Meeting Notes
Health Information Technology Advisory Committee (HITAC)
July 11, 2019, 9:30 a.m. – 12:30 p.m. ET
Virtual

Executive Summary

The Trusted Exchange Framework and Common Agreement Task Force (TEFCA TF) presented their final recommendations, which were voted on by the HITAC. The finalized TEFCA transmittal letter will be sent to the Office of the National Coordinator (ONC) on behalf of the HITAC. The U.S. Core Data for Interoperability Task Force (USCDI TF) reviewed their draft recommendations, and HITAC members offered feedback. The Interoperability Standards Priorities Task Force (ISP TF) reviewed the topic areas they plan to make recommendations on and gathered feedback from HITAC members. There were no public comments, but there were additional comments in the public meeting chat via Adobe.

Agenda

9:30 a.m.	**Call to Order/Roll Call**
9:35 a.m.	**Welcome Remarks**
9:40 a.m.	**Review of Agenda and Approval of June 19, 2019 Meeting Minutes**
9:45 a.m.	**Trusted Exchange Framework and Common Agreement Final Draft Recommendations and Vote**
11:30 a.m.	**U.S. Core Data for Interoperability Phase 2 Task Force Update**
12:00 a.m.	**Interoperability Standards Priorities Task Force Update**
12:15 p.m.	**Public Comment**
12:30 p.m.	**Closing Remarks and Adjourn**

Roll Call

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair
Michael Adcock, Individual
Christina Caraballo, Audacious Inquiry
Cynthia A. Fisher, WaterRev, LLC
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, Change Healthcare
Denni McColm, Citizens Memorial Healthcare
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 Blue Cross Blue Shield
Denise Webb, Individual

FEDERAL REPRESENTATIVES
Jonathan Nebeker, Department of Veterans Affairs
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE
Terry Adirim, Department of Defense
Laura Conn, Centers for Disease Control and Prevention
Tina Esposito, Advocate Aurora Health
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Clement McDonald, National Library of Medicine
Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin
Andrew Truscott, Accenture

ONC STAFF
Zoe Barber, Staff Lead
Seth Pazinski, Director of the Office of Planning, Evaluation, and Analysis
Steven Posnack, Executive Director, Office of Technology
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Donald Rucker, National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy

Opening Remarks
Donald Rucker thanked the members of the TEFCA TF for their time and hard work on their final recommendations and paid special thanks to the co-chairs of the task force, **John Kansky** and **Arien Malec**. **Dr. Jonathan Nebeker**, Deputy Chief Medical Informatics Officer (CMIO) at the Department of Veterans Health Affairs, was welcomed to the HITAC. Members were reminded that the third annual Interoperability Forum will take place on August 20-22, 2019, where current challenges in interoperability will be discussed.

Review of Agenda and Approval of June 19, 2019 Meeting Minutes
The agenda for the meeting was reviewed.

The HITAC approved the June 19, 2019 meeting minutes by voice vote. No members opposed. None abstained.

Trusted Exchange Framework and Common Agreement Final Draft Recommendations and Vote
The membership, overarching charge, and detailed charge of the task force were reviewed. It was explained that the recommendations would be presented by section and, at the conclusion of each section, there would be time for discussion, and a vote would be conducted.

OVERARCHING RECOMMENDATIONS: INTEROPERABILITY RULE

Recommendation 1

The TEFCA should express the broad policy aims of enabling better treatment, quality of care, and a more efficient health system. The TEFCA can only meaningfully advance these aims if it is:

- Carefully crafted to balance the addition of new requirements with complementing/coexisting with existing frameworks and networks, and
- Appropriately adopted by the stakeholders of health and healthcare that must exchange information.

We recommend that ONC consider both "carrots and sticks" for TEFCA adoption, such as:

- Education and outreach across the industry
- Outreach to existing frameworks and networks to coordinate launch and adoption efforts
- Funding aimed at any emerging financial obstacles for qualified health information networks (QHINs) and participants
- CMS encouraging TEFCA participation
- Federal agencies requiring TEFCA participation as a condition of contracts with federal agencies

No comments were made by HITAC members on this recommendation.

Recommendation 2

ONC should align TEFCA with the ONC Interoperability Rule:

- Key definitions such as health information exchange (HIE), health information network (HIN), and electronic health information (EHI) should be the same across both rules.
- Active, good-faith participation in exchange provided through the TEFCA should address and be evidence for compliance with information blocking requirements relevant to cross-network exchange purposes, uses and modalities provided through TEFCA.
- Because TEFCA only addresses a portion of information exchange activities relevant to information blocking, TEFCA participation alone should not be made a formal exception to information blocking or create a safe harbor.
- Participation in TEFCA should not be a condition of maintenance and certification requirements for the information blocking condition as suggested in the ONC's proposed rule. It should however, be an easy and direct path to address relevant requirements.

