

# Patient Data Inquiry Use Case Test Methods

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# Patient Data Inquiry Service

## Test Methods

### Release 1

Version 1.0

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# 1 Introduction

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of HHS's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.

The ConCert by HIMSS™ program is intended to compliment the ONC's efforts in this regard via the validation of HIT products against a set of standards, services and policies, aligned with the ONC CEHRT requirements whenever applicable, that helps enable secure health information exchange over the Internet. ConCert will provide a foundation for the exchange of health information across diverse entities, within communities and across the country, helping to achieve the goals of the HITECH Act. This critical part of the national health IT agenda will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care so as to improve population health.

## 1.1 Purpose of this document

The purpose of this document is to provide specific guidance and clarifications to the conformity assessment testing procedures of the ConCert by HIMSS™ program. It must be used in conjunction with the ConCert by HIMSS™ program document which provides the overall requirements schemes for the program and sets the context and applicability of these testing methods.

## 1.2 Definitions<sup>1</sup>

- **Aggregated CCD** is a consolidation of Continuity of Care Documents retrieved for a patient across multiple Electronic Health Record applications from the provider. An aggregated CCD will be a collection of data from all documents retrieved across disparate clinical applications and placed into one master document.
- **Community-wide Master Patient Index (CMPI)** is a master patient index maintained by each HIO/HIE
- **Connected Entity** is any entity participating in the statewide Patient Data Inquiry Service to request and retrieve patient records such as: Hospitals, HIOs, and/or Physicians directly via their EHR applications.
- **Document types** are any clinical record(s) clinicians may choose to submit or retrieve for a specific patient such as: Continuity of Care Documents, Immunizations, Labs, Discharge Summary, etc.

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<sup>1</sup> Individual actors are defined within each test procedure.

- **Dual Factor Authentication** is a security constraint that requires two independent pieces of evidence to assert an entity's identification, easily summarized by "something one knows", "something one has", or "something one is". Examples of the three independent factors would be a password, an identification card, a fingerprint.
- **Statewide Master Patient Index (SMPI)** is master patient index stored at the state level.
- **Health Information Exchange (HIE)** is defined as the transfer of healthcare information electronically and securely across Health Information Organizations within a region such as a state, community, hospital system or a physician network.
- **Health Information Organization (HIO)** is an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards. As defined by the National Alliance for Health Information Technology Report.
- **HIE Portal** is a Health Information Exchange Portal offered by an HIE vendor for their stakeholders to access health information.
- **IHE Cross Community Access (XCA)** is a profile that supports the means to query and retrieve patient relevant medical data held by other communities.
- **IHE Cross-Community Patient Discovery (XCPD)** is a profile that supports the means to locate communities that hold patient relevant health data and the translation of patient identifiers across communities holding the same patient's data.
- **Local Clinical Application** refers to a clinician's local clinical application such as an Electronic Health Record application, Hospital Information systems, Lab Information Systems, etc.
- **Patient Demographics Query (PDQ)** is a method that provides ways for multiple distributed applications to query a patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application.
- **Patient Identifier Cross-Reference (PIX)** is a method that provides cross-referencing of patient identifiers from multiple Patient Identifier Domains. These patient identifiers can then be used by identity consumer systems to correlate information about a single patient from sources that know the patient by different identifiers.
- **Patient Data Inquiry Service (PLS)** is a statewide patient record look-up service which consists of a SMPI and a statewide RLS to identify patients and their records across disparate health systems.
- **Record Locator Service (RLS)** is a registry of documents available at various HIOs. Allows end users to identify the documents available at various HIOs once a patient has been identified.

