HIT Policy Committee
FINAL
Summary of the August 11, 2015, Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) meeting and called the roll. She reminded the group that this was a Federal Advisory Committee Act (FACA) meeting being conducted with opportunity for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking.

Remarks

National Coordinator and HITPC Chairperson Karen DeSalvo thanked the members. The Strategic Plan and the Interoperability Roadmap will be finalized and published this fall.

Review of Agenda

Vice Chairperson Paul Tang noted the agenda items. The agenda was distributed in advance of the meeting. He asked for a motion to approve the summary of the June 30 meeting as circulated. A motion was made and seconded. The motion was approved unanimously by voice vote.

> **Action item #1: The summary of the June 30, 2015, HITPC meeting was approved unanimously by voice vote.**

Data Update

Vaishali Patel, ONC, showed slides and reported on the interoperability across non-federal acute care hospitals and the draft interoperability measurement framework. According to a survey conducted in conjunction with the American Hospital Association, in 2014, 97% of hospitals reported using certified EHRs, and 75% had a basic EHR system. About 76% exchanged some information with ambulatory care providers or hospitals outside of their networks. These numbers represent a significant increase over previous years. Only 23% of hospitals are finding, sending, receiving, and using data electronically. Hospitals that conduct more interoperable exchange have higher rates of information electronically available at the point of care from outside sources and settings than do hospitals that exchange less information. Hospitals' top barriers to interoperability relate to technical issues and to a lesser extent operational and financial issues. The primary technical barriers are due to exchange partners' lack of capacity. Patel concluded with several detailed and colorful slides that depicted nationwide interoperability in 2016–2017 and post-2017. She pointed out key milestones that will form the basis for measures. Roadblocks and barriers will also be measured. Key concepts to measure in the near term include sending, receiving, and using information across organizational and geographical boundaries and

the availability of and use of information at the point of care for both providers and consumers. Longer-term measures are expected to focus on outcomes that are sensitive to interoperability.

Q & A

In response to a question about exchange partners, Patel explained that although hospitals may have capability to exchange information, other community providers, such as long-term care and behavioral health providers, are less likely to be able to do so. Currently, information on the prevalence of exchange is based on surveys and the meaningful use incentive program. The staff is attempting to identify sources of national-level transactional data.

Troy Seagondollar inquired about exchange across vendor platforms and methods of transmission of the summary of care. Patel indicated that data on the transmissions of summaries of care is being analyzed. No information on hospital-to-hospital exchange when different vendors are involved has been collected.

Gayle Harrell expressed concern that only 23% of hospitals report true interoperability, which is not a good result considering the money expended. She hopes that the next survey will collect more detailed information on barriers. Patel responded that there is not a good source of national data on the exchange capability of long-term care and behavioral health providers. ONC is attempting to work with SAMHSA to collect data on their grantees' capacity. Although the annual survey of office-based physicians asks general questions on barriers, it would be difficult to get too technical with responders.

Anjum Khurshid asked about the collection of quality measures and outcome data. Patel repeated that such data will be defined and collected in the post-2017 phase. Some research is currently underway on quality and outcomes at select sites.

David Lansky acknowledged that progress has been made with exchange. However, ONC is using an overly EHR-centric approach. Nothing seems to be planned for a longitudinal record and cost information from multiple data sources.

Kathleen Blake suggested that the survey of office-based physicians be directed to practice managers who should be able to respond to technical IT questions. She went on to say that future surveys would be most useful when directed to the large proportion of providers using mixed methods of exchanging information. These providers may be a good source for the identification of problems and barriers to interoperability.

Big Data Report

Privacy and Security Workgroup (PSWG) Co-Chairperson Stanley Crosley showed slides and presented recommendations. He explained that the workgroup was asked to consider privacy and security issues and potential harmful uses of big data. He reminded committee members that his report at the June meeting had described preliminary recommendations. Comments at that meeting were used to finalize the recommendations, which were presented in two forms: a 39-page report prepared by MITRE Corporation and a transmittal letter to DeSalvo. Crosley presented these recommendations:

Address Harm, Including Discrimination Concerns

- Encourage ONC and other federal stakeholders to promote more public inquiry to understand the full scope of the problem—both harm to individuals and communities.
- Policymakers should continue focusing on identifying gaps in legal protections against what are likely to be an evolving set of harms from big data analytics.
- Policymakers should adopt measures that could increase transparency about actual health information uses.
- Policymakers should explore how to increase transparency around use of the algorithms used in big health analytics, perhaps with an approach similar to that used in the Fair Credit Reporting Act.

