Trusted Exchange Framework and Common Agreement[SM]

Qualified Health Information Network[TM] (QHIN[TM]) Technical Framework (QTF)

Version 1.1

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OVERVIEW

The 21st Century Cures Act, signed by President Obama in 2016, calls on ONC to "develop or support a trusted exchange framework, including a common agreement [TEFCA] among health information networks nationally." In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the Recognized Coordinating Entity® (RCE™) to administer a network-of-networks enabled by the Common Agreement called for in the Cures Act.

The Qualified Health Information Network (QHIN) Technical Framework (QTF), developed by the RCE, describes the functional and technical requirements that a Health Information Network (HIN) must fulfill to serve as a QHIN under the Common Agreement. The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. The QTF is intended to be consistent with the Common Agreement, but to the extent of any conflict or inconsistency, the terms of the Common Agreement shall control.

The QTF focuses primarily on the technical and functional requirements for interoperability among QHINs, including specification of the standards that QHINs must implement to enable QHIN-to-QHIN exchange of health information.

QTF Version 1.1 Scope

The technical and functional requirements described in the QTF enable two information exchange modalities for QHINs:

- QHIN Query
- QHIN Message Delivery

The QTF also describes high-level functional requirements QHINs must support for exchange within their health information networks. As long as QHINs are able to achieve the required functional outcomes within their networks, they generally have the operational flexibility to select appropriate standards and approaches consistent with the needs of their business environments. In limited instances, the QTF may specify a particular element of Participant or Subparticipant behavior in order to ensure consistency in QHIN-to-QHIN behavior.

The technical and functional requirements described in the QTF reflect many of the technologies and standards used for network-based health information exchange today. For example, organizations supporting health information exchange nationally (e.g., CommonWell Health Alliance, eHealth Exchange, Carequality) generally use Integrating the Healthcare The healthcare industry has started using new exchange methods, such as Representational State Transfer (REST) application programming interfaces (APIs) and standards like Health Level Seven (HL7®)

Fast Healthcare Interoperability Resources (FHIR®)[1]. As discussed in the FHIR Roadmap for TEFCA Exchange[2] (the Roadmap), FHIR Documents or Resources can be exchanged under QTF V1.1 but this will require out-of-band coordination between QHINs. In the next release of the Common Agreement and the QTF, Network Facilitated FHIR Exchange will be implemented as discussed in the Roadmap.

The scope of data for TEFCA exchange is TEFCA Information as defined by the Common Agreement and maintained by QHINs, Participants or Subparticipants. The United States Core Data for Interoperability (USCDI) is a named data standard in the QTF but it is neither a "floor" nor a "ceiling" for data exchange in TEFCA. TEFCA Information maintained by QHINs, Participants and sub participants could be more or less than the data in the version of USCDI specified in the QTF. There is no minimum requirement for QHINs, Participants or Subparticipants to maintain all the data elements in the version of USCDI specified in the QTF. However, the USCDI provides conformance requirements when exchanged in TEFCA. When TEFCA exchange occurs for the data in the USCDI version specified in the QTF, then the data need to conform to the requirements specified in the USCDI. This could be done by the Participants or Subparticipants or by the Responding QHIN depending on the internal configuration and policies of each QHIN.

Definitions

Capitalized terms are used throughout the QTF. Many of such terms are defined in the Common Agreement and are not duplicated in this list. Terms specific to the QTF are defined here:

- **Actor**: A QHIN, Participant, Subparticipant.
- **Access Consent Policy** (ACP): Policies that may influence access control decisions and which can be referenced in queries.
- **Assigning Authority**: The organization that issues a patient identifier.
- **Enterprise Master Patient Index** (eMPI): A system that coordinates patient identification across multiple systems by collecting, storing, and managing identifiers and patient-identifying demographic information from a source system.
- **HomeCommunityID** (HCID): A globally unique identifier for an Actor.
- **Initiating QHIN**: A QHIN that initiates a QHIN Query or QHIN Message Delivery.
- **Instance Access Consent Policy** (IACP): Policy instances (e.g., patient authorization forms) which may influence access control decisions, and which can be referenced by queries.
- **Message Delivery Solicitation**: A request for a QHIN to initiate a QHIN Message Delivery.
- **Message Source**: Originator of a Message Delivery Solicitation.
- **QHIN Directory:** A system used by QHINs to record and resolve the identifiers and endpoints of members of their network (i.e., Participants and Subparticipants). The QHIN Directory includes a local copy of the RCE Directory.

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[1] HL7® FHIR® – latest published version is available at: https://fhir.hl7.org/, including the REST API available at: https://hl7.org/fhir/http.html
[2] *FHIR Roadmap for TEFCA Exchange,* available at: https://rce.sequoiaproject.org/tefca-and-rce-resources

- **QHIN Message Delivery:** The act of a QHIN delivering information to one or more other QHINs (i.e., via QHIN-to-QHIN exchange) for delivery to one or more Participants, Subparticipants, or Individuals (sometimes referred to as a "push").
- **QHIN Query:** The act of a QHIN requesting information from one or more other QHINs (sometimes referred to as a "pull").
- **Query Solicitation:** A request for a QHIN to initiate a QHIN Query.
- **Query Source**: Originator of a Query Solicitation.
- **RCE Directory:** The individual organization entries that form the content of the RCE Directory Service.
- **Record Locator Service** (RLS): A service that provides authorized users the location of records based on criteria such as a patient ID and/or record data type, as well as providing functionality for the ongoing maintenance of health record location information.
- **Responding QHIN**: A QHIN that receives (and responds to as appropriate) a QHIN Query or QHIN Message Delivery from an Initiating QHIN.
- **Responding Source**: Receiver of a message delivery, or the source of any information provided in response to a QHIN query.
- **Uniform Resource Identifier** (URI): a set of characters that identifies a specific logical or physical resource used by Internet related computer programs.

The following actor names are specific to IHE profiles and used within the QTF with the following definitions, for full definitions please see IHE Technical Frameworks General Introduction, Appendix A: IHE Actor Definitions.[3]

- **Initiating Gateway**: A transaction gateway that supports outgoing requests and responses for QHIN Query (Patient Discovery, Document Query, Document Retrieve) and QHIN Message Delivery.
- **Responding Gateway:** A transaction gateway that supports incoming requests and responses for QHIN Query (Patient Discovery, Document Query, Document Retrieve) and QHIN Message Delivery.

The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD","SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in IETF BCP 14.[4]

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[3] *IHE Technical Frameworks General Introduction, Appendix A* Available at:
https://profiles.ihe.net/GeneralIntro/ch-A.html
[4] Best Current Practice 14 - available at: https://www.rfc-editor.org/info/bcp14

QHIN EXCHANGE SCENARIOS

The following QHIN exchange scenarios present basic workflows for the supported exchange modalities. Each scenario depicts a real-world use case that stakeholders might encounter. The scenarios do not represent all possible workflows or use cases. Rather, they generally describe the various functions performed to enable QHIN-to-QHIN information exchange.

Document Query Scenario

In this scenario, a healthcare provider sees a new patient and seeks to find the patient's health information among the QHINs to inform diagnosis and treatment. This scenario assumes basic patient demographic information is available to the provider.

The healthcare provider is a participant in a health information network (state/local HIE, vendor- or payer-based, etc.), which is a Participant of a QHIN. To find health information about the patient, the provider first submits a Query Solicitation to the local network, which is routed to the QHIN over a secure channel. The Query Solicitation may include patient demographic information for patient identity resolution, query parameters indicating which information the provider is looking for, and/or a list of entities to query. The local network also transmits information about the provider's identity, as well as an Exchange Purpose specified by the provider ("Treatment" in this scenario).

The QHIN processes the Query Solicitation and uses the information to initiate a QHIN Query to any appropriate Responding QHINs. If the provider specified a target for the query, the Initiating QHIN checks its QHIN Directory to identify the appropriate Responding QHINs. Otherwise, the Initiating QHIN will initiate a QHIN Query with all other QHINs.

The Initiating QHIN connects to each Responding QHIN using the Internet Engineering Task Force (IETF) Transport Layer Security (TLS) protocol[5] to establish a secure channel for the QHIN Query transaction; each QHIN authenticates the other QHIN (i.e., mutual authentication). After establishing a secure channel, the Initiating QHIN sends each Responding QHIN a Security Assertion Markup Language (SAML)[6] assertion conforming to the IHE Cross-Enterprise User Assertion (XUA) profile along with the query transaction.[7] The SAML assertion preserves

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[5] *The Transport Layer Security (TLS) Protocol Version 1.2* (IETF RFC 5246) - available at: https://tools.ietf.org/html/rfc5246 and *The Transport Layer Security (TLS) Protocol Version 1.3* (IETF RFC 8446) – available at https://tools.ietf.org/html/rfc8446

[6] *Security Assertion Markup Language* (SAML) – available at: https://docs.oasis-open.org/security/saml/Post2.0/sstc-saml-tech-overview-2.0.html

[7] *IHE Cross-Enterprise User Assertion (XUA) profile* - available in the IHE IT Infrastructure (ITI) Technical Framework Volume 1: Integration Profiles at: https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Rev17-0_Vol1_FT_2020-07-20.pdf

information from the Query Solicitation about the Query Source and the Exchange Purpose but is assembled by the QHIN and signed by the QHIN's digital certificate.

A QHIN Query typically involves two major workflows, patient discovery via IHE XCPD and document query (including location and retrieval) via IHE XCA. In the patient discovery workflow, the Initiating QHIN shares patient demographic information via an XCPD request with the Responding QHIN(s). Each Responding QHIN uses the demographic information to resolve the patient's identity (i.e., "patient matching"), and returns an XCPD response with the resolved identity (including a local patient identifier, demographic information about the patient, etc.).

In the document query workflow, the Initiating QHIN sends an XCA request including a patient identifier (e.g., obtained via the Patient Discovery workflow) and query parameters to the Responding QHIN(s) to discover whether clinical documents are available. Each Responding QHIN uses the query parameters and patient identity to discover clinical documents that meet the query criteria and sends an XCA response with a list of document identifiers to the Initiating QHIN. The list of document identifiers is routed through the local network to the provider, who reviews the response and selects the relevant documents for retrieval. The Initiating QHIN then requests the relevant documents, which are retrieved and shared with the Initiating QHIN by the Responding QHIN(s).