The following revisions were proposed:

- Regarding the final bullet, members suggested making clearer that live active sites and certified technology in use should connect to TEFCA. It was further noted that connection to TEFCA is a fundamental piece to achieving interoperability.
- An amendment to the last bullet of the recommendation was proposed. The following amended phrase was added to the end of the bullet "standards relevant for QHINs, Participant, or Participant Members should be considered in future certification requirements."

The HITAC approved the proposed amendment by voice vote. No members opposed. None abstained.

Recommendation 3

ONC should move forward with the requirement for data to be included in a query response as proposed in Draft 2, at a minimum, with the subset of EHI specified in the USCDI if the respondent has the data available, and focus on rapid yet prudent expansion of the USCDI standard.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 1, 2, and 3 by voice vote. No members opposed. None abstained.

OVERARCHING RECOMMENDATIONS: APPLICABLE LAW

Recommendation 4

To add clarity and avoid misinterpretation, ONC should categorize Privacy and Security obligations as:

- Health Insurance Portability and Accountability Act (HIPAA) obligations extended to cover Participants and Participant Members who are not covered entities (CEs) or business associates (BAs).
- New privacy and security obligations which go beyond HIPAA and cover all Participants and Participant Members, such as:
  - o Meaningful Choice
  - o No EHI Outside the US
  - o Specific identity-proofing and authentication policies (IAL2 and AAL2).

No comments were made by HITAC members on this recommendation.

Recommendation 5

To comply with Minimum Required Terms & Conditions (MRTCs), existing HINs/HIEs will likely need to amend the terms and conditions in their participation agreements to enter into and sign the Common Agreement and participate in the QHIN Exchange Network, and those amended terms will flow down and impact Participant and Participant Member agreements as well for TEFCA-related activities. In order to minimize the disruption to existing networks, we recommend the MRTCs be addressable through terms and conditions in existing agreements whenever possible through such means as:

- Allowing the recognized coordinating entity (RCE) to evaluate and approve a QHIN candidate's existing participation agreement or relevant terms of that agreement, with or without modification, as meeting the requirements of the MRTCs. In turn, allow QHINs, with the support of the RCE under a clear governance process established by the RCE, to evaluate and approve existing Participant agreements or relevant terms of those agreements.
- Designating TEFCA terms and conditions as "required" and "addressable."
- When changes to existing agreements are required, allowing Participants and QHINs to participate in TEFCA while having a defined period of time to revise their terms and conditions to avoid disruption to their participant network and existing information exchange. With respect to the RCE-QHIN relationship, the RCE may be able to employ this concept by appropriately grouping cohorts based on their bootstrap period/agreement.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 4 and 5 by voice vote. No members opposed. None abstained.

QHIN TECHNICAL FRAMEWORK (QTF), EXCHANGE MODALITIES, & EXCHANGE PURPOSES

Recommendation 6

The TEFCA should outline functional requirements sufficient to meet the policy goals in the TEFCA and avoid whenever possible identifying specific technical solutions. The QHIN functional requirements should be put front and center to communicate the "what" and leave room for flexibility and innovation on the

"how." Because the RCE and initial QHINs are presumed to have familiarity with exchange standards and approaches, we recommend the ONC remove the QTF, and clearly document functional requirements (perhaps in a QHIN Functional Framework (QFF)). Given the QTF was created as initial guidance for the RCE, which has authority to work out flexible and evolving technical approaches with the QHIN Exchange Network, we recommend the RCE be provided the comments and feedback the ONC received in the comment period. We recommend it be clear the RCE is free to choose any technical enablement(s) of the functional requirements listed in the QFF.

Discussion included the following:
- It was clarified that the RCE will establish the QHIN technical framework, using the QTF as a starting point.

Recommendation 7
We recommend the ONC focus on the functional requirements for QHIN query response, and avoid using the terms Targeted Query and Broadcast Query (or Record Locator Service), which have multiple interpretations/meanings.

No comments were made by HITAC members on this recommendation.

Recommendation 8
All QHINs should serve a floor set of functional requirements, Exchange Purposes and modalities. Participants and Participant Members should be able to serve (and respond to) a subset of Exchange Purposes and modalities that are appropriate to their scenario of usage, constrained as appropriate by the needs of individuals as well as the goal of reciprocity.

