Health Information Technology Advisory Committee

Meeting Summary March 21, 2018

VIRTUAL

The March 21, 2018, Health IT Advisory Committee (HITAC) was called to order at 10:00 am ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

ROLL CALL
(Members in attendance, representing)
Carolyn Petersen, Individual, HITAC Co-Chair
Robert Wah, DXC Technology, HITAC Co-Chair
Christina Caraballo, Get Real Health
Tina Esposito, Advocate Health Care
Brad Gescheider, PatientsLikeMe
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, RelayHealth
Denni McColm, Citizens Memorial Healthcare
Aaron Miri, Imprivata
Brett Oliver, Baptist Health
Terrence O'Malley, Massachusetts General Hospital
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Sasha TerMaat, Epic
Sheryl Turney, Anthem BCBS
Denise Webb, Marshfield Clinic Health System
Cynthia A. Fisher, WaterRev, LLC

Federal Representatives
Ram Sriram, National Institute of Standards and Technology
Lauren Thompson, Department of Defense/Department of Veterans Affairs

Members not in attendance
Michael Adcock, University of Mississippi
Clem McDonald, National Library of Medicine
Patrick Soon-Shiong, NantHealth

Andrew Truscott, Accenture LLP
Chesley Richards, Centers for Disease Control and Prevention
Kate Goodrich, Centers for Medicare and Medicaid Services

ONC Staff
Lauren Richie, Designated Federal Officer, ONC
Don Rucker, National Coordinator, ONC
Genevieve Morris, Principal Deputy National Coordinator, ONC
Jon White, Deputy National Coordinator
Elise Sweeney Anthony, Director of Policy, ONC
Steve Posnack, Director, Office of Technology, ONC
Seth Pazinski, Director, Office of Planning, Evaluation and Analysis, ONC

Welcome Remarks –
Donald Rucker, National Coordinator (ONC)

Donald Rucker: Before we get into today's meeting, I just wanted to make sure that everybody knew about the initiative at HHS and CMS on MyhealthEData, all one word, and the Blue Button 2.0 tool for Medicare. We are building on the work of ONC and CMS and all the prior ONC coordinators in the past in next steps in getting data out. CMS is going to be releasing Medicare claims data. What is different about Blue Button 2.0, is that it is going to be using the open API, FHIR protocol. We hope to get everything on people's smart phones, as you probably have heard there is a lot of interest from the White House. Jared Kushner joined Center for Medicare and Medicaid (CMS) Administrator Seema Verma in announcing this at the HIMSS conference in Las Vegas earlier this month. Department of Health and Human Services (HHS) Secretary Alex Azar has made a number of statements about interoperability, really getting to the work of the HITAC, and that is exciting. Today, we're going to have a brief update from the U.S. Core Data for Interoperability (USCDI) Task Force, and we're going to spend more time on the Trusted Exchange Framework (TEF) Task Force recommendations. Having been on these kinds of committees and subcommittees, I want to thank everyone who has worked on this. I have read the documents that you put out so far, there is a lot of work and thought and great ideas and items that we need to do next steps on together in there. I just want to thank people.

VOTE TO APPROVE MINUTES
Carolyn Petersen (co-chair) called for a voice vote on the minutes from the February 21, 2018 meeting. A clear number of votes were in favor of the motion. There were no abstentions and none opposed.

Presentation 1: U.S. Core Data Interoperability Task Force Update –
Christina Caraballo, Task Force Co-Chair
Terrence O'Malley, Task Force Co-Chair

Terry O'Malley will be reviewing the work the Task Force has generated since its first meeting February 21. The Task Force seeks questions and comments from the full HITAC and especially those that suggest alternative recommendations.

The USCDI Task Force has had very spirited discussions that the Co-chairs have attempted to distill here. The HITAC charged the Task Force to return from its deliberations with recommendations on four specific items:

1. How to get stakeholder feedback;
2. How to propose draft data class promotion with objective criteria;
3. How much to expand the USCDI; and
4. Frequency of publication.

Today we will discuss the proposed stages for data class promotion. This was the focus of extensive discussion in our meetings, though we have much more ahead of us before we can present a consensus recommendation to the HITAC at its next meeting April 18.

Here are the Task Force's proposed categories, three old and three new:

- Stage 1: Proposed Status (new)
- Stage 2: In Preparation Status (new)
- Stage 3: Emerging Status
- Stage 4: Candidate Status
- Stage 5: USCDI
- Stage 6: Widespread Deployment (new)

This is an expanded maturation model for data classes with six rather than the three stages originally proposed in the Draft USCDI. We focus mostly on the inputs and outputs of each stage. Much of our work over the next month will be to add clarity around what happens within each stage to produce required output.

