



Meeting Notes

Health Information Technology Advisory Committee (HITAC)

June 19, 2019, 9:30 a.m. – 12:30 p.m. ET

Virtual

Executive Summary

The HITAC annual report was discussed, and modifications for the next iteration of the report were proposed by HITAC members. Draft recommendations 1-14 from the Trusted Exchange Framework and Common Agreement (TEFCA) Task Force were presented and discussed. The suggestions offered by HITAC members to the TEFCA Recommendations will be included in the final presentation scheduled to be delivered at the next HITAC meeting on July 11, 2019. There were no public comments.

Event Summary

- 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 May 13 and May 22, 2019 Minutes**
- 9:45 a.m. **HITAC Annual Report Update**
- 10:15 a.m. **Trusted Exchange Framework and Common Agreement Draft Recommendations**
- 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
Tina Esposito, Advocate Aurora Health
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
Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin
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

Laura Conn, Centers for Disease Control and Prevention
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Terry Adirim, Department of Defense
Cynthia A. Fisher, WaterRev, LLC
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Valerie Grey, New York eHealth Collaborative
Clement McDonald, National Library of Medicine
Mark Roche, Centers for Medicare and Medicaid Services (CMS)
Andrew Truscott, Accenture

ONC STAFF

Zoe Barber, Staff Lead
Seth Pazinski, Acting Designated Federal Officer (DFO), ONC
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 for their time and hard work and informed them that **Patrick Soon-Shiong** resigned from HITAC and confirmed that a replacement would be appointed. The final recommendations drafted by members of the Trusted Exchange Framework and Common Agreement (TEFCA) Task Force (TF) are expected to be delivered on July 11, 2019.

Review of Agenda and Approval of May 13 and May 22, 2019 Meeting Notes

The agenda for the meeting was discussed, including the importance of the TEFCA TF draft recommendations discussion.

The HITAC approved the May 13, 2019, and May 22, 2019 meeting notes by voice vote. No members opposed. No members abstained.

HITAC Annual Report Update

The workgroup membership, scope, meeting schedule, and annual report planning for the fiscal year 2019 (FY19) were discussed.

- HITAC will receive the next update on the status of the annual report from the workgroup at the September 17, 2019 HITAC meeting. The FY19 annual report outline will remain the same as the 2018 outline, except for the addition of a “HITAC progress in FY18” section after the “Forward and Overview” section.
- Potential topics for the annual report were discussed, and it was clarified that a landscape and gap analysis would be done on all potential topics presented, but action may not be taken on all topics.
- The following additions to the annual report were proposed:
 - Recommend that Congress establish a more uniform privacy law that melds together both



Health Insurance Portability and Accountability Act (HIPAA) and Federal Trade Commission (FTC) regulations, to create a broad privacy framework for patient data.

- Discuss the intended collaboration with the National Committee on Vital and Health Statistics (NCVHS) on improving prior authorizations.

Trusted Exchange Framework and Common Agreement Draft Recommendations

The members and charge of the TEFCA TF were reviewed. The following recommendations were presented, and revisions discussed are noted.

OVERARCHING RECOMMENDATIONS: VALUE PROPOSITION

Recommendation 1

The TEFCA should express the broad policy aims of enabling better treatment, quality of care, and a more efficient health system.

- 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 which must exchange information

No comments were made by HITAC members on this recommendation.

Recommendation 2

ONC should align TEFCA rules and requirements with the Interoperability Rule:

- Key definitions such as Actors and EHI should be the same across both rules; therefore, the definitions should be crafted in such a manner as to be rational and effective when applied in both the Interoperability Rule and the TEFCA contexts.
- Active, good-faith participation in exchange provided through the TEFCA should address 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 certification or requirement for information blocking requirements. It should, however, be the easiest and most direct path to address relevant requirements.
- We believe that a careful balance needs to be struck in order to encourage participation in the TEFCA, while not inadvertently providing bad actors with an opportunity to circumvent regulation compliance.

The following revisions were proposed:

- Require that certified products have clear paths for clients to connect to a Qualified Health Information Network (QHIN) of their choice if they opt not to join TEFCA.
- Require that all participants within the TEFCA offer data for permitted uses while ensuring TEFCA remains a voluntary participation framework.