No comments were made by HITAC members on this recommendation.

Recommendation 9
ONC should clarify the role of the TEFCA relative to other nationwide exchanges served through parallel trust frameworks. In particular, ONC should clarify the intended uses of Message Delivery relative to other uses of network activities that send messages.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 6, 7, 8, and 9 by voice vote. No members opposed. None abstained.

INDIVIDUAL ACCESS SERVICES (IAS)
Recommendation 10, 10a, and 10b
Common Recommendation 10: ONC should place the needs of individuals front and center in the TEFCA, and those needs will certainly be broader than exercising the HIPAA right to access over time. In addition, ONC should clarify the functional requirements for individual access, keeping in mind typical access patterns (for example, health app integration on a mobile device).

Alternative Recommendation 10a: ONC should expand the IAS Exchange Purpose immediately to build in broader functionality for individuals that are not limited to obtaining and accessing a copy of their EHI, and sending to a 3rd party. At a minimum, IAS should include the right for an individual to request an

amendment to their EHI, as defined in HIPAA 45 CFR 164.526. Additional use cases to incorporate include:

- The ability for providers, patients, and payers to participate in shared care planning and to share and retrieve a patient's dynamic shared care plan for purposes of coordinating care.
- EHI that is created by or recorded by the patient, i.e., PGHD, patient-reported outcomes, and remote monitoring.
- The Precision Medicine Initiative led by the National Institutes of Health (NIH) that allows patients to access their health information, as well as research that uses their data to more accurately predict treatment and prevention strategies for specific patient populations.

Alternative Recommendation 10b: ONC should establish a policy framework to get to broader individual services, including amendment, shared care planning, PGHD, and data donation for research with a clear timetable. ONC and the RCE should roll out individual services that are ready for large scale adoption, starting immediately with IAS Exchange Purposes as described in Draft 2 as this constitutes a significant step forward for patient access. ONC should work with the RCEs and QHINs to develop and test the additional forms of individual exchange within the timeline established for the expanded usage.

Discussion included the following:

- It was clarified that the task force recommends that both alternative recommendations be presented to the ONC without offering a preference.
- It was suggested that the last bullet of recommendation 10a be edited to remove the details of the Precision Medicine Initiative. An amendment was proposed to delete the phrase "that allows patients to access their health information, as well as research that uses their data to more accurately predict treatment and prevention strategies for specific patient populations."
- **The HITAC approved the proposed amendment by voice vote. No members opposed. None abstained.**
- An amendment was proposed to insert the phrase "to include full access, exchange, and use" at the end of the first sentence of common recommendation 10.
- **The HITAC approved the proposed amendment by voice vote. No members opposed. None abstained.**
- The need for patients to directly control their information was emphasized, and inclusion of the word "control" in the amendment was suggested but was not supported by committee members.

The HITAC approved Recommendations 10, 10a, and 10b by voice vote. No members opposed. None abstained.

Recommendation 11

ONC should clarify whether all participating entities must respond to requests for IAS or only those with a Direct Relationship to the individual.

No comments were made by HITAC members on this recommendation.

Recommendation 12

ONC should further clarify the meaning of the term Direct Relationship. The MRTC uses this term variously to refer to an individual's designated Participant(s)/Participant Member(s) that are allowed to initiate queries on the individual's behalf, and the relationships to recipients of such queries. For purposes of clarity, ONC should define a clear term (one that does not overlap with existing legal terms regarding treatment relationships), such as Individual Designated Participant/Participant Member, to cover the

former definition.

For the latter definition, ONC should include relationships defined by Applicable Law in the definition. Further, the definition of Direct Relationship should detail the types of services that must be offered in order to establish a Direct Relationship.

No comments were made by HITAC members on this recommendation.

Recommendation 13

ONC should not require all public health agencies to respond to query, including IAS, particularly those that primarily exist for disease surveillance and do not maintain a longitudinal patient record, except when it is required by Applicable Law (such as when a public health agency is acting as a CE under the HIPAA rules).

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 11, 12, and 13 by voice vote. No members opposed. None abstained.