Stage 1: Proposed Status
We felt that any stakeholder should have barrier-free access to proposed data elements or classes with specific value to that stakeholder—no restrictions on who can propose or what is proposed.

The purpose is to give every stakeholder a voice and not just those with the loudest voices. A data class gets in the queue because someone proposes it. Then there is a process—that we have yet to fully identify—in which data elements or classes are aggregated to develop a data set to create value to a wider set of stakeholders. The value of the whole should be greater than the sum of its parts.

The net value of a data set is based on its cost and value to each of the stakeholders. The data sets and preliminary data classes advance out of this stage when their apparent net value is demonstrated. (In the weeks to come the Task Force will focus on out how to estimate the value using such measures as cost efficiency, value to government policy priority, value to many stakeholders, value to society, etc.)

Stage 2: In Preparation Status (new)
The purpose of this stage is to get to a much more tightly specified data class after demonstrating value. So, content, definitions, substitution where appropriate of previous standardized data elements—the work in this stage is meant to balance parsimony with the broadest use possible. This process is intended to create a data set with broad value and clear specifications, which becomes an official data class with the addition of use cases. It is then ready for limited testing in Stage 3.

Stage 3: Emerging Status
At this stage the proposed data class undergoes testing and further specification in limited settings. Testing will likely lead to further adjustments and additional clarity. Semantic interoperability and harmonization occur here. It also undergoes a final net value assessment.

The data class emerges to candidate status when it has sufficient value and is adequately specified so the interoperability can be supported. It will emerge ready for commercial deployment and testing.

Stage 4: Candidate Status
This is when a data class is ready for testing at scale in a commercial enterprise. Barriers to widespread deployment are identified and mitigated. It is now ready for deployment at scale.

Stage 5: USCDI
The purpose of the USCDI is to highlight the data class and take deployment to scale across the country using all policy levers available. Admission to USCDI alerts industry that this data class has reached priority status and will advance, called out by the CMS, HHS, and anyone else that has a lever to pull. Data classes will advance out of USCDI only when they have achieved nationwide deployment and ease of access.

Stage 6: Widespread Deployment (new)

We don't think the USCDI should be the end of the line. One of our charges was about expansion. One thing that has become apparent to the Task Force is that each of these charges requires a fairly complex dynamic to reconcile often-conflicting goals of the stakeholders. The benefits of interoperability are not shared equally, nor are the costs. It is a delicate balance we will try to engineer in the next few weeks.

Regulatory oversight will likely be necessary to push this forward. The main difference between the Task Force's recommendation and the USCDI draft is that we see expansion has been driven by the pace at which data classes can complete this process, rather than by predetermined timelines. We expect that some of the draft data classes will move through these stages faster than others.

HITAC Member Discussion – Presentation 1

Denise Webb: As we are going over Stage 1 proposed data for the USCDI process, I thought the relevance and the alignment to the permitted purposes and use cases in the TEF have to be an important criteria. There should be a balancing between the TEF and the USCDI. They work hand in hand.

O'Malley: Yes, that is absolutely essential. To extend that thought, should we propose use cases to be shared between the TEF and USCDI? To get a data class really ready to roll and use that as a test case for interoperability?

McColm: I was wondering if the committee was planning on taking the currently proposed data elements in the USCDI and pilot them through the process of assessing their value, to see how the process works?

Christina Caraballo: We did do an exercise within the Task Force where each member took a data class through the process, but we have not gone through each of the classes in USCDI. It has not been our charge to look at those specific data classes.

O'Malley: Yes, we focused mostly on the process. But in the next four weeks, that could be a useful exercise. We could take them through the process. Some will be ready to be candidates; others could need a bit more work.

Leslie Lenert: To follow up, how long does the Task Force think it will take to get a set of fundamental recommendations to Stage 4?

Caraballo: We designed the framework so there's no set timeline. We want to align it with the ISA (Interoperability Standards Advisory) and TEF, but it depends on how the data classes move through the Staging processes we defined. A set number won't necessarily make it through to the USCDI on a regular basis.

O'Malley: We can present a slide in next month's presentation that lays that out.

Aaron Miri: Depending on the technology, the cost of going through the process could be quite high. And the cost to QHINs to update technology for new data classes could also be large. Could you create a rubric that shows what the cost could be to discuss a potential class?

Caraballo: That point has come up quite a bit in our meetings.
It is part of that net value that Terry was discussing earlier. We are planning to get into more detail on that. The cost and the level of effort of getting the QHINs to be able to support the data classes is very high on our list of criteria that needs to be evaluated.

