



Meeting Notes

Health Information Technology Advisory Committee

Trusted Exchange Framework Task Force

May 9, 2019, 12:00 p.m. – 2:00 p.m. ET

Virtual

The May 9, 2019, meeting of the Trusted Exchange Framework (TEF) Taskforce of the Health IT Advisory Committee (HITAC) was called to order at 12:00 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll.

Roll Call

Arien Malec, Co-Chair, Change Healthcare

John Kansky, Co-Chair, Indiana Health Information Exchange

Cynthia A. Fisher, WaterRev, LLC

David McCallie, Cerner

Aaron Miri, The University of Texas at Austin, Dell Medical School, and UT Health Austin

Carolyn Petersen, Individual

Mark Savage, UCSF Center for Digital Health Innovation

Sasha TerMaat, Epic

Grace Terrell, Envision Genomics, Inc.

Andrew Truscott, Accenture

Sheryl Turney, Anthem Blue Cross Blue Shield

Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Noam Arzt, HLN Consulting

Kate Goodrich, CMS

Anil Jain, IBM Watson Health

Steve L. Ready, Norton Healthcare

ONC STAFF

Zoe Barber, Staff Lead

Michael Berry, SME

Cassandra Hadley, HITAC Back Up/Support

Alex Kontur, SME

Michael Lipinski, SME



Morris Landau, SME
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Kim Tavernia, SME

Call to Order

Lauren Richie turned the meeting over to the co-chairs.

Opening Remarks – Review of Charge and Membership

Arien Malec welcomed the members, noted the good work done by the task force in Trusted Exchange Framework and Common Agreement (TEFCA) Draft 1 and reviewed the agenda.

Arien Malec then began the TEFCA Task Force, Meeting 1 presentation where he reviewed the following slides (exact presentation contents can be viewed [here](#)).

- Agenda
- Task Force Charge
- Membership

Arien Malec introduced **Zoe Barber** as the next presenter continuing with the current presentation and turned the meeting over to her.

Zoe Barber thanked Arien, noted her familiarity with this effort from her past where she previously led the task force and her work in the past year to include input from the public comment and recommendations from the HITAC. She then moved on to introduce her ONC colleagues who will help in this effort: **Kimberly Tavernia, Alex Kontur, Michael Berry, Morris Landau**. Zoe then continued the presentation where she reviewed the following slides:

- MRTCs Table of Contents
- Common Terms and Definitions
- Framework Agreement Flow-Down
- Summary of Key Changes
- QHIN Technical Framework
- Exchange Purposes
- Individual Access Services (IAS)
- Exchange Modalities
- Fees

DISCUSSION

- **David McCallie** noted his confusion that throughout the presentation there are words such as 'require,' 'voluntary,' 'minimum required,' 'may,' 'shall' etc. and asked that Zoe clarify the binding power of the language. He noted that the text within the document referenced *minimum necessary required* which was linked to the text which included the word 'may.' The juxtaposition of a word such as 'may' along with 'required' caused some confusion on his part.
 - **Zoe Barber** answered that 'shall' means required and others throughout the document that causes concern or confusion should be addressed on a case by case basis.