After retrieving the relevant documents, the Initiating QHIN routes them back through the local network to the provider. Each QHIN involved in the query maintains audit logs of all activities and transactions the QHIN performed in the process of resolving the query, according to the IHE Audit Trail and Node Authentication (ATNA) profile.[8]

Specified standards for a QHIN Query are included in *Table 1*.

Table 1. Specified Standards for QHIN Query	
Query Functions	**Specified Standard(s) / Profile(S)**
Secure Channel	• IETF TLS 1.2 w/ BCP-195[9] or • IETF TLS 1.3 w/ BCP-195
Mutual Authentication	• IETF TLS w/ BCP-195
User Authentication	• IHE XUA
Authorization & Exchange Purpose	• IHE XUA
Query for Patients	• IHE XCPD
Document Query and Retrieve	• IHE XCA
Auditing	• IHE ATNA (Content only)

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[8] *IHE Audit Trail and Node Authentication (ATNA) profile* - available in the IHE IT Infrastructure (ITI) Technical Framework Volume 1: Integration Profiles at:
https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Rev17-0_Vol1_FT_2020-07-20.pdf
[9] *Recommendations for Secure Use of Transport Layer Security (TLS) and Datagram Transport Layer Security (DTLS)* (IETF BCP 195) - available at: https://tools.ietf.org/html/bcp195

Actors

The following lists the Actors and services included as part of the workflow. Cardinality represents the number of that Actor/service expected and which QTF "system" Actor is expected to have that service or Actor role.

Actors/Services	Cardinality	System Actor
Query Source	1..1	Any initiating Actor
Initiating Gateway	1..1	Initiating QHIN
QHIN Directory	1..1	Initiating QHIN
QHIN Directory	1..*	Responding QHIN(s)
Responding Gateway	1..*	Responding QHIN(s)
Responding Source(s)	1..*	Any responding Actor

Assumptions

1) All Initiating and Responding Actors agree on transport level details (specified for transactions between QHINs elsewhere in this document) that allow for the following:
   a) System authentication and encrypted communications over a secure channel.
   b) The ability to provide information in each transaction that identifies security and permission details about the request such as: who is sending, what their role is, and what their Exchange Purpose is.
   c) The ability of Actors to choose if/how to allow a transaction to proceed based on privacy policies, security details, and the requirements of the Common Agreement.
2) The Query Source does not know both the patient identifier(s) and Responding Source(s) for a query.
   a) If the Patient Identifier(s) and Responding Source(s) are known, the patient discovery phase of the query workflow may be omitted.

Pre-conditions

The following workflow assumes the following conditions:

- The Query Source knows sufficient patient demographics for a successful match as determined by the Responding Actor.
- Each Actor has the appropriate service endpoint(s) and other connectivity information for any other Actors above or below it in the hierarchy with which it connects directly.
- The RCE Directory includes the organization facility name(s), and HomeCommunityID(s) for all current Participants and Subparticipants. Each Participant and Subparticipant is matched to the appropriate QHIN.

- Each QHIN maintains an up-to-date copy of the RCE Directory.
- Responding QHINs know the current HomeCommunityIDs for any Responding Sources.
- Each QHIN has either a Record Locator Service (RLS) OR Enterprise Master Patient Index (eMPI) OR uses other techniques to perform patient lookup within the Service Level Requirements timeout limitation as specified in the QHIN Service Level Requirements Policy[10].

Use Case Steps

Patient Discovery
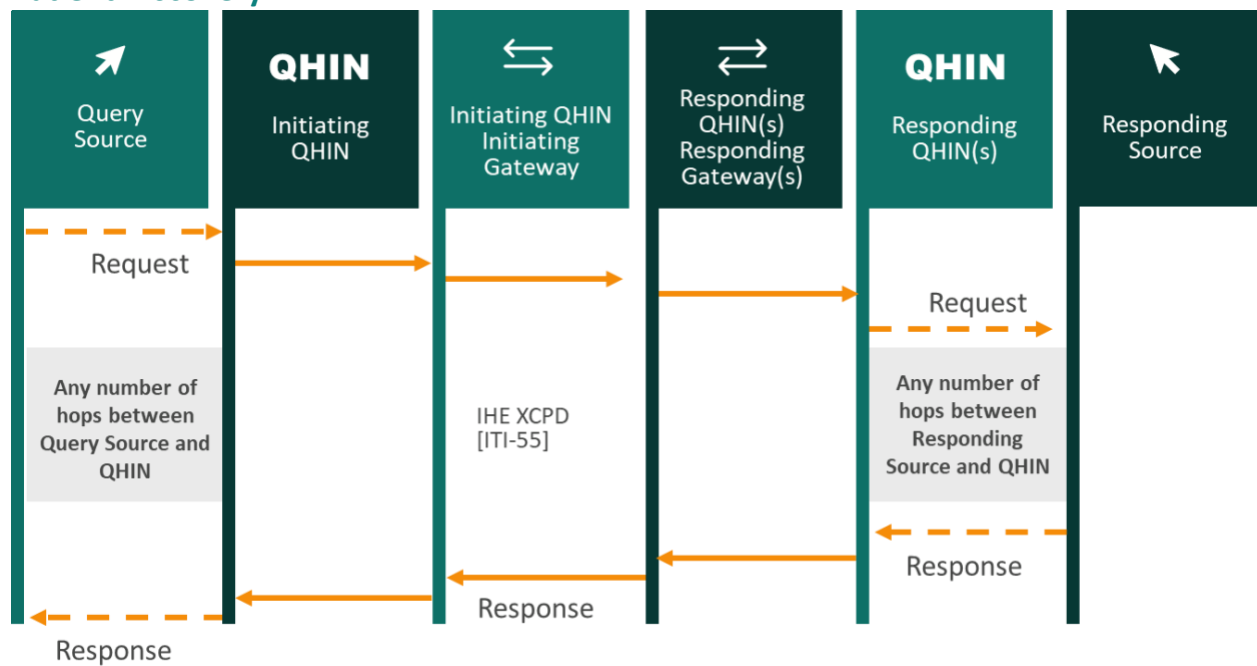
Nominal Flow (QHIN maintains an eMPI or RLS)

1) The Query Source sends a Query Solicitation, through any intermediary Subparticipants or Participant, as applicable, to the Initiating QHIN to discover patient matches by demographics.
   a) The Query Solicitation includes all available patient demographics.
2) The Initiating QHIN creates an IHE Cross Gateway Patient Discovery [ITI-55] request based on the Query Solicitation and sends it via the Initiating Gateway to the Responding Gateways of all Responding QHINs. See *IHE ITI TF-2b: 3.55*.
   a) The Initiating QHIN creates an audit log entry including the HCID of the Query Source and Responding QHIN(s).

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[10] *QHIN Service Level Requirements Policy,* when available, to be located at: https://rce.sequoiaproject.org/tefca-and-rce-resources

3) Each Responding QHIN compares the demographics to its known patients, applying its own algorithm(s) to determine potential matches, and returns an IHE Cross Gateway Patient Discovery [ITI-55] response to the Initiating QHIN's Initiating Gateway.
    a) The IHE Cross Gateway Patient Discovery [ITI-55] response contains one or more patient matches from all potential Responding Sources, including demographics and patient ID as known by the Responding Source. The response may contain multiple entries where each entry reflects a different source of information but will include only one identifier per patient per Responding Source.
    b) The Responding QHIN creates an audit log entry including the HCID of the Initiating QHIN, Query Source, and Responding Source(s).
4) The Initiating QHIN returns the response(s) to the Query Source (through any intermediary Participant or Subparticipants, as applicable).
    a) The Initiating QHIN creates an audit log entry including the HCID of the Query Source, Responding QHIN(s), and Responding Source(s).
    b) Note: Any QHINs participating in the transaction should include any errors in its audit log. QHINs should not include the contents of successful responses in their audit logs but should include the XCPD query.

Alternate Flow 1: Querying Specific Organization(s)

The following flow may be used when the Query Source only wants to query one or more specific organizations:

1) The Query Source sends a Query Solicitation, through any intermediary Subparticipants or Participant as applicable, to the Initiating QHIN to find patient matches by demographics from specific organizations where a patient may have healthcare data.
    a) The Query Solicitation includes all available patient demographics as well as the HomeCommunityID(s) and/or other information about the target Responding Source(s) (e.g., organization name, city, and state). See *IHE ITI TF-1: 27 XCPD Integration Profile* and *IHE ITI TF-2b: 3.55*.
2) The Initiating QHIN queries its QHIN Directory to identify the appropriate Responding QHIN for each Responding Source provided by the Query Source.
3) Nominal Flow resumes at Step 2.

Alternate Flow 2: Query Source asserts an Instance Access Consent Policy or Access Consent Policy

1) The Query Source includes the Uniform Resource Identifier (URI)(s) of one or more Access Consent Policies (ACPs) or Instance Access Consent Policies (IACP) in its Query Solicitation.
    a) An ACP may have an associated instance (IACP, e.g., a signed patient permission form) for a specific patient.
2) Each Responding Source obtains the (I)ACP per the Document Retrieve Workflow.
    a) A Responding Source may incorporate retrieved (I)ACPs into access control decisions made with respect to releasing information in response to a query.

    b) If a Responding Source is unable to obtain the (I)ACP document or is unable to process a retrieved (I)ACP document and would not be able to disclose patient information without a valid (I)ACP, an error response is returned. The flow ends for this Responding Source and the use case continues.

3) Nominal Flow resumes at Step 3.

Alternate Flow 3: QHIN does not maintain an eMPI or RLS

1) Workflow beings in step 3.
2) The Responding QHIN queries its Participants, based on its chosen method that meets SLAs, to discover patient matches using the patient demographics and returns an IHE Cross Gateway Patient Discovery [ITI-55] response to the Initiating QHIN's Initiating Gateway.

    a) The response contains one or more patient matches from all potential Responding Sources, including demographics and patient ID as known by each Responding Source. The response must also include the Responding Participant's HomeCommunityID and Assigning Authority, or the HomeCommunityID and Assigning Authority of any Subparticipants where a match was found. The response may contain multiple entries, where each entry reflects a different source of information, but should not contain multiple patient identifiers for a match at a single Responding Source.