Presentation 2: Trusted Exchange Framework Task Force Draft Recommendations –

Denise Webb, Task Force Co-Chair
Arien Malec, Task Force Co-Chair

Robert Wah: Let me just start by saying thank you to Carolyn, my co-chair, who has stepped up as I have had more connection difficulties than I expected while overseas for the last meeting and for this one as well. We will now move on to the Trusted Exchange Framework and Common Agreement (TEFCA) Task Force Recommendations. There are five sets of recommendations We will hear the presentation of each, followed by a period for questions and comments, then move on to the next set. So it would be appropriate to make your comments or ask questions after each of the five presentations. At the end of all the TEF presentations, there will be a final period for questions. Then we will take a full HITAC vote on the entire bundle of Recommendations.

TEF Task Force Draft Recommendations, Part 1: Overview

Denise Webb: Our Task Force was charged with making recommendations in four areas of Part B of the TEFCA:

- Recognized Coordinating Entity eligibility requirements;
- Qualified Health Information Network (QHIN) definitions and requirements;
- Permitted Uses and Disclosures—Enhancing/clarifying the six permitted purposes and three use cases identified in the TEFCA; and
- Privacy/Security: Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?

We also provided a set of overarching, general recommendations on clarity of policy goals and definitions. My Co-chair Arien Malec will present a summary of those first.

Arien Malec: I was reminded yesterday of why this Task Force and the TEFCA charge exist. My son has a genetic disorder that causes seizures. He had a seizure, fell and was injured so we went to the urgent care clinic where his complete medication record exists. Both the Children's hospital and the urgent care clinic have a Meaningful Use Certified EHR, yet we were forced to go through the laborious process of telling them his complex medication history. Quite obviously, this is an inefficient state and unsafe state of affairs. We can achieve much lower cost, higher quality care if the digital health infrastructure that we have created is able to exchange information as a matter of course. The Task Force asks ONC to:

1. **Clarify policy goals.** The current TEFCA Draft dives into a fair amount of detail on enablements for policy goals, but it doesn't spend as much time describing those goals. That led to some confusion within the Task Force discussions. So we recommend that the ONC and the TEF should express policy goals clearly and what outcomes it wants to enable and prevent. In cases where ONC does go into a level of detail, it should first describe the high-level policy goals that back that level of detail. In general, that articulation of high-level policy goals helps reviewers and implementers ensure that we are following the high-level policy goals appropriately as we work the Framework through the process.
2. **Point to existing documentation where available and call out only specific exceptions or deviations.** For example, there were specific discussions on hashing algorithms and key links and the like, where appropriate pointers to extant documentation from earlier work (e.g., National Institute of Standards and Technology (NIST), ONC FACAs and other documents) would have been helpful. Our recommendation is that, in areas where existing policy or documentation exists, ONC and the TEFCA should point to those documents rather than duplicating that information in the TEFCA itself.
3. **Refrain from naming particular standards or particular implementation mechanisms.** Instead, it might be better for ONC to specify that the RCE work out the details of implementation in conjunction with the QHINs, Standards Development Organizations (SDOs) and Participants. A successful model for this was accomplished with the API requirements for 2015 Edition Certification and MIPS (Merit-Based Incentive Payment System).
4. **Avoid being too prescriptive. Clearly document key policy outcomes and establish clear checkpoints for evaluating whether additional guidance for the QHINs or RCE need to be established.** We note that there are some areas in the TEFCA where ONC has clearly been concerned that the market may evolve in ways that are disadvantageous for certain classes of providers. there are smaller provider organizations that may use EHR and innovative EHRs. ONC can define clear expectations expressed in terms of functional outcomes, with milestones to evaluate those expectations. Policy tools could be reserved in order to drive the right level of action if needed later if market failure or failure to align around an ecosystem that provides the public benefit ONC is seeking.

5. **Work closely with the RCE and coordinate with other Federal actors in areas where policy clarification or coordinated Federal action are critical enablers of QHIN success.** A particular example of this type of coordination is ONC's clarification with HHS Office of Civil Rights (OCR) around the form and format requirements that already exist for the Health Insurance Portability and Accountability Act (HIPAA). What OCR did was make a standards-based API-based access that has been readily deliverable to patients. That level of close coordination, particularly as we extend the permitted purposes under the TEFCA into payment, healthcare operations, quality improvement and the like, will help clarify a number of policy requirements. ONC should make sure that we have a privacy and security policy framework that harmonized standards with Federal actors such as DOD, VA, IHS and SSA, across those settings.
6. **Clarify "Single On-Ramp."** The Task Force found that the term single on-ramp, which was used multiple times in the TEFCA, caused a fair amount of confusion. A Single On-ramp is an aspirational term in the TEFCA. The enablement in the TEFCA is primarily around query-based exchange. However, a number of Task Force members would like the TEF to address specific concerns such as patient generated health data (PGHD) and allow push-based exchange, which is necessary for public health functions. We characterized the two types as Narrow Focus versus Broad Focus. The Task Force was evenly split between those two definitions and was not able to reach unanimity.
   Narrow Focus—The Narrow focus would ask the ONC to clearly define the floor capability for the on-ramp provided by QHINs to be for query-based exchanges. We don't want to imply or encourage policy constraints that prohibit QHINs from offering additional services, or for EHRs connecting to QHINs to offer a broad range of services.
   Broad Focus—The Task Force members who favored the Broad focus also were split between two different definitions, which we called 7B and 7C. The 7B defines the Single On-ramp holistically, relative to all forms of exchange. It leans toward establishing a true, Single On-ramp for multiple forms of exchange. Seven-C (7C) aligns around a Single On-ramp specific to national priority goals over the next three-year period. All of these recommendations should be taken with respect to the first three-year period that marks the RCE evaluation. The alternatives are outlined in more detail on the slides.