Address Uneven Policy Environment

- Promote Fair Information Practice Principles–based protections for data outside of HIPAA:
    - Voluntarily adopted self-governance codes of conduct. In order toTo credibly meet the requirements of both protecting sensitive personal information and enabling its appropriate use, codes must include transparency, individual access, accountability, and use limitations.
    - HHS, the Federal Trade Commission (FTC), and other relevant federal agencies should help guide such efforts to more quickly establish dependable "rules of the road" and to ensure their enforceability to build trust in the use of health big data.
- Policymakers should evaluate existing laws, regulations, and policies (rules) governing uses of data that could contribute to a learning health system to assure those rules promote responsible re-use of data to contribute to generalizable knowledge.
- Policymakers should modify rules around research uses of data to incentivize entities to use more privacy-protecting architectures, for example, by providing safe harbors for certain behaviors and levels of security.
- To support individuals' rights to access their health information, create a "right of access" in entities not covered by HIPAA as part of the voluntary codes of conduct; also, revise HIPAA over time to enable it to be effective at protecting health data in the digital age.
- Educate consumers, health care providers, technology vendors, and other stakeholders about the limits of legal protection; reinforce previous PSWG recommendations.
- Leverage most recent PSWG recommendations on better educating consumers about privacy and security laws and uses of personal information both within and outside of the HIPAA environment.

Protect Health Information by Improving Trust in De-Identification Methodologies and Reducing the Risk of Re-Identification

- OCR should be a more active "steward" of HIPAA de-identification standards.
    - Conduct ongoing review of methodologies to determine robustness and recommend updates to methodologies and policies.
    - Seek assistance from third-party experts, such as the National Institute of Standards and Technology.

- Urge development of initiatives or programs to objectively evaluate statistical methodologies to vet their capacity for reducing risk of re-identification to "very low" in particular contexts.
- OCR should grant safe harbor status to methodologies that are proven to be effective at de-identification in certain contexts to encourage use of proven methodologies.
- OCR should establish risk-based de-identification requirements in circumstances where re-identification risk has been lowered.

Support Secure Use of Data for Learning

- Voluntary codes of conduct that also address robust security provisions should be developed.
- Policymakers should provide incentives for entities to use privacy-enhancing technologies and privacy-protecting technical architectures.
- Public and private sector organizations should educate stakeholders about cybersecurity risks and recommended precautions.
- Recommendations made by the Privacy and Security Tiger Team and endorsed by the HITPC in 2011 with respect to the HIPAA Security Rule should be leveraged.

Discussion

Tang referred to the report as outstanding. David Kotz observed that the report is eagerly awaited by NIH staff working on precision medicine. In response to a question about the probability of success of a voluntary process, Crosley responded that the federal agencies can be persuasive regarding codes of conduct. The expectations would be consistent. Once voluntary codes are agreed to, the FTC is responsible for enforcement. Seagondollar asked about re-identification of data. Crosley responded that the recommendations call for the right of individuals to be informed of how data are used and robust restrictions on the re-identification of data. Lucia Savage, ONC, explained that the concern is that when de-identified data sets are combined, it may be possible to re-identify the individuals.

Hearing no additional questions, Tang asked for a motion to approve the recommendations. It was moved and seconded to approve them.

> **Action item #2: The PSWG recommendations on big data were unanimously approved as presented by voice vote.**

Safety Program Update

Andrew Gettinger, ONC, showed slides and reported on the safety collaboratory roadmap initiative. In 2014, ONC contracted with RTI International to provide a roadmap for three major considerations: the definition of potential activities that a safety collaboratory would support, how the collaboratory might be operated and governed to include active participation from both the private and public sectors, and what funding mechanisms would best align with a successful and sustainable collaboratory. RTI convened a multi-stakeholder task force that met multiple times between December 2014 and April 2015. The task force membership consisted of representatives of ONC, CMS, FDA, Federal Communications Commission, AHRQ, and from private sector stakeholders. They agreed that the collaboratory would have the following limitations:

- Will not engage in direct investigation or surveillance.
- Will not include operating or funding the operations of a PSO.
- Will not include direct data collection.
- Will not include performing functions of federal advisory committees.
- Will not include activities that are exclusively the responsibility of federal entities, and, therefore, cannot be delegated to outside parties, such as the exercise of regulatory authority, establishing government programs, and decision-making related to federal budget expenditures and priorities.