- **Arien Malec** commented, noting that this particular feedback may be too granular for this discussion.
- **David McCallie** asked if there will be an opportunity to discuss if the broader notion of Direct messaging can be discussed.
 - **Zoe Barber** answered that yes, this is within scope to be discussed on 5/14 – 5/16.
- **Andy Truscott** asked if there will be an opportunity for the ability of TEF to demonstrate alignment to Information Blocking regulations.
 - **Zoe Barber** referred him to Michael Lipinski while noting that she believed the potential issues to what Andy was referring would likely to be out of scope for this task force.
 - **Arien Malec** suggested the specifics of Andy’s questions may be out of scope for this task force, but from a policy perspective, the task force may consider what is expected out of TEF and what success would look like and then evaluate TECCA 2 according to that success criteria.
 - **Andy Truscott** agreed with Arien. But asked if these issues aren’t going to be discussed within TEF, then where would they be discussed.
 - **Arien Malec** and **Andy Truscott** agreed to discuss it outside this meeting.
 - **John Kansky** noted that although he doesn’t suggest relitigating definitions such as health information network (HIN), which were developed under extensive scrutiny by the Information Blocking Task Force, it might be valuable to look through the lens of the Information Blocking Task Force to consider the definition of HIN and how it relates to qualified health information network (QHIN) eligibility.
 - **Arien Malec** asked that Zoe capture John’s comment as a discussion item for a later date.
- **David McCallie** noted that data accessed from an Application Programming Interface (API) should follow the same privacy and security rules as data accessed out of a QHIN. He went on to ask that rules and requirements under TEF, regarding privacy and security concerns, be aligned with the Notice of Proposed Rulemaking (NPRM).
- **John Kansky** asked what terminology should be used - TECCA Ecosystem or QHIN Exchange Networks?
 - **Zoe Barber** answered that she has been using ‘Framework Agreement’ and ‘QHIN Exchange Network’ to refer to the overarching TECCA ecosystem but welcomed feedback and suggestions.
- **Mark Savage** referenced slide 12 (Individual Access Services (IAS)) and loosely quoted Zoe as saying that once electronic health information (EHI) is received, it can only be used for individual accessed services. With regard to this, Mark referenced his question previously entered into the chat box which stated: “would the *All of Us Research Program* not be allowed to use this framework to gather information for research purposes, if everything is limited to use for IAS?”
 - **Zoe Barber** answered that only if the EHI is received for the purposes of individual access services can it be reused, exchanged, disclosed for individual access services. She went on to note that this is specifically in complement with the fee restriction that



QHINs are not allowed to charge another QHIN for exchanging EHI for individual access services. She then pivoted to discuss the subject of research and noted that research is not a permitted exchange purpose within the TEFCAs. She went on to detail that there is an exception in Section 2.2.2, 7.2 and 8.2 detailing that it is allowed to reuse the information for another purpose if the consent by the individual has been provided.

- **David McCallie** asked if they could opt to direct their information to a research entity outside of the Health Insurance Portability and Accountability Act (HIPAA) consent requirement.
- **Arien Malec** confirmed this example isn't a QHIN obligation; it is an individual obligation.

Discussion of QHIN Definition, Application, Onboarding, and Designation Process

John Kansky took over the TEFCAs Task Force, Meeting 1 presentation from Zoe where he reviewed the following slides (exact presentation contents can be viewed:

https://www.healthit.gov/sites/default/files/facas/2019-05-09_TEFCAs_TF_Meeting_Slides.pdf)

- QHIN Application Process

DISCUSSION

- **David McCallie** asked what 'already operates a network' means. He went on to question if 'already' means the 'liveness' of the Recognized Coordinating Entity (RCE).
 - **Zoe Barber** answered that it is the time that they submit the application to the RCE.
 - **David McCallie** offered a follow-up question, asking if someone could start from scratch, build a network, and then apply to become a QHIN?
 - **John Kansky** answered yes, as long as the network was operational and met the definitions by that date (pending clarification from ONC)
 - **Zoe Barber** reminded the task force of the QHIN goals which she paraphrased as all QHIN's must: be neutral and accessible to all parties; maximize efficiency and minimize failure; have the proper infrastructure, functionality, and personnel necessary to be successful.
 - **Arien Malec** added that he assumes that the goal is not to have a single cohort as QHINs, but rather to have expanding and changing QHINs over time.
 - **John Kansky** clarified his assumption that when someone submits their application, they are assigned to a cohort.
 - **Arien Malec** interjected that the answer to David's question is that because this is intended to be an evergreen process, 'in production' applies to the time of application as part of a cohort.
 - **John Kansky** asked for clarification regarding the statement 'operates a network.' He suggested that the intent isn't necessarily meant to specify network and preclude framework in this context. **Arien Malec** answered that 'operate a network' means to facilitate the exchanging data.