Discussion:
Robert Wah: I see members of the public making comments in the Chat function. I ask that they be patient and hold their comments until we are discussing the Recommendation that aligns with their comment. If I miss some, please remind me that there are other comments. We also have a lot to discuss, so we are watching time quite closely. We'll open the overarching recommendations up for discussion.

Steven Lane: On Recommendation 6, I think it is helpful to call out the differentiation between the narrow focus that was reflected in the draft TEFCA and the broader focus, which I had raised. Attempting to look at this holistically with the broad focused On-ramp will benefit us even though in the long-term it may mean some more work up front.

Aaron Miri: I would like to stress the importance of Recommendation 5, making sure we point toward harmonizing the NIST guidelines, is critical. We need to ensure that all parties speak the same language. Making sure that we can align and that we continue to stress leveraging those generally accepted criteria and frameworks is especially important.

Caraballo: I was thinking of the USCDI under the TEFCA Task Force's Recommendation 3. One thing that we could do there is point to the ISA and USCDI to address this area as well.

Malec: Later in our recommendations on permitted uses and Disclosures, we ask that ONC and the RCE elaborate on the priorities established for each of the Permitted Purposes. Pointing at the ISA and USCDI is an important callout.

Ken Kawamoto: Can you comment on the Broad Focus and the risks of misidentification of records, such as might happen with two people having the same name?

Malec: The committee did not consider that particular item. There is the possibility of accidental disclosure of information in any form of HIE. But in general HIPAA does accommodate for accidental or incidental notification, particularly in cases where the person to whom information was disclosed follows appropriate procedures. It could be addressed along the lines of our recommendation that ONC collaborate with OCR to work out the policy details.

O'Malley: Following up on the last comment, one item you might want to think about is giving priority to a data class specifically dedicated to unique individual identification. That seems to be a fundamental cog in the machine.

Malec: HIPAA allows data to be used for treatment if it is in fact the same patient. It would be helpful to the community for OCR and ONC to clarify a demographic index to define the right patient, to minimize the downstream risk of disclosure and risk of harm. This topic, however, is secondary to Task Force requirements.

TEF Task Force Draft Recommendations, Part 2: Recognized Coordinating Entity (RCE)

Webb: We are advancing three recommendations on the RCE that address the particular RCE eligibility requirements, how the ONC should judge its success or failure of the RCE, and what milestones might be used for that purpose. We propose that ONC should:

- Establish eligibility criteria for the RCE, requiring not-for-profit status, a clear sustainability model, and a governance model that balances responsibility among the national interests and the dues-paying members of the RCE. The governance model should reflect a broad range of perspectives relevant to priority use cases and permitted purposes under the TEF (Recommendation 10).
- Require the RCE, as it works on standards, implementation guidance, profiles and other enabling material to make such material open to the public without restrictions on use or reuse except as necessary to enforce certification marks or other proofs of QHIN compliance with RCE-defined requirements (Recommendation 11).
- Develop a set of outcomes-based goals, measures, and associated milestones based on expected patient and provider real-world experiences enabled through the TEF and associated RCE activities. The RCE should define a set of satisfaction user experience and process measures and metrics linked to the outcome goals and measures (Recommendation 12).

Aaron Miri: The Task Force discussed items in Recommendation 11 regarding use cases and ideas for measurements at length. I stress that it is very important for the RCE's success criteria be clearly defined. It could help mitigate risks.

Tina Esposito: Recommendation 11 is fantastic; it provides for quantitatively measuring the RCE's success. There should be some thought or discussion about how those metrics will be used, to be clear the metrics are indeed measuring performance, and to ensure outcomes are being achieved. Those metrics also could be used in the election of an RCE.