Document Query
Nominal Flow
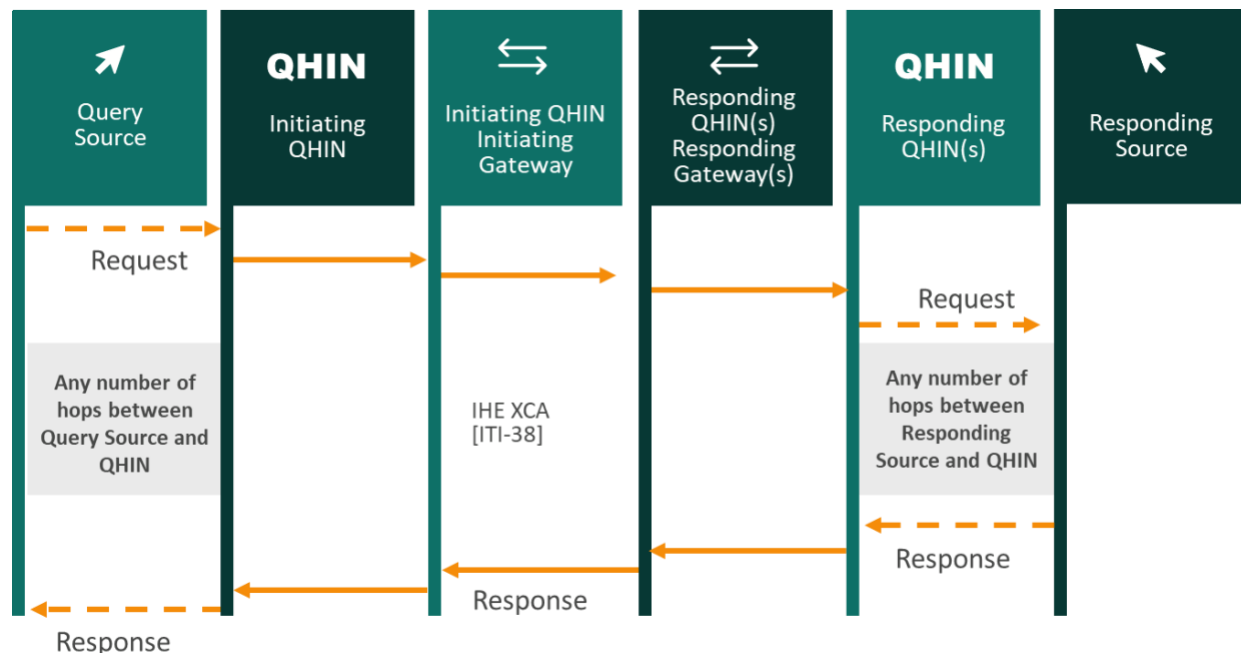
1) The Query Source sends a Query Solicitation, through any intermediary Subparticipants or Participant, as applicable, to the Initiating QHIN to query for document metadata.

a) The Query Solicitation includes some number of patient identifiers and an Assigning Authority and HCID for each.
b) The Initiating QHIN queries its QHIN Directory to identify the appropriate Responding QHIN(s) for each HCID included in the Query Solicitation.
2) The Initiating QHIN creates an IHE Cross Gateway Query [ITI-38] FindDocuments request based on the Query Solicitation and sends it via the Initiating Gateway to each Responding QHIN's Responding Gateway.
a) The Initiating QHIN creates an audit log entry including the HCID and Assigning Authority of the Query Source and Responding QHIN(s).
3) Each Responding QHIN queries its QHIN Directory to identify the appropriate Responding Source(s) and sends a request for document metadata, through any intermediary Participant or Subparticipants as applicable, to each Responding Source.
a) The Responding QHIN's request includes the patient identifier as known by the Responding Source and may include some number of query parameters.
b) The Responding QHIN creates an audit log entry including the HCID and Assigning Authority of the Query Source, Initiating QHIN, and Responding Source(s).
4) Each Responding Source returns a response with document metadata based on any query parameters and/or local access control policies.
5) Each Responding QHIN combines the responses from the Responding Source(s) and returns a single IHE Cross Gateway Query [ITI-38] FindDocuments response to the Initiating QHIN's Initiating Gateway.
a) The Responding QHIN creates an audit log entry including the HCID and Assigning Authority of the Responding Source(s), Initiating QHIN, and Query Source.
6) The Initiating QHIN returns the response(s) to the Query Source, through any intermediary Participant or Subparticipants as applicable.
a) The Initiating QHIN creates an audit log entry identifying the Responding Source(s) and Query Source.

Alternate Flow 1: Query Returns Partial Success

1) This workflow begins at Step 4 of the Nominal Flow.
2) A Responding Source returns an error message (e.g., no document is found, etc.).
3) The Responding QHIN combines the responses from the Responding Source(s) and returns a single IHE Cross Gateway Query [ITI-38] FindDocuments response to the Initiating QHIN's Initiating Gateway.
a) If the Responding QHIN is able to return some but not all available document entries, the response includes all available DocumentEntries, the status urn:ihe:iti:2007:ResponseStatusType:PartialSuccess, and some number of RegistryError elements.
4) The Initiating QHIN chooses to execute one of the following subflows:
a) Subflow 1: If the Query Source is unable to process a Partial Success response, the Initiating QHIN returns the response to the Query Source (through any intermediary

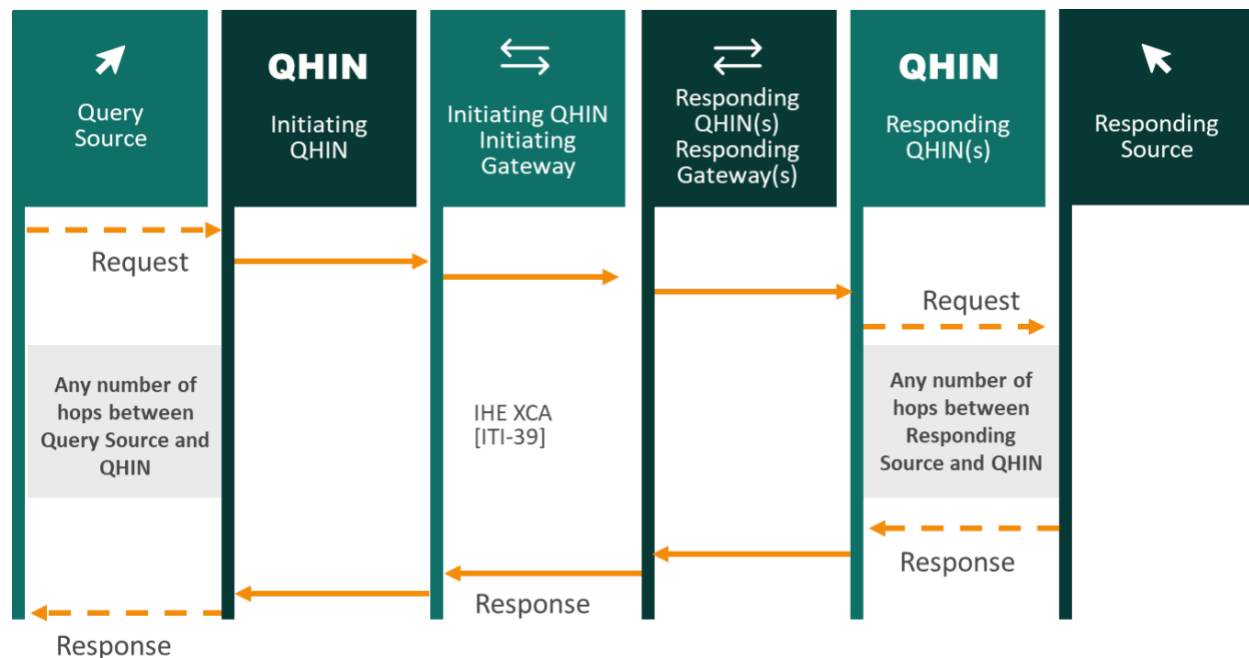Participant or Subparticipants, as applicable) as a Success. The response does not indicate there were errors.

b) Subflow 2: The Initiating QHIN returns the response to the Query Source (through any intermediary Participant or Subparticipants, as applicable), along with information about any errors.

Alternate Flow 2: Query Source asserts an Instance Access Consent Policy or Access Consent Policy

1) The Query Source includes the URI(s) of one or more Access Consent Policies (ACPs) or Instance Access Consent Policies (IACP) in its Query Solicitation.
   a) An ACP may have an associated instance (IACP, e.g., a signed patient consent form) for a specific patient.
2) Each Responding Source obtains the (I)ACP per the Document Retrieve Workflow.
   a) A Responding Source may incorporate retrieved (I)ACPs into access control decisions made with respect to releasing information in response to a query.
   b) If a Responding Source is unable to obtain the (I)ACP document or is unable to process a retrieved (I)ACP document and would not be able to disclose patient information without a valid (I)ACP, an error response is returned. The flow ends for this Responding Source and the use case continues.
3) Nominal Flow resumes at Step 4.