- Related to the QHIN Application Process slide, **David McCallie** noted his interest in exploring entities that are not eligible to become HIN's. He provided the example, asking if a vendor's internal network exchanging data across customers was able to become a QHIN.
 - **Arien Malec** answered by noting that boundary test discussions were interesting and worth investigating and suggested the task force pose the following questions: is Carequality a network under this definition or would it be a perspective RCE? Is a vendor-specific network a network under this definition?
 - **Andy Truscott** noted that within the Information Blocking Task Force they discussed boundary issues such as the differences between health information networks and health information exchanges. He also suggested this task force consider the prior work done with regard to whether organizations were affiliated or unaffiliated would inform this task force.
 - **John Kansky** noted that QHIN eligibility isn't clear enough and the decision is the RCE will evaluate QHIN applications against the eligibility, and they will determine if an organization is eligible or not. He suggested clarification of the eligibility language in the draft.
 - Referring to the QHIN Application Process slide, **Arien Malec** asked ONC representatives if there is a difference between an individual and a person and what does entity mean in this context.
 - **Zoe Barber** answered that within this context there isn't a definition of person per se, but the definition of an individual includes both the individual who is the subject of information and a person or legal representative. There is not a definition of an entity.
- **John Kansky** asked Zoe's advice regarding interpreting the meaning of words like 'live clinical environment,' 'locate and transmit,' 'operates a network' and sought her guidance in terms of the intent of these words.
 - **Zoe Barber** answered that it is important to pay the most attention to those that have definitions and reminded the task force that those capitalized had definitions. She also reiterated that the task force remembers the goals that guided the language, which she paraphrased as all QHIN's must: be neutral and accessible to all parties; maximize efficiency and minimize failure; have the proper infrastructure, functionality, and personnel necessary to be successful. She further noted that within this draft of the TECCA all definitions align to the NPRM.
 - **Andy Truscott** asked if the definitions change within the rulemaking processes, how will those changes be reflected here?
 - **Michael Lipinski** answered that every effort was made to align the definitions, but he understands Andy's point about how the task force will need to see what that final definition is before they approve.
 - **Andy Truscott** noted that the definitions can't be expected to be kept in absolute lockstep, but that communication needs to take place to ensure the TECCA task force is aware of changes, as much as possible.
- **David McCallie** asked why a HIN would decide to become QHINs if they are already successfully exchanging data?



- **John Kansky** answered that the HIN is outside the ecosystem and posed the question of what does the world look like if you are a successful network that chooses to remain outside the ecosystem. John suggested this question be logged and posed to ONC.
- **Mark Savage** circled back to the TECCA definitions discussion above and suggested that the definitions be kept consistent with the other task forces.
- **Sheryl Turney** returned to the issue regarding what would make a HIN transition to a QHIN. Sheryl stated that she agreed that this identifies a serious gap.
- **Aaron Miri** referred back to the HIN transition to a QHIN and noted that academic medical centers are often already connected networks and suggested this situation be considered.
- **John Kansky** noted that the Information blocking NPRM has a definition of HIN that is very broad. Is it problematic in any way that the definition of HIN is pretty broad given that the RCE is going to be vetting applications for the organization's ability to be successful and meet other criteria? Is the intent that any HIN that meets the HIN definition under the Cures NPRM test is a HIN at the top of this funnel, that then is further qualified by the four additional tests or are there additional definitions that are implied prior to these four additional tests?
 - **Zoe Barber** answered that any HIN per the HIN definition in the NPRM and then plus these four additional tests.
- **Arien Malec** asked if 'live clinical environment' implies that the transactions are for clinical purposes?
 - **Zoe Barber** referred back to the policy goals of maximizing efficiency and minimizing failure should help to ensure that organizations that are going to be designated as QHINs are not just in the planning stages or beta testing, but exchanging data in a live environment.
- **David McCallie** noted that according to his understanding of the document, it sounded like it would be possible for a QHIN to perform individual access services only. He then asked if Apple or Google etc. be allowed to become a QHIN. David asked that this scenario be added as a barrier test.
- **Arien Malec** asked that if a HIN becomes a QHIN (assume it's a health IT vendor) and they are found to be information blocking and are decertified, do they lose their QHIN certification status within the entire environment?
 - **Michael Lipinski** answered that the program and Office of Inspector General (OIG) both have jurisdiction. He went on to note that there could be civil monetary penalties plus decertification or banning from the program.
- **John Kansky** referred the task force to slide 23 and sought feedback on the definitions.
 - **Aaron Miri** wondered if there is a definition slide that ties up to an expected liability or ramifications of liability preceding one of these designees.