TEF Task Force Draft Recommendations, Part 3: QHIN Requirements

Malec: Members spent a fair amount of time discussing the language and enablement for participant neutrality. It caused some confusion. We recommend that ONC clarify the policy intent of this term, and define a policy goal that the overall ecosystem is neutral and accessible to all holders. ONC should not prevent data holders from offering QHIN services. We feel there are potential QHIN actors who also could be data holders. Defining the QHIN in that way potentially could limit the number or types of organizations that may want to offer services. In fact, some of the surmised concerns that ONC was trying to mitigate could be fairly trivially solved based on that particular definition. If ONC has a particular concern about participant neutral language, it may consider various ways that perspective QHINs might structure their activities to address those possible restrictions. Concerning the broker system, following our general recommendation that ONC establish the policy "Whats" and allow the RCE ad QHINs to work out the details of the technology enablement "Hows," we ask ONC to define a set of functional requirements documenting the outcomes from the perspective of provider and patient (Recommendation 13).

In addition, the Task Force proposes that ONC should:

- Define a set of functional requirements documenting the outcomes of using a QHIN from the perspective of a provider or patient. The goal of the TEF QHIN fee requirements is to establish reasonable and non-discriminatory fees for QHIN-to-QHIN interchange pricing. In particular, to allow uniform access to all permitted purposes across QHINs, the draft TEF requires QHINs to establish a QHIN-to-QHIN price of zero for some permitted purposes (patient access, public health, benefits determination) and cost-basis fees (attributable costs) for the other permitted purposes required under the TEF. As an example, the Social Security Administration (SSA) might establish or participate in a QHIN for Federal actors. The SSA is otherwise willing to pay for electronic exchange, because of the relative value of electronic exchange to paper-based chart retrieval, handling, and abstraction However, through the TEF fee structure, SSA could request and receive the same data through a Federal QHIN without paying a fee to the providers or QHINs. The combination of zero-based fee structure for QHIN-to-QHIN exchange and the duty to respond may change the market in profound ways (Recommendation14).
- Establish through the TEF the combination of zero or cost-basis QHIN-to-QHIN fee requirements with the duty to respond by QHINs, Participants and End Users only on QHIN-intermediated access required for all Participants and End Users and for reciprocal uses [where both sides of the exchange benefit and participate] (Recommendation15).
- Provide the RCE with authority to employ mechanisms to ensure QHIN-to-QHIN fees are uniform for like services at like performance SLAs and should encourage the RCE to adopt mechanisms, such as auctions that prevent against inappropriate price increases. ONC also should provide appropriate incentives for QHINs to reduce cost structures for QHIN to QHIN exchange over time (Recommendation16).
- Limit, under the TEF, zero cost basis QHIN to QHIN exchange solely to Individual Access purposes [as defined and limited following the Task Force Recommendations under Permitted Uses and Disclosures] (Recommendation 17).

Discussion

Kawamoto: Did you have any particular recommendations for the USCDI Task Force in your set of recommendations?

Malec: We do, in the permitted uses, for tracking the USCDI relative to the specific use cases associated with permitted uses and disclosures.

Wah: I want to make sure that people know the public comments in the chat line do become part of the public record of this meeting. I think it would be best, if possible, and if you have a question or want feedback directly from the Task Force chairs, to use the public comment period at the end of the meeting. If you want a comment added to the record, you can put it in the Chat area. That is how we plan to use the Chat.

Webb: A reminder that if you have comments or questions, please make them now. We will take a vote at the end of the meeting. If there is some concern you need to bring up before you are willing to vote affirmatively, it would be best if you verbally communicate that, rather than using the Chat.

Wah: Yes, it is the committee's work to approve these Recommendations, and this is our opportunity to fully discuss and comment upon them. I will echo Denise Webb's comment that now is the time to fully discuss these recommendations. I would remind the Committee that our plan is to have a vote on the entire set of Recommendations from the TEFCA Task Force at the end of this meeting.

TEF Task Force Draft Recommendations, Part 4: Permitted Uses and Disclosures

Webb: This next group has several Recommendations covering permitted uses and disclosures, and the actual exchange modality use cases, specifically broadcast query, targeted query and population-based queries. We have eight Recommendations to advance. The first three cover the individual access permitted purpose. Then there is a Recommendation on permitted uses and disclosures that are beyond individual access and treatment. After that is a general Recommendation on alignment of USCDI with these Permitted Purposes and Use Cases. Arien Malec detailed this earlier when he spoke about the use case for SSA. The last are Recommendations on payment permitted purpose and population-based queries. In general as a Task Force, we strongly endorse the requirement for individual access. At the same time, we recognize that this is an emerging space and policy and standards requirements are not clearly established. We recommend a scaled roll-in. In these categories, the Task Force suggests that ONC should:

