



Kaiser Foundation Health Plan
Program Offices

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Mariann Yeager, CEO
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RE: Response to Request for Comments on the Draft Qualified Health Information Network (QHIN) Technical Framework

Dear Ms. Yeager:

Kaiser Permanente shares the goal of nationwide vendor agnostic and multi-use case exchange that the Trusted Exchange Framework and Common Agreement (TEFCA) and the QHIN Technical Framework (QTF) aim to achieve. We appreciate the opportunity to offer feedback.

General Comments

Kaiser Permanente recommends leveraging existing technical standards to support the immediate viability of QHIN-to-QHIN exchange. This approach will immediately allow and facilitate exchange across networks, while future versions can incorporate new technical standards. For example, the public health use case may require different protocols than XCA; TEFCA should abide by CDC standards for public health use cases.

Kaiser Permanente particularly supports the record locator service (RLS) and master patient index (MPI) features of QHINs, which should greatly expand the ability to get a complete view of the patient's records nationwide. Additionally, we hope innovative QHINs may provide smaller healthcare organizations with an efficient and inexpensive way to connect to other healthcare entities nationwide.

We are concerned, however, that the added layer of QHINs on top of existing HIEs and EHRs may make the process more cumbersome and expensive for smaller organizations – thus discouraging their participation. Moreover, apart from the RLS/MPI capabilities, many of the QTF's intended goals can already be achieved through Carequality and DirectTrust, so we emphasize the importance of including these features to make the QHIN-to-QHIN exchange worthwhile and eliminate unnecessary overhead.

It is important to distinguish a QHIN's role in trust arrangements, directories, and record location services from its role as a message broker in the middle of EHI-sharing transactions. The former may be necessary and helpful, but the latter may be unnecessary, complex, burdensome, risky, and costly. The QHIN can get information from directories about where to submit the query, but when point-to-point exchange capability exists, the query itself and clinical information does not necessarily need to go through the QHIN.

TEFCA should not support any use case that requires a QHIN to break open the integrity of a digitally signed document or message to extract, manipulate, or disaggregate individual data elements for any purpose without specific individual consent or authorization for each case of such services. Without an authentic chain of custody that provides objective evidence of original authorship and data provenance, the integrity of health data could be undermined or open to question. Also, it is difficult to determine when data de-duplication or reconciliation is precise and reliable. These scenarios carry risks, including potential liability for source and receiving entities, other legal and compliance issues, misattribution of provenance, as well as significant privacy risks. These serious concerns argue against including such functions in QHINs.

Our feedback on QTF provisions is based on our past and current experiences with existing vendor agnostic exchanges, which amounted to over 28 million exchanges in 2020 alone.

Document Query Scenario

Performance

The QTF would expand distributed queries to all QHINs and their participating sources. We recommend establishing very clear timeout requirements to ensure end users are not waiting an inordinate amount of time to receive information back, i.e., the exchange must be scalable. When a QHIN and/or its source participants exceed a certain level of timeouts, the organizations involved should be required to remediate within a certain period and refrain from issuing distributed queries until complete. If organizations continue to experience timeouts, the QHIN and/or its source participants should be suspended from the network until resolved.

The QTF should prioritize targeted queries bypassing the QHIN exchange model when possible (e.g., point-to-point exchange through Carequality) to minimize volume overload. This could be accomplished as a Patient Discovery (IHE XCPD) or minimally a Document Query and Retrieve (IHE XCA) once the links have been established to the responding participant.

Patient Discovery

As we stated above, we support requiring each QHIN to have an MPI or RLS. Nevertheless, we are concerned with the option in QTF-066 for QHINs to query all of

their participants in bulk, within timeout limitations, instead of using an MPI or RLS. While that option may be feasible for QHINs with smaller volumes of participating sources, it may strain overall performance. Even with QTF-067 requiring delegated patient identity resolution functions to respond within an SLA requirement, performance may suffer with queries to too many endpoints.

We recommend denoting a minimum standard patient matching algorithm and demographic attributes to improve ongoing issues with patient matching. At a minimum, the demographic attributes should include first name, last name, date of birth, address, gender, and phone; the QTF should consider including additional attributes to improve matching accuracy (e.g., SSN, email address, historical addresses). Currently, there are no matching criteria and/or algorithms defined for QHIN-to-QHIN interactions. We strongly urge that the TEFCA establish appropriate minimum criteria and standards to enable consistent and predictable expectations to find all of a patient's data across QHINs.