Document Retrieve
Nominal Flow

1) The Query Source sends a Query Solicitation, through any intermediary Subparticipants or Participant, as applicable, to the Initiating QHIN to retrieve documents.
    a) The Query Solicitation includes the HomeCommunityID(s), Repository ID(s) if known, and Document IDs at the Responding Source(s).
    b) The Initiating QHIN queries its QHIN Directory to identify the appropriate Responding QHIN(s) for each HCID included in the Query Solicitation.
2) The Initiating QHIN creates an IHE Cross Gateway Retrieve [ITI-39] request based on the Query Solicitation and sends it via the Initiating Gateway to each Responding QHIN's Responding Gateway.
    a) The Initiating QHIN creates an audit log entry including the HCID of the Query Source and Responding QHIN(s).
3) Each Responding QHIN queries its QHIN Directory to identify the appropriate Responding Source(s) and sends a request to retrieve documents, through any intermediary Participant or Subparticipants as applicable, to each Responding Source.
    a) The Responding QHIN's request includes the repository ID, document ID, and/or any other document metadata as known by the Responding Source.
    b) The Responding QHIN creates an audit log entry including the HCID of the Query Source, Initiating QHIN, and Responding Source(s).
4) Each Responding Source returns a response with the appropriate document(s) and associated document ID(s) to the Responding QHIN, through any intermediary Subparticipants or Participant as applicable.
5) Each Responding QHIN combines the responses from the Responding Source(s) and returns a single IHE Cross Gateway Retrieve [ITI-39] response to the Initiating QHIN's Initiating Gateway.
    a) The Responding QHIN creates an audit log entry including the HCID and Assigning Authority of the Responding Source(s), Initiating QHIN, and Query Source.
6) The Initiating QHIN returns the response(s) to the Query Source, through any intermediary Participant or Subparticipants as applicable.
    a) The Initiating QHIN creates an audit log entry identifying the Responding Source(s) and Query Source.

Alternate Flow 1: Error Flow

1) This workflow begins at Step 4 of the Nominal Flow.
2) A Responding Source returns an error message (e.g., XDSRepositoryError).
3) The Responding QHIN returns a response to the Initiating QHIN's Initiating Gateway including the status urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Failure and one or more regrep:ResponseStatusType:RegistryError elements.
4) The Initiating QHIN returns a failure message to the Query Source for dispositioning.

Alternate Flow 2: Retrieve returns partial success

1) This workflow begins at Step 4 of the Nominal Flow.
2) A Responding Source returns an error message (e.g., no document is found).

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3) The Responding QHIN combines the responses from the Responding Source(s) and returns a single IHE Cross Gateway Retrieve [ITI-39] response to the Initiating QHIN's Initiating Gateway.
    a) If some, but not all requested documents are available, the response includes all available documents, the status urn:ihe:iti:2007:ResponseStatusType:PartialSuccess, and some number of RegistryError elements.
4) The Initiating QHIN chooses to execute one of the following subflows:
    a) Subflow 1: If the Query Source is unable to process a Partial Success response, the Initiating QHIN returns the response to the Query Source (through any intermediary Participant or Subparticipants, as applicable) as a Success. The response does not indicate there were errors.
    b) Subflow 2: The Initiating QHIN returns the response to the Query Source (through any intermediary Participant or Subparticipants, as applicable), along with information about any errors.

Alternate Flow 3: Query Source asserts an Instance Access Consent Policy or Access Consent Policy

1) The Query Source includes the URI(s) of one or more Access Consent Policies (ACPs) or Instance Access Consent Policies (IACP) in its Query Solicitation.
    a) An ACP may have an associated instance (IACP, e.g., a signed patient consent form) for a specific patient.
2) Each Responding Source obtains the (I)ACP per the Document Retrieve Workflow.
    a) A Responding Source may incorporate retrieved (I)ACPs into access control decisions made with respect to releasing information in response to a query.
    b) If a Responding Source is unable to obtain the (I)ACP document or is unable to process a retrieved (I)ACP document and would not be able to disclose patient information without a valid (I)ACP, an error response is returned. The flow ends for this Responding Source and the use case continues.
3) Nominal Flow resumes at Step 4.

Post-conditions

1) The Initiating QHIN has correlated the patient ID(s) and associated demographics received from the Query Source with the patient IDs and associated demographics as known by each Responding Source.
    a) Whether the Initiating QHIN persists this correlation for later use is beyond scope of this workflow and is not specified.
2) The Query Source has obtained all available patient matches.
3) The Query Source has obtained all requested document metadata as known by each Responding Source, per the parameters of the query.
4) The Query Source has retrieved all available documents as known by each Responding Source which does not respond with an error.
5) All requests and responses have audit log entries showing source(s) and destination(s).

Message Delivery Scenario

In this scenario, a healthcare provider treats a patient in an emergency department and seeks to send a summary of the patient's care to the patient's primary care provider(s) through QHIN-to-QHIN exchange.

The healthcare provider is a member of a local network (state/local HIE, vendor- or payer-based, etc.), which is connected as a Participant of a QHIN. To send the patient's care summary, the provider first sends a Message Delivery Solicitation to the local network, which is routed to the QHIN over a secure channel. The Message Delivery Solicitation includes the content of the message (i.e., the care summary), patient demographics and/or identifiers for a single patient, and information about the intended Responding Source of the message. The local network also transmits information about the identity of the provider sending the message, as well as an Exchange Purpose specified by the provider ("Treatment" in this scenario).

The QHIN processes the Message Delivery Solicitation, checks its QHIN Directory to identify the appropriate Responding QHIN, and initiates a QHIN Message Delivery. The Initiating QHIN connects to the Responding QHIN using the TLS protocol to establish a secure channel for the QHIN Message Delivery transaction; each QHIN authenticates the other QHIN (i.e., mutual authentication). After establishing a secure channel, the Initiating QHIN sends the Responding QHIN a SAML assertion conforming to the IHE XUA profile along with the message delivery transaction. The SAML assertion preserves information from the Message Delivery Solicitation about the Message Source, and the Exchange Purpose, but is assembled by the QHIN and signed by the QHIN's digital certificate.

The QHIN Message Delivery transaction uses the IHE Cross-Community Document Reliable Interchange (XCDR) profile[11] to send the provider's message and other metadata from the Initiating QHIN to the Responding QHIN. The Responding QHIN then converts the XCDR transaction into the appropriate internal format, if necessary, and transmits the message to the Responding Source. The message is routed through any intermediary Participant and Subparticipants, as necessary. The Responding Source returns an acknowledgement message with appropriate disposition information to the Responding QHIN, which forwards the acknowledgment to the Initiating QHIN. The Initiating QHIN routes the acknowledgement through its network, including any intermediary Participant and Subparticipants as necessary, to the provider that sent the message.

Each QHIN involved in the QHIN Message Delivery maintains audit logs of all activities and transactions the QHIN performed in the process of delivering the message, according to the IHE ATNA profile.

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[11] *IHE Cross-Community Document Reliable Interchange (XCDR) profile* - available as a supplement to the IHE IT Infrastructure (ITI) Technical Framework at:
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XCDR.pdf

Specified standards for QHIN Message Delivery are included in *Table 2*.

Table 2. Specified Standards for QHIN Message Delivery	
Message Delivery Functions	**Specified Standard / Profile**
Secure Channel	• IETF TLS 1.2 w/ BCP-195 or • IETF TLS 1.3 w/ BCP-195
Mutual Authentication	• IETF TLS
User Authentication	• IHE XUA
Authorization & Exchange Purpose	• IHE XUA
Message Delivery	• IHE XCDR
Auditing	• IHE ATNA

Actors

Actors/Services	Cardinality	System Actor
Message Source	1..1	Any initiating Actor
Initiating Gateway	1..1	Initiating QHIN
QHIN Directory	1..1	Initiating QHIN
QHIN Directory	1..*	Responding QHIN(s)
Responding Gateway	1..*	Responding QHIN(s)
Responding Source(s)	1..*	Any responding Actor

Assumptions

1. All Initiating and Responding Actors agree on transport level details (specified for transactions between QHINs elsewhere in this document) that allow for the following:
a. System authentication and encrypted communications over a secure channel.
b. The ability to provide information in each transaction that identifies security and permission details about the request such as: who is requesting, what their role is, and what their Exchange Purpose is.
c. The ability of the QHIN's Responding Gateway and Participants to choose if/how to allow the transaction to proceed based on this information and the requirements of the Common Agreement.

Pre-conditions

The following workflow assumes the following conditions:

- The Message Source knows a sufficient number of the patient's demographics for a successful match as determined by the Responding Actor.
- The Message Source knows the HomeCommunityID or other organizational information (e.g., organization name, city, and state) necessary to determine the appropriate destination of the message.

- Each Actor has the appropriate service endpoint(s) and other connectivity information for any other Actors with which it connects directly.
- The RCE Directory includes the organization name(s), and HomeCommunityID(s) for all current Participants and Subparticipants who have chosen to participate as a Responding Source of QHIN Message Delivery. Each Participant and Subparticipant is matched to the appropriate QHIN.
- Each QHIN maintains an up-to-date copy of the RCE Directory.
- Responding QHINs know the current HomeCommunityIDs for any Responding Sources.

Use Case Steps

Message Send
Nominal Flow
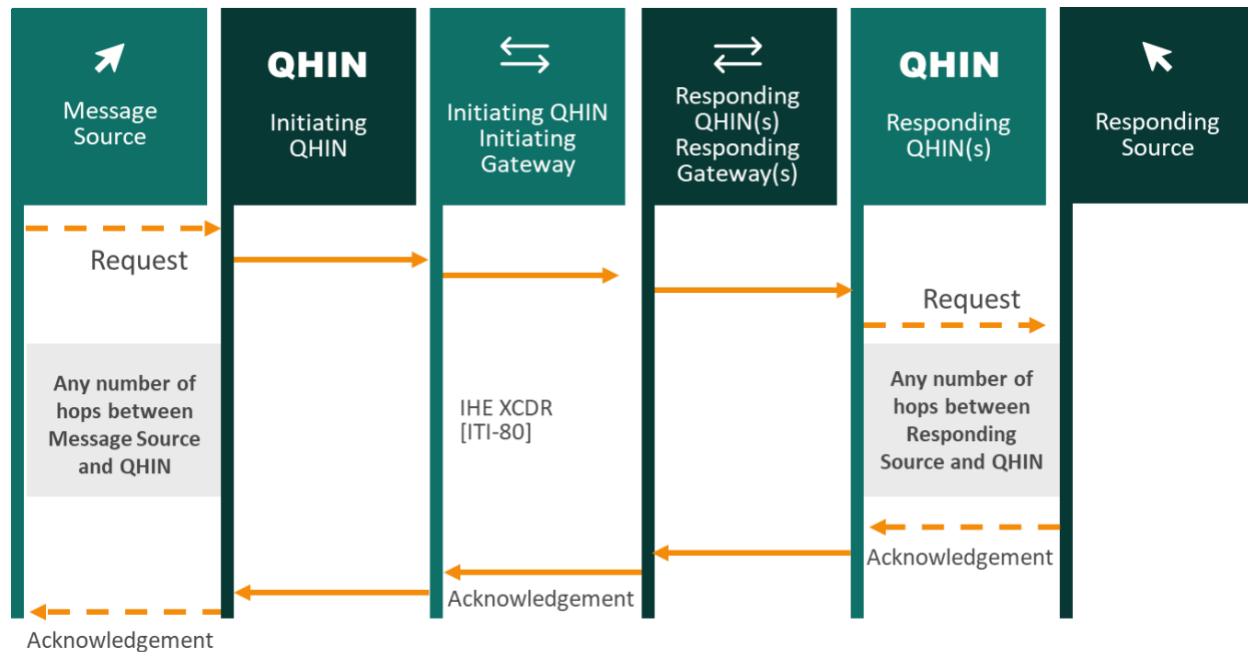
1) The Message Source sends a Message Delivery Solicitation, through any intermediary Subparticipants or Participant, as applicable, to the Initiating QHIN to send a message.
   a) The Initiating QHIN queries its QHIN Directory to identify the appropriate Responding QHIN for each message recipient included in the Message Delivery Solicitation.
2) The Initiating QHIN creates an IHE Cross-Gateway Document Provide [ITI-80] transaction and sends it via the Initiating Gateway to each Responding QHIN's Responding Gateway.
   a) The Initiating QHIN includes the HCID identifying the Responding Source.
   b) The Initiating QHIN creates an audit log entry including the HCID and Assigning Authority of the Message Source and Responding QHIN(s).