- Clearly define “Individual Access” consistent with HIPAA such that aggregator-based access on behalf of the individual is differentiated from individuals acting on their own. Fee restrictions and duty to respond should be restricted to the case where the patient is requesting access to view, download, use or transmit data to an entity or application or utility that the patient manages and subsequent data donation should be optional and under the patient’s control (Recommendation 18).
- Make it clear the duty to respond that is an obligation on the part of other participants and end users is not an obligation on individuals (Recommendation 19).
- Ensure stakeholders (RCE, SDOs and public/private consortia) test and evolve standards implementation guidance, profiles (for identity assurance) and accompanying policies that are sufficient to enable broad-scale individual access within a time frame sufficient to meet the policy goals for individual access and other permitted purposes (Recommendation 20).
- Require individual Access and Treatment permitted uses and disclosures, with those purposes of use defined as per HIPAA. USCDI needs to be evolved in conjunction

with permitted uses and disclosures and should be aligned to the particulars of each use (Recommendation 21).

- Work with stakeholders to align USCDI with the particular needs for each permitted purpose and exchange use case, both to address additional data that may need to be collected, and to address data exchange limitation to minimum necessary standards (Recommendation 22).
- Work with stakeholders to resolve the fee disparities for the SSA disability determination use case (Recommendation 23).
- Clearly define sub-purposes of use under the broad Payment permitted purpose, and define the policy objectives. ONC should work with the RCE to establish enablement, including standards, implementation guidance, policy guidance and profiles for each of the permitted purposes for which duty to respond is required. With respect to the population-based query, the Task Force made a distinction between population access by providers and provider-aligned organizations (such as clinically integrated networks or accountable care organizations) and access by other organizations, including payers (Recommendation 24).
- Work with standards development organizations and public-private stakeholders (e.g., Argonaut Project, DaVinci Project) to define, test, collect feedback and refine standards for population-based query for provider-oriented value-based care use cases (Recommendation 25).

Discussion

Lenert: The introduction to the TEFCA framework called out specifically the use of the infrastructure for research. I have noticed there is not a specific comment on or text here on use of the network for research. Did the Task Force discuss this? Is there any plan for such a recommendation?

Webb: We had talked about some of the other actors in population-based queries, that possibly would include research. Patients are permitted to send their data to whomever they want. That could facilitate the research use.

Malec: I agree. I would also note that the Task Force charge did not ask us to address research needs with regard to the TEFCA nor was research one of explicit Permitted Purposes charged to the Task Force. It's fair to say that it is a great point but we were not asked and didn't do any specific deliberation in that area.

Lenert: On page three of the TEFCA as part of the introductory framework, ONC says it "would like to achieve a system where public health agencies and researchers can deliver cutting-edge treatment by providing access to electronic information." But the Task Force never found its way into the authorized uses of that segment. I think it should be explicitly called out as an authorized use of the national network.

Genevieve Morris (ONC): The section that you read in the introduction is the ultimate vision of where we are headed. In this draft we did not suggest research explicitly for that permitted purpose because we wanted to get feedback to determine when the industry is ready for it. We did receive a number of public comments during the comment period. We are working through those right now.

Morris: In Recommendation 20 there seems to be a conflict. It says the initial permitted purposes were for treatment only, because the others were untested and not ready for prime time. But then in Recommendation 21, you indicate that the SSA will use it for benefits determination. You say it is well tested and applaud its inclusion.

Malec: The Task Force members noted that the permitted purpose is well established and well aligned but the consolidated CDA and current U.S. CDS, (Core Clinical Data Set) is insufficient for the SSA use case. That is where the issue lies in most cases. Those that respond to the SSA determination do so using the SSA's CDA Guide. It calls for additional information over and above the USCDI.

Morris (ONC): The ultimate recommendation there is that the benefits determination not include permitted purpose because the minimum USCDI requirement does not meet all of their needs? Is that what you are recommending?

Malec: In general, we are not making recommendations about prioritizing permitted purposes. We are making more explicit recommendations that certain permitted purposes have all of their technology enablement ready to go. In other cases we are recommending that specifics need to get worked out for the SSA case. The permitted purpose is worked out, the technology enablement is worked out, but the USCDI needs to be aligned to make sure that the data is available for SSA.

TEF Task Force Draft Recommendations, Part 5: Privacy and Security

Arien Malec: (Recommendation 26) We had a fair amount of discussion on individual consent, or what the Privacy and Security Tiger Team (2010-2013) previously called "Meaningful Choice." There are a number of people who have been hoping for some superset of individual choice requirements that would meet or satisfy the needs of all states and localities**.** It was the Task Force's belief that there is no one universal superset that could cover every locality. Nor is it possible for ONC or OCR to establish such a need because state law and regulation may change. In general, we noted the best practice in this area is to push the obligation to achieve Meaningful Choice down to as close as possible to the patient.