PRIVACY: MEANINGFUL CHOICE
Recommendation 14

ONC should clarify the policy goals around Meaningful Choice and leave the granular technical requirements to the RCE. Policy goals should ensure that Meaningful Choice is not just a "check-the-box" exercise, but that it provides meaningful information and opportunity for discussion about where and how an individual's EHI will be used and disclosed. Consent should be meaningful in that it does the following:

- Allows the individual advanced knowledge/time to make a decision. (E.g., outside of the urgent need for care.)
- Is not compelled, or is not used for discriminatory purposes. (E.g., consent to participate in a centralized HIO model or a federated HIO model is not a condition of receiving necessary medical services.)
- Provides full transparency and education. (I.e., the individual gets a clear explanation of the choice and its consequences, in consumer-friendly language that is conspicuous at the decision-making moment.)
- Is commensurate with the circumstances. (I.e., the more sensitive, personally exposing, or inscrutable the activity, the more specific the consent mechanism. Activities that depart significantly from a patient's reasonable expectations require greater degree of education, time to make decision, opportunity to discuss with his/her provider, etc.)
- Must be consistent with reasonable patient expectations for privacy, health, and safety; and
- Must be revocable. (i.e., patients should have the ability to change their consent preferences at any time. It should be clearly explained whether such changes can apply retroactively to data copies already exchanged, or whether they apply only "going forward.")

Discussion included the following:
- Members noted the need for transparency in Meaningful Choice with reliance on real-world examples.
- It was clarified that patients can entirely opt-out of having their data shared, but there is no redaction ability. It was suggested that this is clearly communicated to patients.

Recommendation 15

It is reasonable and practical to permit the use and disclosure of an individual's previously-disclosed EHI following an individual's exercise of Meaningful Choice to not have their EHI shared through the TEFCA in light of the significant challenge created in contemplating how to implement applying such a policy retrospectively.

There was a very strongly held minority opinion that the TEFCA should expand the scope of Meaningful Choice to include restrictions on re-disclosure of exchanged information that has been obtained via the QHIN Network.

No comments were made by HITAC members on this recommendation.

Recommendation 16

As drafted, once an individual exercises his or her Meaningful Choice to not have his or her EHI used and disclosed via the TEFCA, TEFCA 2 constrains the prospective use and disclosure of an individual's data to Exchange Purposes whereas prior to the exercise of Meaningful Choice, the use and disclosure was defined by Section 2.2.2 of the MRTCs. To avoid introducing unnecessary complexity, the TF recommends that the prospective use and disclosure of an individual's information after the exercise of Meaningful Choice continue to be defined and constrained by Section 2.2.2 and not the narrower Exchange Purposes only.

No comments were made by HITAC members on this recommendation.

Recommendation 17

ONC should clarify how broadly an expressed Meaningful Choice will be applied. Specifically, once exercised by an individual, the Meaningful Choice is expected to be communicated "up" the QHIN branch and shared by the QHIN with the other QHINs. Clarify which organizations in the TEFCA ecosystem are expected to be aware of that individual's Meaningful Choice and respect it. Also, clarify whether it is 1) only the organization with the Direct Relationship, 2) all Participants or Participant Members under that QHIN branch where the individual has a Direct Relationship, or 3) all QHINs, Participants, and Participant Members across the TEFCA ecosystem.

The HITAC approved Recommendations 14, 15, 16, and 17 by voice vote. No members opposed. None abstained.

PRIVACY: SUMMARY OF DISCLOSURES AND AUDITABLE EVENTS

Recommendation 18

ONC should align requirements around auditable events and summary of Disclosures. The MRTCs should describe the policy requirements for audit retention, including what's required to be audited and how long it should be maintained, in the MRTCs and not delegate to the QTF. ONC should move the six-year retention requirement to the audit language.

No comments were made by HITAC members on this recommendation.

Recommendation 19

The MRTCs should require a summary of disclosures only from the entity with the Direct Relationship to the requesting Individual (and the associated QHIN). Such a summary should include disclosures when data have been pulled from the associated QHIN and disclosures when data have been requested by the associated QHIN.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 18 and 19 by voice vote. No members opposed. None abstained.

SECURITY: NO EHI OUTSIDE THE U.S.

Recommendation 20

ONC should focus on the need for risk-based security assessment and remediation for QHINs, and not make "where the data reside" the central criterion for security.

The following revisions were proposed:

- An amendment to add an "s" to pluralize the word "reside" was proposed and approved.

This change was approved by member consensus. No voice vote was conducted.

Recommendation 21

In order to clarify governing law, the restriction to have QHINs maintain data center operations and data at rest in the US is reasonable. ONC should define these requirements in terms of operations and data at rest, and not use the term "cloud services," which excludes on premise data center services.

No comments were made by HITAC members on this recommendation.