3) The Responding QHIN queries its QHIN Directory to identify the appropriate Responding Source and sends the message, through any intermediary Participant or Subparticipants as applicable, to the Responding Source.
   a) The Responding QHIN creates an audit log entry including the HCID and Assigning Authority of the Message Source, Initiating QHIN, and Responding Source.
4) The Responding Source returns an acknowledgement (through any intermediary Participant or Subparticipants, as applicable).
5) The Responding QHIN creates and sends an XCDR acknowledgement to the Initiating QHIN's Initiating Gateway.
   a) The Responding QHIN creates an audit log entry including the HCID of the Responding Source, Initiating QHIN, and Message Source.
6) The Initiating QHIN returns each acknowledgement to the Message Source, through any intermediary Participant or Subparticipants as applicable.
   a) The Initiating QHIN creates an audit log entry identifying the Responding Source and Message Source of the response.

Alternate Flow 1: Error Flow

1) This workflow begins at Step 4 of the Nominal Flow.
2) A Responding Source returns an error message (e.g., message cannot be delivered).
3) The Responding QHIN returns a response to the Initiating QHIN's Initiating Gateway including the status urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Failure and one or more regrep:ResponseStatusType:RegistryError elements.
4) The Initiating QHIN returns a failure message to the Message Source for dispositioning.

Alternate Flow 2: Patient Verification

1) This Workflow **precedes** Step 1 of the Nominal Flow
2) The Message Source initiates a Patient Discovery including all available patient demographics and sufficient information to identify the desired message recipient(s), such as the organization name, city, and state, Assigning Authority ID, and/or HCID(s) of the recipient(s).
3) The Message Source includes the Patient Identity in the Message Delivery Solicitation.
4) The Workflow continues at Step 1.

Post-conditions

- The Responding Source has received the document sent by the Message Source.
- The Message Source has obtained acknowledgement of receipt from each Responding Source.
- All requests and responses have audit log entries showing source and destination.

REQUIREMENTS FOR FUNCTIONS AND TECHNOLOGY TO SUPPORT EXCHANGE

Under the Common Agreement, QHINs are exchange hubs for participants in disparate health information networks. QHINs, Participants, and Subparticipants may request to send or receive information through QHIN-to-QHIN exchange and may offer Individual Access Services through which Individuals may send or receive their information through QHIN-to-QHIN exchange.

QHINs are responsible for providing a set of Connectivity Services that support QHIN Query and QHIN Message Delivery. To effectively deliver Connectivity Services, QHINs must perform a consistent set of technical functions.

This section outlines these functions, specifying constraints, standards, and implementation approaches where applicable.

> QTF-001   All requirements pertaining to the IHE ITI Technical Framework profiles, unless otherwise specified, refer to IHE IT Infrastructure Technical Framework Revision 17.0 – Final Text, published July 20, 2020.[12]

Connectivity and Remediation

The basis for QHIN-to-QHIN exchange is connectivity. As such, QHINs must maintain connectivity with their Participants and with other QHINs.

> QTF-002   Each QHIN MUST be able to connect successfully, i.e., able to transact without error, with every other QHIN. Any failure in connectivity MUST be addressed and resolved in the shortest time that is not infeasible, with infeasibility to be determined and demonstrated consistent with 45 CFR 171.204(a)(1) or (3), as applicable based on the reason and circumstances for the failure in connectivity.

> QTF-003   Each QHIN MUST be able to connect successfully, i.e., able to transact without error, to all of its Participants. Any failure in connectivity MUST be addressed and resolved in the shortest time that is not infeasible, with infeasibility to be determined and demonstrated consistent with 45 CFR 171.204(a)(1) or (3), as applicable based on the reason and circumstances for the failure in connectivity.

Certificate Policy

Public key infrastructure (PKI) often serves as the basis for securing electronic communications over the internet. PKI involves the use of digital certificates to assert and authenticate identities, encrypt data, and sign communications.

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[12] The *IHE IT Infrastructure Technical Framework Revision 17* and appropriate Supplements can be found via https://www.ihe.net/resources/technical_frameworks/technical_framework_archives/#IT

QHINs must possess appropriate digital certificates for authentication, encryption, and signing. QHIN certificates will be chained to root certificates issued by Certificate Authorities approved by the RCE. The RCE may also establish a broader certificate policy (e.g., including certificate life-cycle operational requirements, certificate usage policies, naming conventions, etc.).

QTF-004   QHINs MUST obtain TLS server certificates which are X.509 version 3 certificates with a signature that is at least 112 bits in length, and a public key of at least 256 bits in length; such certificates MUST be obtained, installed, and used in accordance with Applicable Law, and any relevant SOPs or implementation guides adopted by the RCE.

QTF-005   QHINs MUST deploy cryptographic modules certified to meet Federal Information Processing Standards (FIPS) Publication 140-2[13] or 140-3.[14]

Secure Channel

Protecting the privacy and security of health information is essential for building trust among participating entities. As such, QHINs must provide a secure channel to ensure transport-level security for all transactions under their domain. Modern networked systems typically rely on the TLS protocol to communicate over the internet. TLS provides privacy and data integrity between systems, using cryptographic techniques to encrypt communications. Specified standards for Secure Channel are included in *Table 3.*

Table 3. Specified Standard for Secure Channel	
Function	**Specified Standard / Profile**
Secure Channel	• IETF TLS 1.2 w/ BCP-195 or • IETF TLS 1.3 w/ BCP-195

QTF-006   When interacting with another QHIN or Participant, a QHIN MUST establish a secure channel using TLS protocol version 1.2 or above.

QTF-007   Use of the TLS protocol MUST be consistent with IETF BCP 195.

QTF-008   A secure channel MUST conform to National Institute of Standards and Technology (NIST) Special Publication 800-52 Revision 2[15] with the exceptions of:

     a. The following extensions MUST NOT be used:

- TLS 1.2 Extension Client Certificate URL
- TLS 1.3 Extension Early Data Indication
- TLS 1.3 Zero Round Trip Time Resumption.

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[13] *Security Requirements for Cryptographic Modules* (FIPS Publication 140-2) - available at: https://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.140-2.pdf

[14] Security Requirements for Cryptographic Modules (FIPS Publication 140-3) - available at: https://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.140-3.pdf

[15] *Guidelines for the Selection, Configuration, and Use of Transport Layer Security (TLS) Implementations (*Special Publication 800-52 Revision 2) – available at https://csrc.nist.gov/publications/detail/sp/800-52/rev-2/final

QTF-009   Use of TLS 1.3 SHOULD be prioritized prior to January 2024 and MUST be prioritized by January 2024.

QTF-010   Servers MUST support both TLS 1.2 and TLS 1.3 connections until TLS 1.2 is deprecated by this framework.

Mutual Authentication

TLS also provides a "handshake" authentication protocol to verify the identities of systems establishing a secure channel. Whereas TLS can be implemented such that only "one side" (e.g., the server in a server-client relationship) is authenticated, this QTF specifies mutual authentication for all QHIN-to-QHIN and QHIN-to-Participant communication. Specified standards for Mutual Authentication are included in *Table 4*.

Table 4. Specified Standard for Mutual Authentication	
Function	**Specified Standard / Profile**
Mutual Authentication	• IETF TLS 1.2 w/ BCP-195 or • IETF TLS 1.3 w/ BCP-195 • OAuth 2.0

QTF-011   When interacting with another QHIN, QHINs MUST mutually authenticate using TLS protocol version 1.2 or higher.

QTF-012   Authentication between QHINs and Participants MUST use TLS 1.2 or higher or OAuth 2.0.

QTF-013   Use of the TLS protocol MUST be consistent with IETF BCP 195.

QTF-014   Use of TLS 1.3 SHOULD be prioritized prior to January 2024 and MUST be prioritized by January 2024.

QTF-015   Servers MUST support both TLS 1.2 and TLS 1.3 connections until TLS 1.2 is deprecated by this framework.

User Authentication

Authentication involves establishing confidence in the identity of an entity or person. All entities and persons requesting QHIN-to-QHIN exchange must be authenticated, and authentication information must be shared "upstream," i.e., the entities' or persons' Participant and/or QHIN, for access control and auditing purposes. A QHIN, for example, needs to know and record the identity of any Subparticipant or user attempting to query for or send information via QHIN-to-QHIN exchange. Because there may be a multi-layer hierarchy of Subparticipants under each Participant, the QHIN relies on each entity to obtain and share authentication information about those "downstream" from it, i.e., further removed from the QHIN in the hierarchy.