Regarding Recommendation 27, we had a fair amount of discussion toward the end of our deliberation around questions such as, "What happens when a patient makes data

available? It flows into a provider organization and what happens to it if flows into the QHIN? Some are looking for ONC to provide a magic linking thread. We didn't have the time or the expertise to answer those questions, so we punted to ONC and HHS OCR to address them. Our recommendation is that ONC should share all the information it has available to the RCE but not lock down specific requirements for patient education or patient matching. As to specific requirements for identity assurance, for certificates, cyphers and the like, the Task Force points back to our overarching recommendations that ONC use established policy or assign the details to the RCE to address.

Kawamoto: In Recommendation 25, a can you clarify how the practices are already defined?

Malec: There is an established practice, and we see this for e-prescribing networks, for existing work from Commonwell, from national HIEs across state boundaries. And the success practice in this area—call it a coordinated punt—establishes through language the obligation on provider organizations to appropriately follow state and local regulations for supplying and authorizing patients for index and data retrieval.
As an editorial note, States' opt-in language varies. And there's no uniform way of establishing requirements. There is not even a universal opt-out language. So we recommend to flow it down to the providers in the patients' locality so the opt-in would meet local and State laws.

Kawamoto: So the Federal government, HHS and ONC do not have the authority to define a standard?

Malec: HIPAA establishes a national floor for patient privacy, but States can go beyond that floor. HHS OCR and other Federal agencies have no authority to establish a ceiling for activity in this area.

Morris (ONC): Yes, that is accurate. Where state law sets a higher bar than HIPAA (Health Insurance Portability and Accountability Act), we don't have the authority to change that. We do have some leeway for exchanging that consent information.

Aaron Miri: We are asking for more clarification, continuing on the great work that the ONC and OCR in previous advisory committees did, of identifying where the overlap is in the various use cases. I would point to the API Advisory Committee from April 2016. There, each use case was laid out with the jurisdiction under which it fell. Those are from real-world applicability cases. This can get tricky, depending on the use case. We are looking for and recommending development here.

The other comment I want to make is on Recommendation 26 regarding the individual identity assurance. This is another one of those items that points to the universal framework, so that everybody is following the rules and working together.

Malec: We do point to the 2016 API Task Force and the ONC Playbook. There is an ever-expanding circle of guidance here. In some cases, the issue is pointing to it and finding it, not whether it exists in the first place. But there's a lot to read here.

Kawamoto: Patient demographics, for example from credit reports, could be used to match data from a State to see whether a patient had lived there. There's a lot of focus on forgetting data, but I think it would be good to make sure that we don't accidentally pull the wrong data. We don't want the providers to make wrong decisions based on inappropriate data.

Malec: We did not specifically discuss that in the Task Force. I would refer to the ONC Playbook to provide adequate background on best practices for data handling that allows proper matching. ONC has done some data matching challenges and put a report out on them. There is a fair amount of information on HIT.gov. I have commented to ONC in the past that it's not that ONC has not done the work, but that there is so much work already done; now it is just a cataloguing and indexing problem.

Kawamoto: I like the initial comments on making functional requirements clear. One suggestion for data matching—it would be useful to ask what is the expectation from government on how accurate that should be? For a hypothetical example, that it happens in 1 out of 1,000 patients, or 5 in 10,000.

Sasha TerMaat: There are a lot of issues we might have discussed within the Task Force but didn't have a chance to because of the ONC directives and time constraints. But, as noted on Slide 36, we did not discuss potential different alternatives to the model proposed in the TEFCA draft. There was not conversation about alternatives to the RCE structure with QHIN networks nor comparisons of other possibilities that might have been implemented under the 21ST Century Cures Act. There is openness in the Act that might have permitted that.

Caraballo: You point out that individual access is a principle, but the framework does not specify how patients and other individuals will participate fully and equally to access information. We should recommend that ONC ensures there is a dedicated QHIN that advocates for individuals as its main constituency. It wouldn't necessarily have patient access as one of its functions.

Malec: I want to point out with regard to the patient and individual access, the current recommendation does not go in that direction. It recommends that the RCE fully establish and represent the patient point of view. The overall ecosystem should be responsive to the needs of patients, as well as multiple provider organizations. I think the idea is captured in the Task Force recommendations, it's just not that specific.

Steven Lane: I believe patient access will end up coming through multiple QHINs, and they should all need to be sensitive to that use case. I imagine that there will be more than one QHIN that has, as a primary purpose, the patient access use case. The market likely will provide that.

VOTE ON TEFCA TASK FORCE RECOMMENDATIONS:
Carolyn Petersen (co-chair) called for a voice vote on the entire set of recommendations from the TEF Task Force. A clear number of votes were in favor of the motion. There were no abstentions and none opposed. The Recommendations will now be passed on to the National Coordinator.

