



## Meeting Notes

### Health Information Technology Advisory Committee Trusted Exchange Framework and Common Agreement Task Force June 3, 2019, 12:00 p.m. – 1:30 p.m. ET Virtual

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The June 3, 2019, meeting of the Trusted Exchange Framework and Common Agreement (TEFCA) Taskforce (TF) 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  
Anil Jain, IBM Watson Health  
David McCallie, Jr., Individual  
Aaron Miri, The University of Texas at Austin, Dell Medical School, and UT Health Austin  
Mark Savage, UCSF Center for Digital Health Innovation  
Grace Terrell, Envision Genomics, Inc  
Sasha TerMaat, Epic  
Andrew Truscott, Accenture  
Sheryl Turney, Anthem Blue Cross Blue Shield  
Noam Arzt, HLN Consulting

#### MEMBERS NOT IN ATTENDANCE

Steve L. Ready, Norton Healthcare  
Denise Webb, Individual  
Carolyn Petersen, Individual

#### FEDERAL REPRESENTATIVES

Mark Roche, Federal Representative, Centers for Medicare and Medicaid Services (CMS)  
Laura Conn, Federal Representative, Centers for Disease Control and Prevention (CDC)

#### ONC STAFF

Zoe Barber, Staff Lead  
Michael Berry, SME  
Debbie Bucci, SME  
Cassandra Hadley, HITAC Back Up/Support  
Alex Kontur, SME



Morris Landau, SME  
Kathryn Marchesini, Chief Privacy Officer, ONC  
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer  
Kim Tavernia, SME

**Lauren Richie** turned the meeting over to John Kansky, co-chair.

**John Kansky** noted that the TEFCA TF would be focused on the remainder of the TEFCA TF Discussion Matrix, beginning with meaningful choice.

## Discussion on Privacy Provisions

### MEANINGFUL CHOICE

- **John Kansky** reviewed meaningful choice as stated in the matrix and sought feedback from the TEFCA TF members. John asked if a meaningful choice request is made by an individual, can they make that request to a participant or a Qualified Health Information Network (QHIN) and it is expected that request be communicated up and down that network, so it is honored across the QHIN exchange network.
  - **Zoe Barber** stated that this understanding is largely correct but made one clarification by noting that they can ask whoever they have the direct relationship with, which can be either the QHIN participant or participant member.
- **John Kansky** sought to clarify the text “exceptions for things like treatment” as written in the matrix.
  - **Zoe Barber** stated that it’s an all-or-nothing opt out of the network, and as drafted, there are no exceptions.
  - **Laura Conn** noted that reporting to public health when required by law at the local level cannot be opted out of and asked how that fits in with meaningful choice for individual levels.
  - **Zoe Barber** answered there are no exceptions aside from anything required by applicable law.
  - **Noam Arzt** referred to the all or nothing aspect of the opt-out and noted his concern in jurisdictions where patients are opting out of public health registry inclusion when they may not really mean to.
- **John Kansky** referenced the text “meaningful choice as it relates to sensitive information” as written in the matrix and noted Zoe’s all-or-nothing comment above also applied to this subject and offered the members the chance to comment.
- **Andy Truscott** asked how “meaningful choice as it relates to sensitive information” as written in the matrix lines up with consent and the conveying of consent.
  - **Zoe Barber** answered based on her understanding that Andy Truscott is referring to local consent or consent that is required through applicable law. She provided the example of an opt-in state like Rhode Island and stated the opt-in consent would have to be held by the entity that has a direct relationship with the patient. Referring to the Rhode Island example, she noted it would be the provider’s responsibility to obtain and maintain that opt-in consent for Rhode Island specifically which is separate from the exercise of meaningful choice which would be held by the entity that has a direct relationship with the patient.
- **Arien Malec** noted that it’s appropriate in the minimum required terms and conditions (MRTC) to raise the notion of meaningful choice as expressed by the Health IT Policy Committee’s Privacy and Security Tiger Team. He went on to note that the way the MRTC is to work is by requiring the



recognized coordinating entity (RCE) to establish appropriate flow-down terms that obligate participants and participant members to provide appropriate, meaningful choice as an obligation. He also stated the details that the TECCA TF is debating, for example, whether it's all in, all out, or if there are exceptions for sensitivity, etc. should not be the matter of the MRTC's. He suggested expressing policy goals that provide patient-specific and actionable information and choice related to the kind of information flows that happen through the trusted exchange framework (TEF) and QHIN's.