Recommendations 3A

Whenever possible, align TEFCA privacy and security obligations with HIPAA privacy and security obligations. While it is understood that new Exchange Purposes create uses beyond HIPAA-defined Treatment, Payment, and Operations, and EHI expands the relevant data beyond PHI, alignment of privacy and security obligations will minimize the impact on Covered Entities (CEs) and Business Associates (BAs) and increase the probability that they will adopt TEFCA.

No comments were made by HITAC members on this recommendation.

Recommendations 3B

To add clarity and avoid misinterpretation, ONC should clearly identify new obligations beyond HIPAA that may require updates to existing operations, policies, and agreements, as well as stating where meeting existing obligations for CEs and BAs would also meet TEFCA requirements. ONC should develop a mapping process to help map existing HIPAA terms and conditions to TEFCA terms and conditions.

No comments were made by HITAC members on this recommendation.

Recommendations 4

There is an understanding that existing Health Information Networks (HINs)/Health Information Exchanges (HIEs) will need to amend the terms and conditions in their participation agreements to sign the CA and participate in the QHIN Exchange Network, and that those amended terms will flow down and impact Participant and Participant Member agreements as well. In order to minimize the disruption to existing networks, we recommend that MRTCs be addressable through terms and conditions in existing agreements whenever possible through such means as:

- Allowing the RCE (with respect to QHINs) and QHINs (with respect to Participants) the latitude to agree to time-limited “bootstrap” periods whereby existing networks already under operation would be able to participate in TEFCA while having a defined, agreed upon 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 grouping cohorts appropriately based on their bootstrap period/agreement.
- Allow the 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”

No comments were made by HITAC members on this recommendation.

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

Recommendation 5

In the released version of the TEFCA, ONC should align all descriptions and diagrams to the functional requirements outlined in the MRTCs; RCEs, QHINs and the ONC should ensure that the QTF technical requirements address the functional requirements, and should ensure that technical requirements do not accidentally turn into functional requirements.



The following revision was proposed:

- Offer examples of specific instances in which the recommendation is applicable.

Recommendation 6

ONC should explicitly address the gap between information blocking requirements and TEFCAs requirements for cross network exchange. For example, when a requestor desires additional EHI not currently part of the USCDI, it is the requestor's responsibility to make that request directly to the information source, outside of the process established by the TEFCAs.

No comments were made by HITAC members on this recommendation.

Recommendation 7

The TEFCAs should outline functional requirements that are sufficient to meet the policy goals in the TEFCAs 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". In general, the QTF should be minimized in favor of giving the RCE authority to work out flexible and evolving technical approaches with the QHIN Exchange Network.

No comments were made by HITAC members on this recommendation.

Recommendation 8

We recommend ONC avoid the use of the term Targeted Query, Broadcast Query (or RLS) and instead offer a clear functional description of QHIN query response obligations.

The following revision was proposed:

- Expand on the abbreviations included in the recommendation.

Recommendation 9a and 9b

Recommendation 9a: [Requires more discussion] As currently stated in the TEFCAs, ONC and the RCE should require QHINs to serve all defined exchange modalities and purposes.

Recommendation 9b: [Requires more discussion] ONC and the RCE should allow and support "specialized QHINs" to serve a subset of Exchange Modalities and Purposes?

The following revisions were proposed:

- Specialized QHINs should be considered, especially public health and patient-focused/driven QHINs.
- The utilization of multiple paths for different types of QHINs (general purpose QHINs and specialized QHINs). Both types of QHINs are necessary and should be in place.
- The TEFCAs TF should discuss and include in the recommendation the exchange purposes for which specialization is recommended, and state that all other exchange purposes will be treated generally.
- State that the type or specialty of QHINs should not preclude a patient from obtaining their medical information from that organization.
- Clarify that all QHIN's, whether patient focused or not, must respond to patient access queries.



- To streamline the process of gathering personal information, offer patients a condensed place where all of their information can be accessed. Multiple use cases were offered to reiterate this need, including the National Institutes of Health's *All of Us* Research Program.

