEs. Robinson replied that it is used as a verb. Rishel referred to the prevalence of confusion. He suggested that a definition of HIE be included in slide 11. Additionally, better exemplars can be found. He suggested that MIRTE scan for exemplars.

Malec requested clarification of the recommendations. The response to the first question refers to two camps while the response to the second question contains multiple uses of could, would, and should. Exactly what is being recommended? Lehmann repeated that the subgroup members had diverse opinions. What is written on the slides is the best consensus reached and represents the lowest common denominator of opinion. Malec went on to note that governance is a big word. He proposed that members break governance into specific problems and work to unanimity.

In response to a question about U.S. entities that might possibly serve as such a consortium, Lehmann said that they did not take on that level of detail. Egerman referred to slides 6 and 7 and wondered about any points on which there was consensus. The co-chairs listed the helpfulness of the HIE examplar governance, more education and outreach, measurement, incentives, government as convener, and research. Egerman advised them to put the list in the letter. Regarding slide 13, he asked that they consider what it would take to move forward.

Harrell approved of the public private consortium recommendation, saying that public service commissions are a good model of working on infrastructure. Laws are passed to address failures. There must be a way to deal with bad actors. Performance measures are needed. The Interoperability and HIE Workgroup needs to move quickly and boldly on the recommendations.

McGraw referred to a previous governance workgroup and acknowledged that the subgroup had a difficult task. She suggested that they identify the things that need to happen and then look at how to govern them. The workgroup can think about what needs to be done and then identify the levers. On what is more governance needed? Where are the gaps? Robinson responded that the subgroup began with a list of problems. But the members were unable to agree on their prioritization. She indicated that someone should determine who the right people are to agree on a process. McGraw speculated that another group will not be able to solve the governance problem.

Bechtel agreed with McGraw and Malec. Giving the task to a private public consortium has been attempted. There was AHEC and later the HITSC and HITPC. A consortium would have to be funded, which would result in a paid membership and inequality of influence. She preferred a stronger role for the federal government and a more narrowly defined focus. More governance with standards is needed in comparison to policy.

Ferguson mentioned slide 12 and asked for the addition of a principle of explicit balance of stakeholder interests, including potentially regulated entities and others. Moreover, balance must be enforceable.

Baker said that the June 2012 NwHIN Power Team recommendations were relevant to a public private consortium. She suggested that those recommendations be reviewed for consideration. There are three significant barriers to exchange. One is variation in state laws on public health, and privacy and security. The second is vendors' business practices and the third is provider practices. The first is not amenable to ONC intervention. The consortium would have to make something work within the context of different states. Harrell said that the federal government would have a role in setting guidance and making appointments to a consortium.

Probst announced that he agreed with Bechtel. For 3 years groups have been talking about governance. Something must be done because lives are being lost while concepts are being discussed. The federal government can make things happen. He referred to the federal highway system.

JASON Report Recommendations

Halamka introduced the agenda item, saying that it was a challenge to interpret and comment on the report, which was produced by an esteemed group thought to be capable of solving all problems. The task force (or public) was not allowed to know the authors' identity or to question them directly. HITPC-HITSC JASON Task Force (JTF) Co-chairpersons Micky Tripathi and David McCallie showed slides to review their charge and process. They gave a very brief synopsis of the report, reminding the members of their previous presentations to the respective committees. Unlike the Governance Subgroup, the JTF reached consensus and agreed with JASON on three points: foundation of interoperability should be an orchestrated architecture based on Public APIs; current interoperability approaches are functionally limited and need to be supplemented and gradually replaced with more comprehensive API-based models; and stage 3 should be used as a pivot point to initiate this transition. But the JTF disagreed with several findings and conclusions of the JASON Report. Members believe that: the JASON report does not accurately characterize the current state of interoperability; an evolution toward an API-based architecture should, or could, require migration from current clinical and financial systems; the barriers to interoperability are not primarily a software engineering problem; and market mechanisms are not ineffectual, if not harmful, means of advancing interoperability. Members believe that market

mechanisms will be the primary driver of enhanced interoperability, and minimal, if any, federal regulatory intervention is desirable at the current stage of market development. They do not agree with the JASON Report's implicit assumption that strong top-down control of unifying software architecture is either feasible or desirable in today's health care market. The task force made detailed recommendations in the following six areas:

Focus on Interoperability: ONC and CMS should re-align the MU program to shift focus to expanding interoperability, and initiating adoption of Public APIs.