The task force determined that the safety collaboratory will have three essential and non-redundant functions: to convene, to support research, and to disseminate. As part of the convening function, it would assemble stakeholders to find solutions in high-priority HIT safety areas. Under the research function, the collaboratory would support and inform the development of solutions to high priority issues through scanning and assessing existing analysis related to HIT safety, identifying gaps, and subsequently supporting the development of best practices, tools, interventions, and educational resources to fill those gaps. The roadmap describes an operational model supported by a federally funded host organization and led by an executive director. Supporting the executive director is an advisory board, made up of selected public and private sector members. The advisory board serves to direct and prioritize the activities of the collaboratory. Workgroups, also composed of public and private sector members, would be convened as major focus areas are defined by the advisory board. With support and input from collaboratory staff, workgroups would produce products such as solution or educational resources for review and approval or endorsement by the advisory board and executive director. Gettinger delineated three phases. Year 1 is start-up with seed funding through a cooperative agreement to the host organization. In-kind support would come from collaborators and members. In years 2 and 3, federal funding and in-kind support would continue with financial support from other sources initiated. During years 4 and 5, federal funds would taper off as other funding sources are initiated and increased. Staff estimates the cost for full operation across 5 years at $17.8 million to $20.6 million. For additional funding details, including the number and level of staff and other supporting costs included in the funding estimates as well as alternate funding models, see www.healthitsafety.org.

Q & A

Tang wondered what would change without new ways of gathering data other than by PSOs. Gettinger said that ways could be designed so that PSOs could share data. The National Transportation Safety Board's model could be replicated. Task force members were concerned about federal agencies having information and believe that a private sector organization is the better approach. ONC and its partners must consider a collective response. Congressional funding and possibly additional authority will be necessary.

Harrell asked about governance and protection of information. Gettinger said that he anticipates that the hosting organization would work this out as its initial project. ONC's project with the Joint Commission on sentinel surveillance could be a model. Legal constraints will be required. He repeated that congressional funding by authorization or appropriations will be required. The 2015–2016 ONC budget request includes funds to get the project underway. The cost can be shared with other agencies. Eventually, the collaboratory should be self-sustaining. The general approach is one of no regulatory component and no blame. Regarding the likelihood of non-federal funding, Gettinger indicated that task force members believe that monies can be raised from companies, developers, and grant-making organizations. Some continued government support may be needed. Individual organizations could have fewer safety events as a result of collaboratory activities and, therefore, may be willing to contribute to its operations.

Blake referred to a Brookings Institution report on a national safety surveillance program that described similar sustainability issues. The return on investment would vary across stakeholders. A robust analysis is required for stakeholders to justify expenses of participation.

CMS Inpatient Prospective Payment System NPRM

Quality Measure Task Force (QMTF) Chairperson Blake presented recommendations on the 2016 CMS proposal in three areas: appropriate use criteria (AUC) for radiology CDS, revision of CEHRT to require eCQM reporting using CMS' QRDA IG, and a meaningful use measure for accountable care organizations. The following recommendations were presented:

AUC Principles:

- Ordering professionals should be able to use certified HIT demonstrating applied usability principles to access approved AUC for advanced diagnostic imaging seamlessly at the point of care.
- Certified HIT should support APIs as a means of gaining access to approved AUC that are updated regularly, in keeping with guideline updates, and delivered through certified HIT tools.
- Certified HIT should enable users to easily switch between approved AUC content providers.
- Certified HIT should allow capture of additional information within established workflows, about why AUC were not followed, and to support continuous quality improvement and provide meaningful performance feedback that promotes learning, improves clinical decision-making, and enables further refinement of decision support tools over time.
- Certified HIT should display seamless actionable recommendations to clinicians based on third party data derived from AUCs.
- AUC should be available in standardized formats that can be consumed by any certified HIT application.

ONC and CMS will need to focus on:

- Currently available CDS standards may not be ready to serve these needs today. ONC should continue supporting pilot testing to assure standards will be more mature when needed.
- An API should be required at minimum. A link to a hosted service embedded in the EHR may serve as a robust complement to a decision support standard.
- ONC should anticipate the challenges of addressing potential differences between AUC guidelines developed by multiple organizations.

The CEHRT definition should be revised as proposed to require providers to possess technology that can report eCQMs using industry standards (QRDA Cat I and Cat III) *and* in the form and manner of CMS submission (according to the CMS QRDA IG).

Meaningful Use Measure for Accountable Care Organizations

- The task force supports the direction of future expansion of the measure, to include more eligible providers when platforms are usable and have achieved the necessary level of interoperability, as a strategy for ensuring that more providers are being incentivized and rewarded to use more advanced functionality.
- The current measure does not provide incentives to innovate. The task force supports updating the current measure to motivate and reward providers who have achieved higher levels of meaningful use.
- The task force recommends additional measures focusing on the use of HIT to align with improving patient outcomes. Recommendations include measuring:
    - Preventable harms
    - Re-admission rates
    - Timely and reliable closing of the referral loop as one category of care transition between providers
    - Medication reconciliation during transitions of care
- This is an area of great need for innovation and support for APIs during early stages of development.
- A technical requirement to demonstrate accurate and automatic collection of data during process of care should be included.