The IHE XUA Profile leverages SAML to communicate claims about an authenticated entity in transactions that cross enterprise boundaries. This QTF specifies that QHINs implement IHE XUA

to support exchange of authentication information among QHINs. Specified standards for User Authentication are included in *Table 5*.

Table 5. Specified Standard for User Authentication	
Function	**Specified Standard / Profile**
User Authentication	• IHE XUA

QTF-016 Use of SHA-1 is deprecated within TEFCA; All use of SHA in SAML metadata MUST use SHA3-256

QTF-017 When initiating a QHIN Query or QHIN Message Delivery, a QHIN MUST transmit a SAML assertion using IHE XUA, identifying the user or staff member at the QHIN, Participant, or Subparticipant or identifying the Individual who requested use of the QHIN's Connectivity Services.

QTF-018 When a QHIN rewrites the SAML information to sign it using the QHIN SAML certificate, the new SAML assertion MUST persist the originating user and, as applicable, organization information.

QTF-019 Following the IHE XUA[16] requirements, the SAML assertion MUST include:

> User information including name, UserID, Subject-Role, and, if appropriate, National Provider Identifier (NPI),
> Organization name and HomeCommunityID of the Query or Message Source initiating the transaction, and
> Patient Identifier including Assigning Authority, if known.

QTF-020 The SAML assertion MAY include the Authz-Consent Option.[17]

QTF-021 QHINs MUST be capable of receiving authentication information from Participants, including the authenticated identity of any Subparticipants and/or Individuals and/or users requesting the use of Connectivity Services.

QTF-022 QHINs MUST specify the mechanism(s) (i.e., format and content) by which Participants transmit authentication information to the QHIN.

Authorization & Exchange Purpose

Authorization involves verifying whether an entity or person is eligible to access a requested network or service. The Common Agreement requires that all requests to send and receive information through QHIN-to-QHIN exchange fall under a defined set of Exchange Purposes.

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[16] See IHE IT Infrastructure Technical Framework Volume 2b section 3.40, available at
https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Rev17-0_Vol2b_FT_2020-07-20.pdf
[17] See *IHE IT Infrastructure Technical Framework Volume 2b section 3.40.4.1.2.2*, available at
https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Rev17-0_Vol2b_FT_2020-07-20.pdf

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QHINs use SAML assertions based on the IHE XUA profile to identify the Exchange Purpose when initiating a QHIN Query or QHIN Message Delivery. Specified standards for *Authorization & Exchange Purpose* are included in *Table 6*.

Table 6. Specified Standard for Authorization & Exchange Purpose	
Function	**Specified Standard/Profile**
Authorization & Exchange Purpose	• IHE XUA

QTF-023   QHINs MUST be capable of receiving and transmitting authorization information, including a representation of the Exchange Purpose, along with any request for use of Connectivity Services.

QTF-024   When initiating a Patient Discovery, QHIN Query or QHIN Message Delivery, a QHIN MUST transmit a SAML assertion using IHE XUA, including the Exchange Purpose as identified by the staff or users at the QHIN, Participant, or Subparticipant requesting the use of Connectivity Services.

QTF-025   The Initiating QHIN MUST verify the Query Source's asserted Exchange Purpose against those listed for the Query Source in the RCE Directory Service. A transaction without an Exchange Purpose that is listed in that Query Source's directory entry MUST NOT be accepted.

QTF-026   The PurposeOfUse in the SAML assertion MUST be one of the following codes corresponding to the Exchange Purpose, as defined in the Common Agreement or codes assigned in an associated SOP:

Table 7. Exchange Purpose Accepted Codes	
Exchange Purpose	**Code**
Treatment	T-TRTMNT
Payment	T-PYMNT
Health Care Operations	T-HCO
Public Health	T-PH
Individual Access Services	T-IAS
Government Benefits Determination	T-GOVDTRM

QTF-027   The XUA PurposeOfUse Option[18] MUST be used and the purpose of use MUST be consistent with the SAML Purpose of Use information.

QTF-028   All XUA and SAML metadata MUST be consistent. Where discrepancies exist, they MUST be resolved prior to the next step in the workflow.

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[18] See *IHE IT Infrastructure Technical Framework* Volume 2b Section 3.40.4.1.2.3 PurposeOfUse Option for details: https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Rev17-0_Vol2b_FT_2020-07-20.pdf

QTF-029   QHINs MUST specify the mechanism (i.e., format and content) by which Participants transmit authorization information, including an Exchange Purpose, to the QHIN.

Patient Discovery Query

Health information exchange workflows typically begin with a search for matching patients. IHE provides a widely implemented profile supporting patient discovery: XCPD.

XCPD enables entities to locate communities that hold relevant patient health data and correlate patient identifiers across communities holding the same patient's data. XCPD is frequently used to discover patients prior to an XCA query.

QHINs must implement the IHE XCPD profile to enable query-based QHIN-to-QHIN patient discovery. The specified standard for patient discovery is included in *Table 8*.

Table 8. Specified Standard for Query	
Function	**Specified Standard / Profile**
Patient Discovery	• IHE XCPD

QTF-030   QHINs MUST ensure that Query Solicitations unambiguously and accurately identify the Query Source.

QTF-031   QHINs MUST implement the IHE XCPD profile for QHIN Patient Discovery.

QTF-032   Initiating QHINs MUST be capable of receiving Query Solicitations from a Participant.

QTF-033   Initiating QHINs MUST be capable of processing Query Solicitations to determine the appropriate Responding QHIN(s) via their QHIN Directory.

QTF-034   If the Query Source does not indicate specific providers or facilities to be queried, all QHINs MUST be queried using provided demographics.

QTF-035   Initiating QHINs MUST be capable of processing Query Solicitations to identify patient demographic information to include in XCPD requests to Responding QHINs.

QTF-036   Responding QHINs MUST be capable of processing XCPD requests to resolve patient identity (see Patient Identity Resolution function).

QTF-037   Initiating QHINs MUST be capable of processing XCPD responses and sending the results to the Query Source (through any intermediary Participant or Subparticipants, as applicable).

QTF-038   Initiating QHINs MUST include all patient demographics provided in the Query Solicitation in the XCPD request resulting from that Query Solicitation, unless demographics are provided that are not supported by the XCPD profile.

QTF-039   Each Patient Discovery match (i.e., RegistrationEvent) MUST include the code NotHealthDataLocator to indicate that the corresponding community does not maintain

externally available location information about this patient. See *IHE ITI TF-2b: 3.55.4.2.2.5 Specifying Support as a Health Data Locator*.

QTF-040   Patient Discovery responses MUST include the Responding Source's HomeCommunityID, Assigning Authority, and the patient identifier when a successful patient match is found.

QTF-041   Data for address fields used in Patient Discovery Queries SHALL be converted, if needed to conform to Project US@ Technical Specifications[19], by the Initiating QHIN prior to being transmitted to any Responding QHINs. However, if the field does not contain a street address but contains other geographical details, it is recommended that whatever information that the patient provided not be abbreviated.

QTF-042   A Responding QHIN MUST NOT reply to a query with the demographics used to initiate the Patient Discovery Query. The Responding Source MUST return the demographics as known in its system.

QTF-043   A Responding QHIN MUST NOT respond to a Patient Discovery query with a request for additional demographics.

Document Query and Retrieve

Locating patient records for retrieval involves multiple steps, including determining what information in the form of documents is available, and actual retrieval of the desired documents. The IHE XCA profile specifies this process.

XCA supports the means to query and retrieve relevant patient health data held by other communities in the form of documents. Using XCA requires knowledge of patient identity and the HomeCommunityID of the Responding Source when querying for and retrieving clinical documents.

IHE does not define a document beyond "a collection of bytes, including proprietary and textual formats."[20] Therefore an XCA document may be any form of information including C-CDA 2.1, FHIR® resources, PDF, or other formats. For purposes of Document Query and Retrieve, C-CDA 2.1 is the expected format for all patient information. If a Responding Source is unable to return a C-CDA 2.1 document, the data may be converted to the C-CDA 2.1 format by a Responding QHIN, Participant, or Subparticipant prior to transmission to the Initiating QHIN.

QHINs must implement the IHE XCA profile to enable query-based QHIN-to-QHIN document exchange. The specified standard for Document Query and Retrieve is included in *Table 9*.

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[19]*Project US@ Technical Specification.* – available at
https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=180486153
[20] *IHE IT Infrastructure White Paper Health Information Exchange: Enabling Document Sharing Using IHE Profiles*– available at https://profiles.ihe.net/ITI/HIE-Whitepaper/index.htmlf

Table 9. Specified Standard for Document Query	
Function	Specified Standard / Profile
Document Query and Retrieve	• IHE XCA

QTF-044   QHINs MUST implement the IHE XCA profile for QHIN Document Query and Retrieve.

QTF-045   Initiating QHINs MUST be capable of processing Query Solicitations to identify query parameters to include in XCA requests to Responding QHIN(s).

QTF-046   When initiating a QHIN Query, an Initiating QHIN MUST use ITI-38 Document Query and ITI-39 Document Retrieve, even if using a non-IHE transaction to receive the query from their Participant.

QTF-047   A Responding QHIN MUST accept only ITI-38 Document Query and ITI-39 Document Retrieve from an Initiating QHIN for QHIN Query IHE transactions but may use any exchange method with their Participants.

QTF-048   When a Responding Source is unable to generate C-CDA 2.1 format documents, QHINs MAY offer document conversion services, except where the use of another format is consistent with QTF-050 and QTF-052.

QTF-049   A QHIN converting a document to C-CDA 2.1 format MUST convert to one of the templates as defined in HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm.[21]

QTF-050   Responding QHINs SHOULD transmit any specific document format requests (provided by the Initiating QHIN via the IHE XDSDocumentEntryFormatCode XCA parameter) to Responding Sources.

QTF-051   Responding QHINs SHOULD provide C-CDA 2.1 documents that follow recommendations as presented in Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes.[22]

QTF-052   All C-CDA 2.1 format documents adhering to the Continuity of Care Document template MUST include all appropriate data classes and elements from the United States Core Data for Interoperability (USCDI) V1 when data are available.[23] The RCE will update the QTF to enable the use of future versions of USCDI that are consistent with ONC rules for health IT certification compliance.