Recommendation: Limit the breadth of MU to shift the focus to interoperability. MU Stage 2 experience shows that overly broad and complex requirements slow progress on all fronts. Focused on interoperability will send strong signal to market and allow providers and vendors to focus resources.
Recommendation: Three complementary HITECH levers should be exercised. Add certification of highly constrained Public API to CEHRT standards. Encourage and motivate vendors to grant third-party access to Public APIs based on appropriate business and legal conventions. Structure incentive requirement programs (MU Stage 3 and others) so that providers grant third-party access to Public APIs based on appropriate business and legal conventions.
Recommendation: ONC and CMS should act with urgency to use HITECH to motivate industry-wide API-based capabilities. ONC should immediately engage the FACAs to further flesh out JTF recommendations on Public API-based architecture. ONC should immediately contract with an SDO or other recognized operationally active industry consortium to accelerate focused development of initial Public API and Core Data Services and Profiles for inclusion in MU Stage 3 and associated certification. CMS and ONC should consider delaying or staggering MU Stage 3 incentives to accommodate an accelerated development process for a feasible initial Public API specification

Industry-Based Ecosystem: A coordinated architecture based on market-based arrangements should be defined to create an ecosystem to support API-based interoperability.

Recommendation: A market-based exchange architecture should be defined by industry and government to meet the nation's current and future interoperability needs based on the following key concepts:

- Coordinated architecture. A loosely couple architecture with sufficient coordination to ensure that a market-driven ecosystem emerges for API-based exchange.
- Data Sharing Network (DSN). An interoperable data sharing arrangement whose participants have established the legal and business frameworks necessary for data sharing.
- Conform to the coordinated architecture and use the public API.
- Could include, but is certainly not restricted to, existing networks such as those run by vendors or providers or health information exchange organizations.
- Public API. A standards-based API that is to be implemented with certain obligations and expectations governing public access to the API.
- Core data services. Fundamental, standards-based data services that implementations of the Public API are expected to provide. Note: use of the term HIE is generic in nature and refers to general interoperability functions and should not be confused with health information exchange organizations, which are often called HIEs or health information exchanges.
- The coordinated architecture should not be single, top-down architecture; loosely coupled based on scalable internet principles to accommodate implementation heterogeneity;

leverage and build upon existing networks, while encouraging new networks; and do not envision that the coordinated architecture is necessarily an entity or actual implementation, but rather, standards and principles based on internet principles and building blocks

Data sharing networks in a coordinated architecture: The architecture should be based on a coordinated architecture that loosely couples market-based data sharing networks.

Recommendation: The nationwide exchange network should be based on a coordinated architecture that loosely couples market-based Data Sharing Networks (DSN)

The data sharing networks are **d**ata sharing arrangements that provide facilitating policy and infrastructure to support use of Public APIs. Within the DSN, facilitating API-based exchange among entities has a technical component (e.g., what technologies are used to identify patients or authenticate users across entities?), and a policy component (e.g., what data or documents are accessible through a Public API, and what are the allowed purposes for data or documents accessed through a Public API?). Across DSNs, implementing services will be used to bridge across different DSNs, when this is deemed necessary. This will have cross-network technical components (e.g., which standards and protocols are used for different DSNs' patient-matching or authentication technologies to interact with each other?), and policy components (e.g., how are out of network entities authorized, and what data or documents are accessible to authorized out of network entities?). Clinical and financial systems that expose the Public API will have the ability to exchange data without needing a DSN

Public API as basic conduit of interoperability: The Public API should enable data- and document-level access to clinical and financial systems according to contemporary internet principles.

Recommendation: The Public API should enable data- and document-level access to clinical and financial systems in accordance with Internet-style interoperability design principles and patterns. The coordinated architecture and data sharing networks create an ecosystem to facilitate use of the Public API.

The Public API comprises two components, an implementation of certain technical standards (the “API”) and an agreement to meet certain obligations governing public access to the API. What makes an API a Public API is a set of conventions defining public access to the API. A Public API does not imply that data is exposed without regard to privacy and security. However, there are legal and business considerations that must be addressed before any given healthcare provider and/or vendor would allow another party to use the API to access information. What is public in a public API is that the means for interfacing to it are uniformly available, it is based on non-proprietary standards, it is tested for conformance to such standards by trusted third parties, and there are well-defined, fairly-applied, business and legal frameworks for using the API.