- **John Kansky** sought to confirm his understanding that a request for meaningful choice made at any level in the tree has to go up and down.
- **Zoe Barber** answered that it needs to be shared up to the QHIN, not down to participants and participant members. She went on to note that if a participant member receives the request for meaningful choice, they would have to send that up to the participant in the QHIN. If the participant got that request, they would have to send it up to the QHIN, but they don't have to send it down.
- **Mark Savage** asked why the TECCA TF is not choosing to build in a level of granularity around meaningful choice which would solve many relevant problems. He also communicated concern and referred to the notion that if one exercises meaningful choice and their information was previously disclosed, it continues to be used and disclosed for an exchange purpose, and noted this does not align with most people's expectations.
  - **Zoe Barber** responded that it's a result of the standards that are available today for communicating such consent through network to network exchange.
  - **Kathryn Marchesini** added that it is similar to how the Health Insurance Portability and Accountability Act (HIPAA) individual authorization works regarding the right to revoke.
- **John Kansky** asked if a QHIN has data from the past and the patient has authorized their data for some use that's outside the exchange purposes, but then they exercise their meaningful choice, does that necessarily void that authorization?
  - **Kathryn Marchesini** answered that she's not sure if the answer to that question is captured in the MRTC.
- **David McCallie** noted that the meaningful choice requirements were underspecified and more complicated than these proposals cover. That coupled with the lack of any good technical means tested on any scale led him to urge caution to the degree this is pushed onto the QHIN's.
- **Mark Savage** noted that people exercise meaningful choice to opt out and then re-opt in again and asked if there is a provision for re-opting in.
  - **Zoe Barber** answered that in the definition of meaningful choice, it is revocable on a prospective basis with written notice.
  - **Arien Malec** stated that discussion of meaningful choice as either opt-out or opt-in is counter to the notion of meaningful choice which is meant to ensure that people clearly understand what's happened to their data and can exert reasonable control over it.
  - **David McCallie** noted that either the details need to be more granular or there needs to be a lot more trust placed in the RCE and stakeholders to figure it out within some broad policy goal.
  - **Sasha TerMaat** noted that she agrees with the use of research purpose and clinical care purpose. She then noted that quality reporting falls in the middle where it's less clear-cut whether data that has been incorporated into quality reporting or quality improvement initiatives can be removed or no longer used even if an individual is changing their preference



midway through a quality reporting period. She agreed with David McCallie's concerns that there is more complexity than has been evaluated.

- **John Kansky** asked if a participant/participant member or QHIN's failure to include information prior to a meaningful choice constitutes information blocking?
  - **Morris Landau** shared some of the background on the policy behind meaningful choice and offered the answer to John Kansky's question by stating there is a proposed exception for exercising consent and noted that information blocking is based on many different factors.
  - **Zoe Barber** confirmed that John Kansky's question made sense and there was a consensus that it warranted further study.
- **Cynthia Fisher** sought clarification regarding the ability for the patient to articulate their choice to opt in or opt out and asked if that is showing the various ways their health information is being transferred and utilized, with prospective prices as well as the audit trail of the provenance.
  - **Zoe Barber** answered that the instructions on how to exercise meaningful choice needs to be included in the written privacy summary that is published by the entities providing the individual services. Future use comes from a patient's approval after receiving minimum information.
  - **Cynthia Fisher** followed up by stating her concern is the lack of ability for the patient to see the path or choose not to have certain paths and have control of the management of their information, and her goal is to empower the patients with clear information and stop the practice where EHR vendors obscure or hide privacy information.
  - **Zoe Barber** responded by noting that the definition of meaningful choice outlines that it cannot be used as a condition for receiving medical treatment or for discriminatory purposes. She outlined some of the finer points within the definition of minimum information and noted that any recommendations Cynthia has about other ways ONC can ensure that information is accessible to the individual would be helpful.
  - **Arien Malec** noted that the intent is to create patient informed decision making and not the mechanics of, for example, adding a checkbox to a screen.
  - **David McCallie** noted the QHIN or the TEF will not change much as the meaningful choice is simply going to impact the QHIN's ability to share a record to remote providers should an individual be in a remote place and need care.