QTF-053   Responding QHINs MAY provide patient information in other document formats if required by Applicable Law or if an alternative format is requested by the Initiating QHIN via the IHE XDSDocumentEntryFormatCode XCA parameter.

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[21] C-CDA (HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm) available at: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=492

[22] *Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes* -- available at https://carequality.org/wp-content/uploads/2022/04/Improve-C-CDA-Joint-Content-WG-v2.0-20220316-DISTRO.pdf

[23] *The United States Core Data for Interoperability (USCDI)* – available at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

QTF-054   The minimum required parameters for a FindDocuments transaction are the Responding Source's HomeCommunityID, patientId, and Assigning Authority for each patient record returned, and the status of the document entries to return, typically urn:oasis:names:tc:ebxml-regrep:StatusType:Approved. "Approved" in this context means that the document is available for patient care and has not been superseded by a new version.

QTF-055   If such a request is indicated by the Query Solicitation, Initiating QHINs MAY specify a document status of urn:oasis:names:tc:ebxml-regrep:StatusType:Deprecated to obtain historical document entries that have been superseded or are not considered the most current version.

QTF-056   Responding QHINs SHOULD provide to Responding Sources any specific document status requests provided by the Initiating QHIN in the FindDocuments transaction.

QTF-057   QHINs MUST support the $XDSDocumentEntryServiceStartTimeTo and $XDSDocumentEntryServiceStopTimeFrom parameters for limiting the number of documents returned from a query and Responding QHINs SHOULD transmit any such parameters to the Responding Source.

QTF-058 $XDSDocumentEntryServiceStartTimeTo and $XDSDocumentEntryServiceStopTimeFrom are optional parameters that MAY be included in the FindDocuments query to limit the number of documents returned. Usage MUST follow the guidance of Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes Appendix A.3 IHE XDS Query Parameters. serviceStartTime and serviceStopTime are defined ITI TF-3 Table 4.1.3.2-1. These query parameters are among the metadata parameters that MUST be returned with objects in all LeafClass Query for Documents responses. serviceStartTime and serviceStopTime MUST be requested as UTC in DTM format.

QTF-059   The FindDocuments request MAY include both DocumentEntryType parameters with values of urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1 and urn:uuid:34268e47-fdf5-41a6-ba33-82133c465248 to specify that Stable and On-Demand Documents should be included where both are available. If only Stable or On-Demand Documents are available, only those DocumentEntries should be sent.

QTF-060   The Initiating QHIN MUST specify a returnType parameter value of LeafClass, which means to return full metadata contents. See *IHE ITI TF-1: 18 Cross-Community Access (XCA) Integration Profile*, *IHE ITI TF-2b: 3.38*, and *IHE ITI TF-2a: 3.18*.

QTF-061   Responding QHINs MUST be capable of processing XCA requests to identify and retrieve appropriate documents.

QTF-062   Initiating QHINs MUST be capable of processing XCA responses and sending the results to the Query Source (through any intermediary Participant or Subparticipants, as applicable).

QTF-063   The QHIN Initiating Gateways MUST support the XDS Affinity Domain XCA option for both IHE Cross Gateway Query [ITI-38] and IHE Cross Gateway Retrieve [ITI-39].

Message Delivery

In addition to query-based document exchange, many health information networks also provide capabilities for users to send (i.e., push) patient data to other entities. The QHIN-to-QHIN exchange enabled by the Common Agreement supports push capabilities using the IHE XCDR[24] profile. QHINs function as hubs for routing messages sent to and from their networks.

The specified standards for message delivery are included in *Table 10*. Message delivery transactions between QHINs and Participants may use the XCDR profile or may negotiate a different delivery method that supports the local workflow.

Table 10. Specified Standard for Message Delivery	
Function	**Specified Standard / Profile**
Message Delivery	• IHE XCDR

QTF-064   All QHINs MUST implement Cross-Community Document Reliable Interchange (XCDR) Rev. 1.6 for message exchange with other QHINs.

QTF-065   All QHIN XCDR Responding Gateways MUST be grouped with an IHE XDR Document Recipient.

QTF-066   QHINs MAY implement the XCDR profile for exchange with their Participants or negotiate other methods of exchange.

QTF-067   Initiating QHINs MUST be capable of processing Message Delivery Solicitations to determine the appropriate Responding QHIN(s) via their QHIN Directory.

QTF-068   All Initiating QHINs MUST return acknowledgement of delivery of the message to the Message Source (via any intermediary Participant and Subparticipants, as applicable).

QTF-069   QHINs MUST specify the format and content of acceptable message delivery acknowledgements from Participants.

QTF-070   Initiating QHINs MUST be capable of receiving Message Delivery Solicitations from a Participant.

QTF-071   Initiating QHINs MUST be capable of processing Message Delivery Solicitations to identify documents and associated metadata to include in XCDR transactions to the appropriate Responding QHIN(s).

QTF-072   Responding QHIN(s) MUST be capable of processing XCDR transactions to send documents and associated metadata to the Responding Source (via any intermediary Participant and Subparticipants, as applicable).

QTF-073   QHINs MUST be capable of sending and receiving message delivery acknowledgements to and from QHINs and Participants.

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[24] *IHE Cross-Community Document Reliable Interchange (XCDR)* - available at
https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XCDR.pdf

QTF-074   A Responding QHIN MUST transfer the content of the XCDR transaction to the appropriate Participant for management or transfer to their Subparticipant.

QTF-075   A Responding QHIN that is unable to deliver the content of a Message Delivery must return the XDSUnavailableCommunity error.

Patient Identity Resolution

Patients frequently cross network boundaries when receiving care, contributing to fragmentation of records, duplicate records, and inconsistent representations of patient identity across disparate providers. Accurately resolving patient identity is necessary for ensuring appropriate access to information, particularly in query-based contexts. Some QHINs might use a centralized master patient indexing service to manage identity information associated with patients under the QHIN's domain. Other QHINs might rely on more federated approaches to resolve patient identity (e.g., by sending patient demographic information and requesting matches from each Participant connected to the QHIN).

QTF-076   A QHIN MUST be capable of accurately resolving requests to match patient demographic information with patient identities under its domain via an Enterprise Master Patient Index (eMPI) or Record Locator Service; OR

QTF-077   A QHIN MAY use other innovative methods or delegate the patient identity resolution function to its Participant(s).

QTF-078   A QHIN MUST fulfill SLA requirements for all Patient Discovery queries.

QTF-079   A patient identity resolution function MUST be able to respond to a QHIN Query within any service-level agreement (SLA) requirements adopted by the RCE for QHIN-to-QHIN exchange.

Record Location

The exchange functions enabled by QHIN-to-QHIN exchange depend on accurately determining which entities maintain relevant information. Query functions, in particular, rely on accurate and comprehensive record location. This QTF does not specify a particular technology or standard for QHINs to use to locate patient records.

QTF-080   A Responding QHIN MUST be capable of identifying which, if any, of its Participants and/or Subparticipants are the Responding Source.

Directory Services

Directory services enable entities to manage information associated with healthcare organizations and persons. A provider directory, for example, may include information about a provider's demographics (e.g., name, date of birth), relationships (e.g., where a provider works), and electronic endpoints (e.g., a Direct address, HL7® FHIR® server URL). QHINs will rely on directories to route transactions. For instance, a QHIN might use a directory to identify the appropriate recipient(s) of a QHIN Message Delivery or QHIN Query.

The RCE Directory Service is an HL7 FHIR-based service using a profile on the Organization resource and custom transactions. The RCE Directory Service will be the primary location for determining the HomeCommunityID and Responding QHIN for QHIN-to-QHIN data exchange. QHINs will be responsible for updating the RCE Directory Service with HomeCommunityIDs of their connected Participants and Subparticipants. QHINs are expected to maintain a local copy of the contents of the RCE Directory Service to support their Connectivity Services and facilitate query and message delivery transactions.

This QTF specifies the following directory service constraints:

QTF-081   The QHIN Directory MUST maintain the Responding QHIN and HomeCommunityID for all Participants and Subparticipants.

QTF-082   An Initiating QHIN MUST be capable of accurately identifying the Responding QHIN for a QHIN Query or QHIN Message Delivery via its QHIN Directory.

QTF-083   All connections to the RCE Directory Service MUST conform to the requirements of the RCE Directory Service Implementation Guide.[25]

QTF-084   A QHIN MUST update the RCE Directory Service with any new Participant and Subparticipant information at least 48 hours prior to the Participant and Subparticipant commencing production activities.

QTF-085   A QHIN MUST create a directory entry for each individual facility within a Participant's or Subparticipant's organization.

QTF-086   A QHIN MUST include all intended Exchange Purpose codes a Participant or Subparticipant will use for all initiated transactions.

QTF-087   A QHIN MUST ensure that all updates and changes to Participant or Subparticipant HomeCommunityID(s) are submitted to the RCE Directory Service prior to taking effect.

QTF-088   QHINs MUST retrieve all changes to the RCE Directory Service and merge them into their QHIN Directory no more often than once per hour and no less often than once per day.

Auditing

Maintaining records of activities and transactions supported by the Connectivity Services can assist with troubleshooting and help facilitate monitoring for improper use. Moreover, audit records support a QHIN's ability to maintain and produce an accounting of disclosures, where required by Applicable Law and/or the Common Agreement.

The IHE ATNA profile describes several foundational elements of secure systems, including node authentication, user authentication, telecommunications encryption, and event audit logging. QHINs must implement the IHE ATNA profile requirements specific to event audit logging for activities and transactions between QHINs and between QHINs and Participants, including the

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[25] *RCE Directory Service Implementation Guide*, when available, to be located at:
https://rce.sequoiaproject.org/tefca-and-rce-resources

standard schema for encoding reported events, standard reportable events, and standard transport methods. Other elements of secure systems defined by ATNA, such as authentication, are specified elsewhere in this QTF. Specified standards for auditing are included in *Table 11*.