Priority API Services: Core Data Services and Profiles should define the minimal data and document types supported by Public APIs.

Recommendation: Core Data Services and Profiles should define the minimal data and document types supported by all Public APIs. HITECH should focus initially on clinician-to-clinician exchange and consumer access use cases. The Core Data Services are: read/write access to both clinical documents (e.g., CCDA, discharge summary, etc.) and discrete clinical data elements (e.g., problems, medications, allergies, etc.). Initial focus areas for the industry are: clinician-to-clinician exchange (including ancillary service providers); consumer access;

pluggable apps; population health and research; and administrative transactions. The core data profiles are tightly specify data elements and formats used in Core Data Services. Priority profiles should be developed for clinician-to-clinician exchange and consumer access. The initial recommended focus of HITECH is clinician-to-clinician exchange; complement current document-centric approaches that exist in the market today; and consumer access.

Government as market motivator: ONC should assertively monitor the progress of exchange and implement non-regulatory steps to catalyze the adoption of Public APIs.

Recommendation: Federal government should take the following actions to help the industry overcome these barriers:

- Transparency. Aggressive and ongoing public monitoring of the pace of development and use of network mechanisms through collection of API usage data and development of an adoption evaluation framework to facilitate Public API-based exchange
- Guidance. Issuing authoritative, ongoing guidance to provide industry-wide direction and benchmarks, and to encourage specific actions for the development of DSNs and the Coordinated Architecture
- Organization. Convening existing exchange networks (i.e., prospective DSNs) to catalyze adoption of the Public API and development of industry-based governance mechanisms

Recommendation: Federal government *should* take the following steps to motivate adoption of Public APIs:

- Incentive alignment. Aligning incentive programs and existing regulatory processes to stimulate use of the Public APIs, such as ACO contracts, LTPAC regulation, lab regulation, etc.
- Federal operational alignment. Requiring federal healthcare entities to adopt the Public APIs in their technology procurement activities and day-to-day market interactions, such as Medicare/Medicaid, DoD, Veterans Administration, Indian Health Services, NASA, etc.

Recommendation: Federal government *should consider* taking the following steps to enable orchestration of Core Services across the DSNs:

- DSN bridging standards. Developing voluntary standards for vendor-neutral, cross-DSN bridging to fully enable the narrow set of robust transactions required for the loosely coupled architecture (such as patient identity reconciliation, authorization/authentication, key management, etc.)
- Nationwide shared services. Developing standards for, and ensuring deployment of, universally necessary shared services that are highly sought after and thus would facilitate DSN alignment, such as public use licensed vocabularies, and perhaps nationwide healthcare provider and entity directories, etc.

Recommendation: The government *may* choose to consider direct regulation of DSNs in the event that the market does not develop effective coordination mechanisms. Such actions would involve a significant increase in the government's regulatory authority over health information exchange activities, which would have high risk of unintended consequences that could slow market progress. Any such increase in regulatory authority should be carefully considered through evaluation of reasonable and meaningful benchmarks, and specifically calibrated to address any remaining barriers that the market has failed to overcome.

McCallie concluded that the JASON Report presents the opportunity to rethink and take a new approach. He said these recommendations would mean a new way of doing things. Most APIs today represent spokes and do one thing well. These APIs are capable of doing many things. FHIR is the best candidate to solve many problems. Halamka said that action on the recommendations is required. He repeated the six recommendation headings (listed above). He observed that DSN can be used to refer to different things.

Discussion

Kennedy wondered how a public API would improve the underlying use case. Interoperable data are more important than a public API. More emphasis on data architecture is needed. ONC could help with an overlying data architecture. McCallie explained that FHIR defines resources, which make up architecture. The profile is the data architecture that moves across the wire. What is done within a system is another matter. FHIR profiles are easy to change. Tripathi said that the recommendation is to focus on a narrow set of profiles and to build from the bottom up. The core set can be expanded.

Bechtel asked whether DSNs exist today. Tripathi explained that DSNs can be an entity or an arrangement. CommonWell and Epic CareEverywhere are examples. FHIR is a new HL 7 standard that addresses APIs. Bechtel announced that she disagreed with delaying stage 3 incentives. She said that she understood the logic of the recommendation, but was concerned about the implications outside of these recommendations. As a result, she said that she could not support the set of recommendations as long as that item was included. Tripathi reminded her that meaningful use and certification are decoupled. The recommendation is "should consider". Halamka reminded her that there are no incentives in 2017; penalties kick in at that point.