## EHI OUTSIDE THE US

- **Arien Malec** reviewed background related to 'EHI Outside the US' as stated in the matrix, offered some related background and asked for clarification regarding ONC's intent relative to, for example, support people being onshore or offshore as well as service members who are deployed worldwide and may want to participate in the QHIN.
  - **Debbie Bucci** noted that there was the recognition that there are people overseas that need to have access to the data.
- **Sasha TerMaat** noted that she sees a presumption that there would never be any exchange through a QHIN with another country, which she stated was short-sighted and raised that for consideration. She also stated she agrees with Arien's concerns regarding support personnel overseas.
- **David McCallie** noted that the success of cloud providers proves that it doesn't matter where the data is reposed, what matters is network protocols and security protocols that govern network access. He stated that the focus should be on security requirements for the networks, data encryption at rest, who has access to the keys, verifiability of access pathways, etc.



- **Mark Savage** shared the example of a US citizen permanently moved to Mexico for his retirement and asked if that means that U.S. citizen would still be able to request access to his data from Mexico through one of the QHIN's and obtain that data for further care in Mexico or another Caribbean country?
  - **Zoe Barber** noted that the provision in 2.2.11 specifies that there's an exception for the individual who requires his or her electronic health information (EHI) be disclosed outside the United States.
- **John Kansky** shared the example of large corporations holding and sending data across borders outside the US as well as radiology images being read overseas.
- **Arien Malec** mentioned the DoD and State Department were good use cases where the data may reside overseas and noted these are examples that occur all the time and one of the main reasons for the work of the TEFCO TF. He further noted that the restriction to have a QHIN's technical operation be in the US is a reasonable restriction that most HIN's already adhere to.
  - **Debbie Bucci** noted that a patient has a right to their data, and rules and regulations are already in place to handle somebody who is overseas and needs emergency access.
- **Arien Malec** suggested the TEFCO TF recommend that ONC clarify that technical capabilities for exchange operations for the QHIN be housed in the U.S.

## SUMMARY OF DISCLOSURES

- **John Kansky** reviewed some background and his understanding of summary of disclosures. He then shared an example where a request made by an individual who has a direct relationship and asked if they are asking the whole TEFCO ecosystem or are they asking for disclosures made by their point of contact.
  - **Debbie Bucci** referred to a discussion she recalled regarding participants in TEFCO not being covered by HIPAA, but she noted it is desired that there be an accounting of where that data has gone.
- **John Kansky** asked if it is an accounting of the TEFCO transaction by the organization with which the individual has an underlying direct relationship or is the organization that the individual has a direct relationship with just the organization they go to in order to make the request of their summary disclosures that have made it across the TEFCO ecosystem.
  - **Morris Landau** noted the goal was to be somewhat parallel to an accounting of disclosures under HIPAA. He went on to note that the notion is if an individual requests a summary of disclosures in which it had a direct relationship that that entity would not necessarily have to go to the entire ecosystem but would have to be within their purview to provide a summary of content they had in the contours of the direct relationship.
- **John Kansky** stated that he looked at the definition of disclosure in 160.103 and noted that it is broad. He noted that if you ask for HIPAA accounting of disclosure, you get information on the margins. He then sought to confirm his understanding that there was such a constraint on the summary of disclosures under TEFCO. He stated that it appears it includes every transaction made by that organization, whether it be Treatment, Payment, and Healthcare Operations (TPO) or any other circumstances.
  - **Zoe Barber** clarified that 9.5.3 lays out the exceptions for the summary of disclosure which are the same as the exceptions that are found in the accounting of disclosure within HIPAA.
- **Arien Malec** sought to confirm his understanding that the accounting of disclosures requirement means that a HIN operator must maintain records of disclosures that are beyond TPO and must make



those accounts available to participant and participant members who request it inside the network. He went on to note that the intent is to flag information access requests that come through the TEF.