QHINs should be required to persist patient links; this should not be optional, and we recommend requiring a mechanism for responding participants to indicate a patient link is no longer valid, thus triggering a new patient discovery message.

We recommend including a process for sources (initiating and responding) to coordinate with each other when a false negative query occurs. There should also be a phone directory to help coordinate confirming and updating patient demographics so that a match can be made.

We also recommend a process for QHINs and their sources to coordinate unlinking patient records if the links were made in error. At a minimum, the RCE directory should include QHIN or source organization phone numbers to call for assistance with unlinking. Ideally, a technical mechanism would be available to send notices to the QHIN/source organization regarding unlink requirements and, when trusted, perhaps even to unlink bidirectionally.

In addition to the access consent policy (ACP) workflows, QHIN-to-QHIN exchange should support "point of care" authorization, allowing the querying organization to retrieve the responding organization's authorization form for the patient to sign at the point of care, when required. When no standards exist supporting this workflow, each organization should minimally have a mechanism allowing patients to opt into the exchange if/when opt-in is required by law.

Error messages should clearly state when a patient discovery message fails at the responding organization due to lack of authorization on file. Also, while source organizations are responsible for authenticating their own users, we recommend including confirmation in the message that the query is authorized.

Document Query and Retrieve

Kaiser Permanente recommends that QTF-049 not limit QHINs and their participating sources to producing only static documents in response to a query, as this proposal may create unnecessary barriers to exchange.

For example, many EHRs currently cannot produce and send C-CDAs for admitted patients until they are discharged. This is particularly problematic in skilled nursing facilities (SNFs) when continuing care providers need to review a patient's record prior to rounding at the facility. We are also concerned this limitation may implicate Information Blocking rules if it results in no response to a request for information. Therefore, we recommend the QTF encourage organizations to generate on-demand documents and only allow production of static documents when on-demand capabilities are not available.

We also recommend the QTF should not permit QHINs to combine/consolidate data from multiple sources unless original source provenance can be retained and authenticated indelibly, such as by sending underlying source documents in addition. Please see comments above regarding serious risks and issues with QHINs manipulating data extracted from source artifacts.

We support QTF-042 which mandates that USCDI v1.0 be sent starting Jan 1, 2023 to align with CEHRT timelines. For clinical treatment exchanges, we also suggest adding a requirement to send USDCI data discretely, specifying it will not be sufficient to send, for example, a C-CD

QTF-048 allows organizations to include start and stop time parameters in their document retrieve messages. These bulk document retrieves may make sense in certain use cases (e.g., benefit determinations) but are often problematic in treatment use case – they can crash systems when too many documents are returned.

We recommend a better approach would be to send a complete list of all documents that are available and allow the end users to select and retrieve the ones they need. Alternatively, supporting the use of additional filters in the bulk retrieves would help to target needed documents (e.g., “all inpatient encounters over the last X time period”).

Message Delivery Scenario

The QTF should allow for message delivery services that do not rely on the sending provider knowing whom to notify about the patient's care. That could be achieved by supporting a provider lookup function in the QHIN (similar to MPI/RLS for patient matching) that can match the patient to the provider's care team, then route the message to the care team without the sending provider knowing the external provider's Direct address.

A patient/provider lookup feature must be able to verify the provider is still actively part of the patient's care team, thus should be notified of the patient's care. The feature may require a patient/provider subscription service that is integrated and updated in real time with the source systems. Without a sophisticated provider lookup function in the QHIN,

it is not clear what additional services QHINs may provide that HISPs do not already provide for message delivery. Responding organizations should be able to decline messages if they are not interested in receiving certain message types.

The QTF should promote consistency in how organizations are represented in the directory for both the Message Delivery and Query scenarios. Sometimes an organization is set up for point-to-point/exchange with Direct, but then query/response goes through their “parent” EHR organization, creating two separate links to the same organization in the patient’s chart with the same data that cannot be de-duplicated.

Miscellaneous Comments

Kaiser Permanente recommends the RCE should notify the community of new QHIN participants at a minimum of once per month (follow-up to QTF-072).