Recommendation 22

Because of the need to have data follow the patient and because of the existence of international settings of care (e.g., Department of Defense Military Treatment Facilities), ONC should not restrict data access and exchange to US national boundaries and permit international data access and exchange.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 20, 21, and 22 by voice vote. No members opposed. None abstained.

SECURITY: CONTROLLED UNCLASSIFIED INFORMATION (CUI)

Recommendation 23

The TF recommends that ONC remove the section related to CUI.

No comments were made by HITAC members on this recommendation.

Recommendation 24

The TF recommends that ONC make it clear that the additional obligations on CUI handling or other specific requirements will be borne by Federal partners. As Federal partners onboard to TEFCA-administered exchange, ONC should work with Federal partners to ensure additional security

requirements do not impede the principle of reciprocity.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 23 and 24 by voice vote. No members opposed. None abstained.

SECURITY: PRIVACY/SECURITY LABELING
Recommendation 25
ONC should add Privacy/Security labeling to the TEFCA only via a common standards and policy framework that is implemented in provider workflow systems. As the HITAC recommended previously to ONC, there would be value to this proposal but more work is required to make labeling implementable. In particular, there should be accompanying policy guidance for how to handle labeled data. In particular, the policy framework should address when labelled data can and cannot be used, and how duplicate data that is labelled and un-labelled should be handled.

No comments were made by HITAC members on this recommendation.

SECURITY: CERTIFICATE AUTHORITY, ID PROOFING, AUTHENTICATION
Recommendation 26
The TF believes the ONC should not include Certificate Authority (CA) services as part of the MRTCs. The TF notes the requirements to be a trusted CA go far beyond the proposed MRTC terms and should be considered out of scope for TEFCA.
We recommend that ONC delete this provision.

No comments were made by HITAC members on this recommendation.

Recommendation 27

For purposes of clarity, the TF recommends the ONC overtly state that QHINs can accept the identity proofing of Participants and Participant Members under its QHIN branch on the basis that all Participants and Participant Members have agreed to flow-down agreement terms specifying the same identity proofing standards as in the Common Agreement.

No comments were made by HITAC members on this recommendation.

Recommendation 28
We agree with ONC's inclusion of AAL2 and IAL2. We recommend the ONC allow appropriate time for industry to accommodate these requirements.

No comments were made by HITAC members on this recommendation.

The HITAC approved Recommendations 25, 26, 27, and 28 by voice vote. No members opposed. None abstained.

U.S. Core Data for Interoperability Phase 2 Task Force Update
Draft Preliminary Promotion Model Recommendations from the USCDI TF were presented and discussed.

It was explained that feedback from HITAC members would be considered by the task force for the next draft of the recommendations. Discussion among HITAC members included the following:

- The risk of the bombardment of data elements that could result in a denial of service was noted
- It was suggested that the process of categorizing data elements may be problematic

Interoperability Standards Priorities Task Force Update

The overarching and specific charges of the ISP TF were reviewed prior to the discussion of domain areas for future recommendations. Input from HITAC members was welcomed by the task force to aid in the creation of future recommendations. Input from the HITAC included the following:

- It was suggested that the Structured Medication Sigs topic should be given more thought
- It was suggested that health IT standards be clarified to the public in a way that is easier to understand to make the public availability of the standards more effective

It was noted that if HITAC members would like to be involved in reviewing the final ISP TF recommendations, they can email either task force co-chair, **Ken Kawamoto** or **Steven Lane**.

Public Comment

There were no public comments on the phone.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE

Zoe Barber: I'm also taking notes

John Kansky: What I heard Arien's edit: "Standards relevant for QHINs, Participant, and Participant Members should be considered in future certificaiton requirements"

John Kansky: Or... not And

John Kansky: Noting that Sasha is nit-picky

John Kansky: :-)

Zoe Barber: Minimum Required Terms and Conditions

Denise Webb: Lauren I joined the call about 15 min late and was included in the voting

Lauren Richie: thanks Denise

Arien Malec: ", to include full access, exchange and use"

Brett Oliver: I strongly agree with Steven

Christina Caraballo: me too

Noam Arzt: Actually, I think she is confusing the floor to opt out fully with a presumption that all data is always sent. The latter is NOT the case, right?

John Kansky: I think Rec 3 provides a key part of the answer. TEFCA says that only what's in USCDI is shared.

Closing Remarks and Adjourn

The task force co-chairs were thanked for their work, and it was noted that the approved TEFCA transmittal letter will be sent to ONC on behalf of the entire HITAC. The next HITAC meeting will be held in-person on September 17, 2019. The meeting was adjourned at 12:30 p.m.