- **Zoe Barber** answered that it's available to individuals who use the QHIN participant or participant member for individual access services. The QHIN has to do it if they provide direct to consumer services.
- **Arien Malec** followed up by asking if the individual has to request the QHIN disclosures or is it secondary to the individual asking for their accounting of disclosures of their participant or participant member who would then have the obligation.
- **Zoe Barber** answered that the way the obligation is drafted right now, it's only the entity that has a direct relationship with the patient. If it were the participant, the patient would ask the participant directly, and they would only get the disclosures that the participant did. The participant would not be required to go up to the QHIN.

## AUDITABLE EVENTS

- **Arien Malec** shared some background, noting that there's specific language around the auditable events that a QHIN must maintain and it is the goal of the TEFCA TF is to make sure those requirements are in line with the accounting for summary disclosures. He then recommended this language be at the policy level rather than make a forward reference to the QHIN Technical Framework (QTF).
- **David McCallie** noted that the energy should be put into finding the auditable events and disclosures can exist in the content of the auditable event.
- **Arien Malec** noted the auditable events should not delegate all the hard work to the QTF but instead describe the policy of audit, audit retention, what's audited, what's required to be audited, etc.
- **David McCallie** noted that a reasonable assumption at the policy level would be that every transaction that a QHIN or participant has with respect to a patient should be audited. The debate can be around exemptions to that and definitions on what subset of the data needs to be kept in the audit log.

**Lauren Richie** opened the lines for public comment.

## Public Comment

There were no public comments.

## COMMENTS IN THE PUBLIC CHAT FEATURE OF ADOBE

**Sasha TerMaat:** John, are you thinking of this QTF excerpt:

**Sasha TerMaat:** A QHIN MUST collect and utilize Meaningful Choice notices received from any First Degree Entity or QHIN. A QHIN MUST electronically communicate Meaningful Choice notices to all other QHIN so A QHIN MUST electronically maintain Meaningful Choice notices A QHIN MUST use electronically maintained Meaningful Choice notices to determine whether to initiate QHIN Queries or QHIN Message Deliveries

**Grace Terrell:** I completely agree with the concern about signing blind forms. This is now standard at the health system I am most familiar with and appears to be an intentional choice as technology has been invested in for every practice entry point across the system.



**Sasha TerMaat:** With respect to activities that are subject to these terms and conditions and the Common Agreement, no QHIN shall Use or Disclose any EHI outside the United States except as required by Applicable Law or as provided below.(i) QHINs shall not Use or Disclose any EHI to any person or entity outside the United States (or allow any third party acting on its behalf to take such action) except to the extent that an Individual User requires his or her EHI to be Used or Disclosed outside of the United States. (ii) QHINs may only utilize cloud-based services that are physically located within the United States. All EHI provided to a cloud services provider shall be stored physically within the United States and shall not be transferred to or located in any other countries or jurisdictions.

**Sasha TerMaat:** Mark, I think (i) would cover your concern.

**Grace Terrell:** Within the context of sharing data outside the US, for patients with very rare disease, this is a very crucial issue. If there are only 50 cases of a particular rare genetic disease known in the world, for example, internationally integrated clinical data is crucial for research and improved outcomes. Rare disease would seem to be the quintessential use case for thinking through disclosure outside the U.S.

**David McCallie:** Remember that TEF says nothing about those existing non-QHIN-mediated data

**David McCallie:** TEF doesn't have any say-so about those use-cases

## Next Steps and Adjourn

The meeting was adjourned the meeting at 1:30 p.m. ET