Discussion

Tang requested clarification of the first recommendation on AUC. Blake explained that the recommendation is for certification of AUC developers, not for the AUC themselves. This is not an area for the federal government to do itself. Developers need to agree on the frequency of look-backs to stay abreast of medical evidence. Tang pointed out that certification of developers would be different from the current approach of certifying EHR products. The recommended approach seems to focus on HIT being able to incorporate AUC standards and goes further than the current approach. Blake explained that the task force deliberated on the challenges involved with integration and supports a cloud-based strategy. It would be unwieldly for every EHR to have to develop an integration strategy. Tang asked for members' opinions on this new approach.

Lansky referred to concern with a lack of standardization of CDS. CMS is required to identify a library of AUC standards by April 2016. Perhaps it would be better to focus on an aggressive set of recommendations to use for the April 2017 standards. Blake referred to protections, saying that the statutory requirement is specific to advanced diagnostic imaging. Although much AUC development is underway, the two subject matter experts provided by ONC advised that the readiness of AUC content varies. There is no agreed-upon standard for periodic updates. Access to a good content library should be the focus.

Seagondollar said that he supports APIs, but he was concerned about their use in CDS: What happens when a network system goes down? Blake explained that the statute excludes the requirement for CDS use by emergency medicine providers. Although the ordering provider is required to apply the criteria, the performing provider is only required to report results.

Tang said that a cloud-based approach means looking for a plug-in. The development of the necessary standards is at a very early stage. A cloud-based CDS server is not currently available. Insofar as the various components are in motion, he indicated that he would only be comfortable if the recommendation were phrased in terms of a vision. Blake did not object, but she pointed out that CMS

is required to take the first steps next year, and the task force had considered what to do to meet the required time deadline. Tang talked about standards and format standards to provide a base for execution. Blake agreed to a modification of the recommendation to refer to a vision. Seagondollar agreed. Tang told Blake to reframe the recommendation in terms of a vision for automation in the future. Blake agreed. Tang requested a motion to that effect. It was moved and seconded to accept the recommendations as modified by Tang. The motion carried unanimously by voice vote. Blake will work with staff on the modification language, which will be submitted to Tang for his approval.

> **Action item #3: It was moved and seconded to accept the recommendations of the QMTF on the CMS prospective payment NPRM as modified by Tang. The motion carried unanimously by voice vote.**

Public Comment

An unnamed attendee wrote:

> Regarding the AUCs, the HIMSS Standards and Interoperability Committee worked to agree/disagree and or recommend standards to be followed. In order to measure this, it is important to use established metrics which are recognized by specific national entities (Radiology, CV, Trauma, etc.). I think the "cloud" is too fluid, and cannot be vetted in real-time to be reliable for a national effort to utilize effective diagnostics.

SUMMARY OF ACTION ITEMS

> **Action item #1: The summary of the June 30, 2015, HITPC meeting was approved unanimously by voice vote.**
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> **Action item #2: The PSWG recommendations on big data were unanimously approved as presented by voice vote.**
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> **Action item #3: It was moved and seconded to accept the recommendations of the QMTF on the CMS prospective payment NPRM as modified by Tang. The motion carried unanimously by voice vote.**

Meeting Materials

- Agenda
- Summary of June 30, 2015, meeting
- Presentations and reports slides
- Draft transmittal letter to ONC

MEETING ATTENDANCE

Name	08/11/15	06/30/15	05/22/15	05/12/15	04/07/15	03/10/15	02/10/15
Alicia Staley						X	
Anjum Khurshid	X	X	X	X	X	X	X
Aury Nagy							
Brent Snyder	X	X	X	X			
Chesley Richards	X				X	X	
Christoph U. Lehmann	X			X	X	X	
David Kotz	X	X			X	X	X
David Lansky	X	X	X	X	X	X	X
Devin Mann						X	X
Donna Cryer	X	X	X	X			
Gayle B. Harrell	X		X	X	X	X	X
Karen DeSalvo	X	X	X	X		X	X
Kathleen Blake	X	X	X	X			
Kim Schofield	X	X	X		X		X
Madhulika Agarwal		X			X		
Neal Patterson				X	X		X
Paul Egerman			X	X	X	X	X
Paul Tang	X	X	X	X	X	X	X
Scott Gottlieb			X		X		X
Thomas W. Greig		X			X	X	
Troy Seagondollar	X	X	X	X	X	X	X
Total Attendees	**13**	**12**	**12**	**12**	**14**	**13**	**13**