Recommendation 10a and 10b

Recommendation 10a: ONC should expand the IAS Exchange Purpose immediately to build in broader functionality for individuals that is 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 may 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.

Recommendation 10b: ONC should start with IAS Exchange Purposes that are mature locally and scale nationally through the TECA. ONC should work with stakeholders to develop and test additional forms of individual exchange (including amending, shared care planning and data donation for research) and work with the RCE and QHINs to scale those forms of exchange over time as those forms mature.

No comments were made by HITAC members on these recommendations.

Recommendation 11 and 11a

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. 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.

Recommendation 11a: [Requires more discussion] ONC should not require all public health agencies to respond to IAS, particularly those that primarily exist for disease surveillance and do not maintain patient-centered data, except when it is required by Applicable Law (such as when a public health agency is acting as a CE under the HIPAA rules). However, where the capability exists or in cases where bi-directional exchange is currently happening (e.g. immunization registries), the TF does not wish to discourage such reciprocity from occurring even if different standards that those incorporated in the QTF are used.

No comments were made by HITAC members on this recommendation.

PRIVACY: MEANINGFUL CHOICE

Recommendation 12

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.”)

No comments were made by HITAC members on this recommendation.

Recommendation 13 and 14

Recommendation 13: [Requires more discussion] ONC, in the MRTCs, should not allow for the use and disclosure of individuals’ previously disclosed EHI following an individual’s exercise of Meaningful Choice.

Recommendation 14: [Requires more discussion] ONC should clarify the extent of Meaningful Choice and how Meaningful Choice will be communicated. Specifically:

- Will Meaningful Choice only apply to an individual's information exchanged for defined Exchange Purposes within the TEFCA, or is Meaningful Choice expected to apply more broadly to govern the sharing of the individual’s information outside the TEFCA ecosystem?
- Once exercised by an individual, their Meaningful Choice is expected to be communicated “up” their QHIN branch and shared by their QHIN with the other QHINs. Which organizations in the TEFCA ecosystem are expected to be aware of that individual's MC and respect it? Only the organization with the Direct Relationship, all Participants or Participant Members under QHIN branch where the individual has a Direct Relationship, or all QHINs, Participants, and Participant Members across the TEFCA ecosystem?

The discussion centered on how the ecosystem should be modeled. Two opposing models were presented. One model in which an individual (patient) is at the center and connects directly with everybody, and the other where the individual connects directly with a QHIN which coordinates and enables exchange. The current TEFCA draft is based on the latter model, with a direct connection between the individual and the QHIN.

Public Comment

Since there were no public comments, **Robert Wah, HITAC co-chair**, used the time to recognize Patrick Soon-Shiong, expressing his appreciation for his time, experience, and expertise while serving on the



HITAC. He then provided an opportunity for Patrick to speak to the committee and share why he felt the need to resign.

- **Patrick Soon-Shiong** shared that the committee has been amazing. He noted that he is leaving due to the limited time he has available since taking over the LA Times and the work he is doing on a vaccine. Due to these other priorities, it is difficult for him to regularly attend meetings and contribute as much as he would like. He noted that the work is critically important to the nation and he wanted to be sure that there was someone in the slot that could dedicate more time.

QUESTIONS AND COMMENTS FROM THE CHAT WINDOW

Denise Webb: If TEFCA works as envisioned, then the SSA could gather the medical evidence needed for a disability determination through participation in one network (could choose one on-ramp to use) that would advance the query through the respective QHIN across the TEF ecosystem and return all the patient's information.

Denni McColm: To Dr. Rucker's point, can't a patient-focused entity be a HIN under the TEFCFA framework? What advantage is there for the patient-focused entity to be a QHIN vs. a HIN participating in TEFCFA?

Closing Remarks and Adjourn

The TEFCFA TF recommendations to the National Coordinator will be finalized at the next HITAC meeting on July 11, 2019. HITAC members were encouraged to submit any further comments and suggestions to the TEFCFA TF at their earliest convenience.

The meeting was adjourned at 11:30 a.m.