Cris Ross asked whether there is one API to be used everywhere. McCallie referred to the appendix of the report. When there is a need to do more than can be done by the core API, the same approaches can be used. FHIR is self-expandable. The core API is the minimum necessary. There are many APIs, several of which could be in the core. In response to another question about the alignment of market activities, Tripathi said that market demand has changed in the past few years. Providers are demanding interoperability.

Halamka asked that members limited their comments to one question. Kelly Hall supported continuing consumer work and innovating. McGraw asked about vendors that built to the spoke of the wheel. How would the transition be managed? She indicated that a discussion in the JTF on the topic was not referenced in the report. McCallie said that many vendors have APIs. They would need to have some agreement on a set of APIs. Certification would be a mechanism for alignment.

Jeremy Delinsky observed that this would be a profound change for providers and would change what data look like to providers. This would allow incorporation of outside data. The effort currently required to consume a document is tremendous and this would reduce the effort. Behaviors to measure could expand.

Harrell, a member of the JFT, declared that recommendation # 1 is so important. Exchange is essential for the goals of HITECH. Interoperability was put off in stages 1 and 2, but it must be done in stage 3. Halamka reminded members to be brief.

A member expressed concern with transition planning, operational disruptions, and burden. She suggested that language be added to describe the consideration of these concerns and how FHIR may be an appropriate solution.

Lansky said that he felt queasy about replying on the market. The first and sixth recommendations are the most important in that they suggest a role for government. More dialogue with purchasers, including the government agencies, is needed. The quality use case should be described as a primary use case.

Egerman indicated agreement with Bechtel. He was also concerned about the urgency of creating APIs for stage 3. There is a lack of experience with what will work. For instance, everyone was originally excited about Direct, but to date the results are not good. Consumers is a tricky area. No one knows what consumers will want. Experience in designing consumer systems is lacking among the members. Halamka responded that in stage 3 attestation and certification are decoupled. McCallie emphasized that the recommendations are not saying design consumer systems. Tripathi added that app developers say that they cannot design in the current standards environment. With DSNs in place the market can take more accountability.

Reider pointed out that it would be helpful in the transmittal letter to ONC to give examples of what APIs would offer. He told them to be explicit and precise and to describe what it will look like, read like and write.

Malec, a member of the JTF, observed that the recommendations contained too much abstraction. He proposed that the first recommendation be modified in the third sub-bullet listed on the slide to say that CMS and ONC should consider the overall time burden. He said that such a change would remove Bechtel's and Egerman's objections. Halamka said that it was a friendly amendment and accepted it.

Andy Wiesenthal pointed out the importance of implementing the recommendations pertaining to DoD and VA procurements. This is an opportunity within the next 12 to 18 months that must not be missed. Rishel observed that for the past 15 years the approach has been to define data architecture from the top down. FHIR defines data architecture bottom up. This is an opportunity to put that into practice.

Halamka said that it was time to vote on the recommendations. He repeated the six general themes: focus on Interoperability: ONC and CMS should re-align the MU program to shift focus to expanding interoperability, and initiating adoption of Public APIs; industry-based ecosystem: A coordinated architecture based on market-based arrangements should be defined to create an ecosystem to support API-based interoperability; data sharing networks in a coordinated architecture: The architecture should be based on a coordinated architecture that loosely couples market-based data sharing networks; public API as basic conduit of interoperability: the public API should enable data- and document-level access to clinical and financial systems according to contemporary internet principles; priority API services: core data services and profiles should define the minimal data and document types supported by public APIs; and government as market motivator: ONC should assertively monitor the progress of exchange and implement non-regulatory steps to catalyze the adoption of public APIs. Along with the friendly amendment to take into account development burden in setting time lines, he said that these are general principles with much remaining work for the FACAs for 10 years. He asked about objections to the general themes. He said that the amendment would give latitude to ONC regarding consideration of development time lines. In response to comments heard in the background, Tripathi pointed out that the statement to which the so-called friendly amendment applied contained the term should consider. That is, no specific action is being recommended. Halamka said the amendment is that ONC should consider total development burden in its time lines as initiatives are rolled out. Bechtel requested confirmation that there was no reference to a delay of stage 3. Reider talked about two concepts—a set of technical capabilities that could be represented in certification and motivators and incentives that could apply to various programs. The FACAs have a broader scope than meaningful use. Bechtel proposed saying that CMS and ONC should consider mechanisms to accommodate an accelerated process for a feasible initial public API specification. Halamka asked for objections to Bechtel's change.