- **David McCallie** sought information from ONC regarding why there is so much granularity with regard to the QHIN definition.
 - **Zoe Barber** answered that the goal was to provide proper support and technical assistance for that overall onboarding and implementation process to become a QHIN.
 - **John Kansky** asked if the RCE in their judgment decided that the requirement for a cohort is unhelpful, and if so, do they have the latitude to change that or be able to put that in the form of a recommendation?
 - **Arien Malec** interjected to reframe the question by asking if a cohort of one is legally permissible.
 - **Zoe Barber** answered Arien detailing that there is no language precluding a cohort of one. She went on to answer John's question by noting that there is leeway to modify the cohort process with ONC approval.
 - **Michael Lipinski** noted that one of the reasons they chose this route was to ensure fairness in the process, so there wasn't one QHIN ahead of the game.
- **David McCallie** clarified that a QHIN can be in the data business for other reason and not be disqualified as long as they meet the other minimum requirements.
 - **Zoe Barber** confirmed this description.
- **John Kansky** noted that there is a disqualifying affiliation between QHIN and RCE. He then asked if there is any guidance that can be provided on the word affiliation in that context?
 - **Michael Berry** noted they are developing an official response to this question as there were previous related comments submitted, and until the official response is published, he is unable to answer.
 - **Aaron Miri** asked if an identified QHIN is allowed to take the overall data across the network even if it was never specifically allowed per the agreement?
 - After much back and forth discussion, the task force concluded that more discussion on this subject needs to take place.

Lauren Richie transitioned to public comment.

Public Comment

- **Chris Baumgartner** with the Washington State Department of Health sought to understand how the proposed rulemaking, as well as TEFCA draft 2.0, would impact public health and asked two questions. 1) Would public health as a participating entity be required to respond to an individual access service request? He noted that some of laws and rules may not allow for this and provided an example of the immunization registry. He went on to note that if there were an individual requesting all of their immunization records his organization would likely not have the capacity to make that happen through the trusted exchange framework given their resourcing. 2) Public health is defined in the TEFCA and seems to cite the fact that his organization is not a covered entity or business associate but that they are a health oversight entity. He's concerned about the minimum necessary requirements applying to all participants.



- **Zoe Barber** provided a couple of fact-based answers noting the definition of public health references the HIPAA rules and any other applicable law. She went on to note that the definitions of Common Agreement, Participant QHIN Agreement and Participant Member Agreement list precedents in case of any conflicts or inconsistencies between the common agreement and applicable law. The second answer she provided is that as it is written today, immunization registries or any public health entity are required to respond for individual access services.

Comments in the Public Chat

Chris Baumgartner: Would public health as a participating entity be required to respond to IAS requests?

Mark Savage: For example, would All of Us not be allowed to use this framework to gather information for research purposes, if everything is limited to use for IAS?

David McCallie: Does "already exchanging" mean as of NOW, or as of RCE activation or ??

Chris Baumgartner: Public health is not a covered entity under HIPAA. It is a health oversight entity. Is the Min Necessary requiring Public Health to become a covered entity?

David McCallie: How well do these P&S requirements align with API and Data Blocking requirements under the NPRM?

David McCallie: For example, if an individual elects to not share their data via TEF, does that also apply to API access under NPRM?

Next Steps and Adjourn

- **Zoe Barber** suggested task force members come prepared for the next meeting to discuss the exchange purposes, modalities, reciprocity and permitted future uses of EHI.
- **Arien Malec** suggested task force members read the Technical Framework Draft 1 (QTF Draft 1).

The meeting was adjourned at 2:00 p.m. ET