Public Comment

Leslie Kelly Hall: I would like to echo Christina's comment about defining patient advocacy and sponsorship throughout this work. There isn't a natural sponsor for patients, either In terms of influence or commercial sponsorship to advocate for particular standards or for operability. I encourage ONC to take on that role. Electronic access without explanation places a continued burden on physicians. As a former CIO, when I provided access to patients including open notes, calls to the physicians increased by 30 percent within a week. The burden was overwhelming. When we added patient education, the calls went down 12 percent from before the open notes change. This is important for patients' ability to understand their care. The National Library of Medicine (NLM) provides this free and there are commercial offerings as well.

Erin Richardson, Federation of American Hospitals—One recommendation that the Federation put forth is that there are many outstanding issues in the TEFCA, and core questions, so we would like to see a second draft before the TEFCA goes final.

The following public comments were made in the Chat window during the meeting:

Thompson Boyd: In the Annual Release of the USCDI, may wish to include a discussion of the Standard's "Adoption Level" and the Standard's "Implementation Maturity".

One also needs to consider the operations of HINs having a narrow [financial] margin. Such HINs may be serving Providers and other Stakeholders in Rural and in Under-served areas. Increasing the financial and the regulatory burden of such HINs may result in some of these HINs going out of business, leaving Providers and other Stakeholders devoid of important services provided by the HIN. Thank you.

TEFCA Recommendation Letter (16-pages): Page 1: Section 1.2.4 Privacy and Security, would edit as: Are there standards or technical requirements that ONC should specify for identity proofing, authentication, and authorization particularly of individuals, particularly

of individuals. Page 12, line 4, would change "...performed identity assurance and authentication..." to "performed identity assurance, authentication, and authorization"

One should add clear language in the TEFCA that the Recognized Coordinating Entity (RCE) should not have incentives, should not have policies nor procedures that promote or encourage Information Blocking. Philadelphia, PA.
--Thank you, Thompson Boyd MD. Hahnemann University Hospital. Philadelphia, PA

Catherine A Schulten: Recommendation 5 makes a distinction between federal identity assurance requirements and commercial standards and the need to harmonize the two. Can you please explain what is meant by commercial standards around identity assurance?

John Loonsk: Does not the Congressional language for the TEFCA specify "full exchange"? How does that not equate to the committee's "broad focus"?
-- I apologize for jumping the gun earlier. The 21st Century Cures Act requires ONC to develop or support a TEF and CA "for the purpose of ensuring full network-to-network exchange" of health information. Given the limits of querying for data by name, how can the Congressional intent not be interpreted as meaning the "broad" articulation of the TEFCA "single on-ramp?"

Gerard Scheitlin: In the USDCI, the Task Force needs to look at data element removal, as well as data element addition. With the changes in medical technology, it is likely that data is obsoleted, triggered by a decrease in adoption, or general consensus. This will help prevent massive, non-value added data sets, reducing storage costs. Gerard Scheitlin - CRO, VP Security, Risk and Assurance - Orion Health

Mark Segal: Recommendation 9 - Two suggestions - (1) on conflicts of interest, add modifier focusing on prevention of "undisclosed or mitigated" conflicts; also, per discussion in Task Force meeting, do not presuppose a specific funding or governing model (e.g., revise mention of "dues" and dues payers having "fiduciary" role. –Mark Segal, Digital Health Policy Advisors, LLC

Don Mon: Regarding Recommendation 10, which states RCE "works on standards..." The current wording could be construed as the RCE being directly involved in developing standards. It would be clearer to state that the RCE will work in conjunction with, or collaborate with, standards development organizations (SDOs). No duplication that way. Also, it enables the SDOs to fully participate in the TEF and supports their business models.
--My earlier comment is addressed by Recommendation 24. Thank you!

John L. Burch: Please clarify the justification for the RCE. Creating a new, external, public-private bureaucracy will add a great deal of time (several years) to the process of stabilizing a standards-based exchange infrastructure. In the meantime, so much will happen in the private sector that TEF will be too little too late and irrelevant to what's

actually happening. By continually neglecting its legal obligation to create a data exchange standard for all to follow, ONC is simply making itself irrelevant and allowing alternate exchange frameworks to develop. It will be (already is to some extent) a matter of Betamax vs. VHS on steroids.

NEXT STEPS

The next meeting of the HITAC is an in-person meeting scheduled for April 18, 2018 at the Key Bridge Marriott near Washington, DC. The USCDI Task Force will meet over the next few weeks and its final Draft Recommendations on the USCDI will be presented at that meeting.

Lauren Richie adjourned the meeting at 12:24 pm ET.