None were heard. A member referred to a principle of the roadmap that standards not be recommended without testing. She wondered whether they were voting on FHIR. Halamka assured her that they were not. Hearing no objections, he declared that there was consensus to approve the recommendations.

> **Action item #1: The recommendations of the JTF with were approved without objection for submission to ONC as stated with an amendment that CMS and ONC should consider mechanisms to accommodate an accelerated process for a feasible initial public API specification.**

Additional Comments

Reider recognized a long list of achievements by and thanked Doug Fridsma, as well as Judith Murphy, both of whom are leaving ONC. DeSalvo thanked them for their work.

Recap and Next Steps

Galvez said that it is clear from the presentations that there is a sense of urgency on interoperability. Trade-offs and difficult decisions are ahead. The roadmap is about people and technology support for people and their health. The Interoperability and HIE Workgroup will look at the recommendations on governance and JASON and how to incorporate them into the roadmap. Final recommendations will be presented to the HITPC in December. The next version of the roadmap will be released for comment in January. Other workgroups may wish to comment at that time. DeSalvo thanked everyone for leaning in.

Public Comment

David Tao, ICSA Labs, commented on the roadmap. He said that usability and usefulness were missing. Usability has an importance influence on safety. The Implementation, Usability and Safety Workgroup should consider the safety of information being exchanged, including what information should be selected, transmitted, and searched. More guidance is needed. The roadmap should commission guidance on what information clinicians need.

Eric Helfin, Healtheway, cited several examples of public private governance structures that work. Full stakeholder representation must be ensured. There are already public APIs in use, which the JTF did not recognize. There is risk in the rush to FHIR. Best practices not being followed at the national level. Detailed national use cases must be designed against which to measure FHIR.

Diane Jones, American Hospital Association, commented that hospitals share ONC's vision for interoperability. Her organization submitted written comments on the roadmap. She listed several topics with which her association is particularly concerned. The lack of a universal patient identifier must be addressed. Networks that include patient and provider directories are needed. Providers are being pressured to share and move information across system boundaries; interoperability is essential. The roadmap should prioritize its recommendations and take a realistic timeline into account.

Mari Savickis, American Medical Association, commented on physicians' concerns about the protection of patient data. There is often confusion about legal requirements. Requirements should be stated in plain language. OCR should be engaged. There is confusion. She said doctors want interoperability and that she is encouraged by the JTF recommendations. Stage 3 regulations should be dialed back. The use of public APIs will drive down costs. The AMA has groups working on some of these topics and wants to be a constructive partner. The AMA recently posted on its web site a document describing eight priority areas.

SUMMARY OF ACTION ITEMS:

Action item #1: The recommendations of the JTF with were approved without objection for submission to ONC as stated with an amendment that CMS and ONC should consider mechanisms to accommodate an accelerated process for a feasible initial public API specification.

Meeting Materials

Agenda
Summary of September 2014 meetings
Reports and presentation slides
Select letters and comments

HITSC Meeting Attendance

Name	10/15/14	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14
	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	X		
James Ferguson	X	X	X	X	X	X	X	X
Jeremy Delinsky							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

HITSC Meeting Attendance, continued

Name	10/15/14	09/10/14	08/20/14	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14
Keith J. Figlioli	X	X				X		X
Kim Nolen		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	
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**	**22**	**23**	**22**	**24**	**21**	**23**	**24**

HITPC Meeting Attendance

Name	10/15/14	09/03/14	08/06/14	07/08/14	06/10/14	05/08/14	05/07/14	05/06/14
Alicia Staley			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		X			
David Kotz	X	X	X		X			X
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			X
Joshua M. Sharfstein			X					X
Karen Desalvo	X	X	X	X	X			X
Kim Schofield		X	X	X	X			
Madhulika Agarwal			X					X
Marc Probst	X	X	X	X	X		X	X
Neal Patterson	X	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			
Thomas W. Greig		X	X	X	X			X
Troy Seagondollar	X	X	X	X				X
Total Attendees	**13**	**16**	**19**	**16**	**15**	**2**	**3**	**19**