We strongly support the requirement in QTF-095 that all QHINs maintain a test instance. We frequently must test new workflows in Production (particularly with other HISPs), which is not desirable.

For the reporting metric, “Total number of documents retrieved via QHIN Query,” we recommend the QTF consider distinguishing the metric by total document lists exchanged vs. total documents exchanged. Document lists are a better indication of how many *patient* exchanges occur, as opposed to total documents, which will often include many documents per patient.

We recommend the QTF require QHINs and their source participants to consistently send standard clinical content codes such as SNOMED CT, RxNORM, and LOINC to support better use of discrete data, including de-duplication, decision support and reporting. We recommend that a conformity assessment framework should be established to test and verify the use of ONC required and recommended standards for clinical data content. Measures of standards conformity should be developed and reported to demonstrate that these data content requirements are being fulfilled.

We recommend requiring that data element reference IDs remain consistent.

QHINS that store clinical information in document or discrete repositories should be subject to robust security requirements using the NIST security framework, aligned with industry best practices to safeguard against ransomware or other cyber-attacks. System and organization controls (SOC 2) audits should be required for QHINs based on AICPA trust services criteria for security, availability, processing integrity, confidentiality, and privacy, and QHINs should be encouraged to communicate their cybersecurity risk using the SOC for Cybersecurity framework. SOC2 reports, along with SOC for Cybersecurity reports, should be available to QHIN customers and stakeholders.

Comments regarding the Common Agreement

We are concerned about the different layers/intermediaries involved in QHIN-to-QHIN exchange from a troubleshooting perspective. Frequently, questions arise when exchanging with existing HIEs about identifying who is on point to resolve an issue and how to engage them (HIE, EHR, source organization or others). We recommend establishing clear guidance on the process for troubleshooting across and within QHINs, and possibly setting explicit service level agreements.

Specific Questions

1. Should the QTF include QHIN Message Delivery? If you believe QHIN Message Delivery should be included, how should it be technically specified? Note: if QHIN Message Delivery is excluded from the first version of the QTF that would mean QHINs would not be required to support QHIN-to-QHIN message delivery during the initial go-live under the Common Agreement. To facilitate better understanding of the public feedback, the RCE requests that responses consider the following three options. The preferred option, as included in this Draft 2 of the QTF is Option 1:

- o Option 1: **Require** “QHIN Message Delivery” modality in QTF using the Integrating the Health Care Enterprise (IHE) Cross-Community Document Reliable Interchange (XCDR) profile with a future transition to FHIR; or*
- o Option 2: **Defer** “QHIN Message Delivery” from QTF until a FHIR based solution is readily available; or*
- o Option 3: **Include** “QHIN Message Delivery” using XCDR as **optional** in QTF until a FHIR based solution is readily available.*

ANSWER:

Kaiser Permanente supports Option #3. As we note above, it is not clear what additional functions QHIN message delivery can offer that are not already provided by existing HISPs in the DirectTrust network. As a result, QHIN Message Delivery should not be a required element until further functionality (such as FHIR) is made available in the QHIN model.

2. What elements should be included in a TEFCA FHIR Roadmap to provide predictability and a clear direction for QHIN-to-QHIN exchange regarding the implementation of FHIR for QHIN Query, QHIN Message Delivery, and for enabling FHIR data to be used by Health IT systems?

ANSWER:

Kaiser Permanente supports the development of a TEFCA FHIR Roadmap that builds and expands on the current services, as outlined in the QTF. We also support the addition of FHIR based services and data sharing that allow QHINs to facilitate point-to-point connections among participants and sub-participants to utilize the dominant data sharing methods and frameworks of the current and future internet and world wide web. The roadmap should outline how FHIR based document exchange can be used to migrate nationwide document exchange from IHE profile-based to a FHIR-based model over time.

KP Comments
Sequoia Project RFC TEFCA QTF

Please feel free to contact Jamie Ferguson (415.250.0561; jamie.ferguson@kp.org) or [Zach](mailto:zachary.m.gillen@kp.org) Gillen (510.418.7438; zachary.m.gillen@kp.org) with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "JA Ferguson". The signature is written in a cursive, flowing style.

Jamie Ferguson
Vice President, Health IT Strategy and Policy
Kaiser Foundation Health Plan, Inc.