Table 11. Specified Standards for Auditing	
Function	**Specified Standard / Profile**
Auditing	• IHE ATNA (content only) • ASTM E2147-18

QTF-089   A QHIN MUST create and store audit records in with content requirements as specified in the IHE ATNA profile for all activity and transaction events involving another QHIN or Participant.

QTF-090   A QHIN MUST follow auditing guidance in any of the IHE transactions and profiles specified by this QTF.

QTF-091   A QHIN MUST create and store audit records for activity events related to the QHIN's operation.

Error Handling

Activities and transactions enabled by a QHIN's Connectivity Services may fail or otherwise generate errors. Error messages should clearly communicate the cause of the error along with any other appropriate details to assist in resolving the issue.

QTF-092   A QHIN MUST be capable of generating, sending, and receiving error messages for activities and transactions involving other QHINs as defined in IHE profiles specified by this QTF.

QTF-093   A QHIN MUST be capable of sending and receiving error messages for activities and transactions originating from Participants, translating them as needed into error messages as defined in IHE profiles specified by this QTF, and returning them in responses to the Initiating or Responding QHIN, as necessary.

Constraints for Query or Message Source(s) and Responding Source(s)

For proper operation of the transactions enabled by QHIN-to-QHIN exchange, QHINs will need to ensure that Participants and Subparticipants provide information necessary for QHIN functions. The following requirements must be complied with at the level of Query or Message Source and/or Responding Source, as applicable, regardless of whether the Query Source, Message Source, or Responding Source is a QHIN, Participant, or Subparticipant:

QTF-094   All TEFCA Exchange SHALL be authenticated with a TEFCA-issued certificate.

QTF-095   A Query Source MUST include all known demographics supported by the IHE XCPD profile in its Query Solicitations for patient discovery with the exception of a Social Security Number, which MAY be included.

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QTF-096   A Responding Source SHALL send only one patient identity for each matching patient in response to a patient discovery query.

QTF-097   Data for address fields used for patient discovery query SHOULD conform to Project US@ Technical Standards. However, if the field does not contain a street address but contains other geographical details, it is recommended that whatever information that the patient provided not be abbreviated.

QTF-098   A Responding Actor SHOULD provide C-CDA 2.1 documents that follow recommendations as presented in Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes[26], when the information held by that Responding Actor is organized around a clinical encounter construct.

QTF-099   A Responding Actor MUST use nationally standardized code systems for all data exchange, where such code systems exist (e.g., LOINC, RxNORM, SNOMED-CT, etc.)

QTF-100   All C-CDA 2.1 format documents adhering to the Continuity of Care Document template MUST include all appropriate data classes and elements from USCDI V1[27] when data are available. The RCE will update the QTF to enable the use of future versions of USCDI that are consistent with ONC rules for health IT certification compliance.

QTF-101   A Responding Source SHOULD NOT respond to a patient discovery query with a request for additional demographics.

QTF-102   A Responding Source MUST NOT reply to a query with the demographics used to initiate the Patient Discovery Query. The Responding Source MUST return the demographics as known in its system.

QTF-103   The QHIN Initiating Gateways and Responding Gateways SHOULD support the On-Demand Document option.

QTF-104   An (I)ACP document reference MUST be accompanied by one of the following OIDs to declare the format of the consent document:

OID	Representation
urn:oid: 2.16.840.1.113883.3.7204.1.1.1.1.2.1	(I)ACP Document contains access consent and is in scanned PDF format of a signed document
urn:oid: 2.16.840.1.113883.3.7204.1.1.1.1.2.2	(I)ACP Document contains access consent and is in XACML format
urn:oid: 2.16.840.1.113883.3.7204.1.1.1.1.2.3	(I)ACP Document contains access consent and is in HL7 FHIR® Consent resource format
urn:oid: 2.16.840.1.113883.3.7204.1.1.1.1.2.4	(I)ACP Document contains access consent and is in Kantara Consent Receipt format

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[26] *Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes* -- available at https://carequality.org/wp-content/uploads/2022/04/Improve-C-CDA-Joint-Content-WG-v2.0-20220316-DISTRO.pdf

[27] *The United States Core Data for Interoperability (USCDI)* – available at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

QTF-105   Any (I)ACP asserted by a Query Source SHALL be available for retrieval using the Document Retrieve Workflow.

QTF-106   If a query request is accompanied by an (I)ACP document, the Responding Source SHOULD attempt to retrieve the document via the Document Retrieve Workflow, prior to responding to the query.

QTF-107   If an (I)ACP cannot be retrieved and the Responding Source is not able to disclose patient information without a valid (I)ACP, an appropriate error response MUST be returned.

QTF-108   If a retrieved (I)ACP cannot be processed by a Responding Source and the Responding Source is not able to disclose patient information without a valid (I)ACP, that Responding Source MUST respond with an appropriate error indicating that the (I)ACP could not be verified.

QTF-109   If a query request is not accompanied by an (I)ACP document and the Responding Source is not able to disclose patient information without a valid (I)ACP, an appropriate error response (e.g., AccessDenial) SHOULD be returned.

QTF-110   All transactions between QHINs and Participants and/or Participants and Subparticipants MUST be represented in audit log entries that adhere to the content requirements in ASTM E2147-18[28] §7 Audit Data and Audit Report Content as a minimum requirement.

QTF-111   Participants and Subparticipants MUST provide all necessary information to their QHIN for the RCE Directory Service entry prior to the information affecting the production environment.

QTF-112   Participants and Subparticipants MUST communicate all changes to their RCE Directory entry to their QHIN no less than 48 hours prior to the changes being implemented in the production environment.

Testing Procedure Supporting Requirements

QHINs will need to complete testing procedures as part of the initial Designation process and must be prepared to engage in testing activities on an ongoing basis. Details of these processes are outlined in the Onboarding & Designation SOP[29].

QTF-113   All QHINs MUST create and maintain a test instance of the QHIN system to support testing and operations.

QTF-114   Each QHIN MUST create a test patient record and have a test clinician record created for diagnostic and onboarding testing per the Onboarding & Designation SOP, in both test and production environments.

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[28] ASTM E2147 – 18 *Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems*– available at https://www.astm.org/e2147-18.html

QTF-115   QHIN test patients MUST be named with given name "QTF TEST" and family name QTFTEST-### (e.g., QTFTEST-001).

QTF-116   QHINS MUST NOT register test data into the production RCE Directory Service. During testing procedures, QHINs MUST determine facility routing information via their QHIN Directory.

QTF-117   The test patient data MUST include at least one C-CDA 2.1 document with fictional clinical data that can be queried and retrieved.

QTF-118   All QHINs SHOULD create at least one C-CDA Discharge Summary and Progress Note template document for the test patient. QHINs serving outpatient clinics and inpatient hospitals MUST create such documents. Any encounters, etc. MUST be linked to the clinician created for QTF-122.

QTF-119   Additional test data records MAY be created and made available as desired by the QHIN.

QTF-120   An outgoing patient discovery query using the test data as per the Onboarding & Designation SOP MUST include all available demographics.

QTF-121   An outgoing patient discovery response using the test data as per the Onboarding & Designation SOP MUST return all available demographics.

QTF-122   A test clinician record per the Onboarding & Designation SOP MUST be available for QHIN Message Delivery receipt and be available in both test and production environments.

QTF-123   A "Document Query Nominal Flow" of the test data per QTF-113 MUST return the C-CDA 2.1 document(s) associated with a test patient.

Performance Measures

In order to accurately measure the effectiveness of QHIN-to-QHIN exchange, the RCE will collect several performance measures from QHINs. These data are meant to assess the performance of QHINs for each use case. The measures by themselves will not directly impact a QHIN's Designation status.

QTF-124   The following data MUST be submitted to the RCE for each calendar month by the 15th of the following month:

- Downtime for the QHIN's gateway Actors (e.g., Initiating Gateway, Responding Gateway) in minutes in the reporting month. Reports MUST include planned and unplanned downtime by Actor.
- As a QHIN Initiating Gateway:
  a. Raw count of successful (i.e., completed without error) QHIN-to-QHIN transactions, per Responding QHIN, within the reporting period for each of:
     1. Patient discovery,
     2. Document query,
     3. Document retrieve, and

4. Message delivery.
   b. Raw count of errors in QHIN-to-QHIN transactions, per Responding QHIN per IHE metadata error code received within the reporting period.
   c. Raw count of connectivity errors per Responding QHIN received within the reporting period.
   d. Average response time for each QHIN-to-QHIN transaction, per Responding QHIN transacted with during the reporting period. Each data point must include the message type, average response time, and Responding QHIN.
   e. Total number of documents retrieved via QHIN Query within the reporting period.
   f. Total number of documents successfully delivered via Message Delivery within the reporting period.

- As a QHIN Responding Gateway:
   a. Average response time for each QHIN-Participant transaction by HCID within the reporting period.
   b. Total number of messages received via QHIN Message Delivery within the reporting period.

QTF-125   The following data must be submitted to the RCE for each calendar quarter (three-month period):

- Total number of member organizations and/or facilities connecting as or through the QHIN's Participants and Subparticipants with counts for each hospital, clinic, mental health center, post-acute/long-term care facility, public health entities, and payer organizations as well as an aggregate count of any other member organizations and/or facilities not matching these categories.
- Total number of clinicians connecting through the QHIN's Participants and Subparticipants.
- Total number of consumers/patients participating in Individual Access Services through the QHIN, its Participants, or Subparticipants.

QTF-126   A QHIN MUST execute a test of the *Nominal Flow* defined for each QHIN-to-QHIN transaction in Production on a quarterly (three-month) basis with all QHINs not transacted with in the preceding three months. If one or more tests fail, the results MUST be immediately reported to the RCE, and corrections MUST be executed as per QTF-002 and communicated to the RCE.

QTF-127   When initiating a transaction per QTF-126 in Production, a QHIN may claim any Exchange Purpose within the transactions used for the connectivity test, including Treatment, as long as: (i) the patient record used in the transaction is a dummy record deliberately constructed so that it is reasonably expected not to match legitimate patient records; and (ii) the QHIN is acting in good faith to perform a test as required by the QTF and is not knowingly attempting to access data for a real patient.