## 2 System Functions

### 2.1 System Functions

The Patient Data Inquiry Use Case includes the system functions for the following worksteps:

Priority Definition: R = Required, O = Optional

*Table 3.1-1 System Function and Priority*

Workstep	Priority	Description
FR-1 Patient Publish & Document Publish (for SMPI+RLS model – Tier 2)	O	Publish new, or changes to patient demographics to the statewide SMPI from the HIO CMPI or EHR vendors via patient identity feeds. Document types that are available at each connected entity for a given patient will be published at the state RLS as well via document register feeds.
FR-2 Patient Consent	R	Meets patient consent policy as defined by each state or locally identified consent policies.
FR-3 End User Authentication	R	End users must be authenticated prior to submitting a patient search query by local application.
FR-4 Node Authentication	R	Nodes on a network will be authenticated using Transport Layer Security (TLS) based on NwHIN Production Standards
FR-5 Patient Query	R	The local clinical application will send a query for a patient (using Patient Demographic Query (PDQ), Patient Identifier Cross-Referencing (PIX), or XCPD for Patient Discovery).
FR-6 Document Query	R	Document request from the local clinical application will be sent either directly to the Responding Gateway or to the RLS to retrieve a list of all available documents for the matched patient. A list of available documents will be presented to the end user to retrieve.
FR-7 Record Retrieval	R	Retrieval of patient records from all connected entities once they have been identified.
FR-8 Record Viewing	R	Once selected documents are retrieved, they can be viewed by the end user through their local clinical application.

## 3 Test Methods

### 3.1 FR-1 Patient Publish & Document Publish

#### 3.1.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

Priority: Optional (applicable to Tier 2 SMPI + RLS Model Only)

Description: Publish new, or changes to patient demographics to the statewide SMPI from the HIO CMPI or EHR vendors via patient identity feeds. Document types that are available at each connected entity for a given patient will be published at the state RLS as well via document register feeds.

Purpose: The system shall support publishing of new and updated (changed) patient records to the statewide SMPI and registering of available document types for a given patient at the state RLS.<sup>2</sup>

Derived compliance shall encompass:

- “The centralized MPI option requires patient information and updates be sent to the SMPI and document metadata sent to the RLS for a patient. This transaction is not only for the Tier 2 approach using an SMPI+RLS, as regional or local HIEs may have a local MPI that would involve Patient Publish, but is required for use in the SMPI model.” (Statewide Patient Data Inquiry Service Technical Specification, 2011, p. 14)
- An EHR shall be able to publish patient information to the SMPI through a direct connection or through a CMPI (community master patient index).
- A Patient Identity Feed (ITI-8)<sup>3</sup> transaction SHALL be used for communication of patient information. In the case of systems requiring the implementation of HL7 version 3, a supplement to the HL7 v3 for PIX and PDQ profiles may be used as this includes an implementation for Patient Identity Feeds (ITI-44)<sup>4</sup>. The ITI transaction will be used for Patient Publish, i.e. the sending of patient information and updates to the SMPI.

For Tier 2 models document metadata SHALL be sent to the RLS. “The Provide and Register Document Set-b (ITI-41) and Register Document Set-b (ITI-42) allows the Document Source actor to provide a set of documents to the Document Repository, request that they be stored there, and then register the

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<sup>2</sup> Reference Statewide Patient Data Inquiry Service Functional Specification version 3.0 approved Final October 04, 2011.

<sup>3</sup> Reference IHE IT Infrastructure Technical Framework Volume 2a (ITI TF-2a) Transactions Part A – Sections 3.1 – 3.28.

<sup>4</sup> Reference IHE IT Infrastructure Technical Framework Supplement Patient Identifier Cross-Reference HL7 V3 (PIXV3) and Patient Demographic Query HL7 V3 (PDQV3) Trial Implementation.

documents with the Document Registry.”<sup>5</sup> (Statewide Patient Data Inquiry Service Technical Specification, 2011, p. 14)

### 3.1.2 Test Procedures

#### Test Requirements

- TRFR1-1. (Optional)<sup>6</sup> Patient records MAY be published to an SMPI using an EHR that has a direct connection to the SMPI. An ITI-8 transaction, or an ITI-44 transaction for systems using the HL7 v3 supplement, SHALL be used to publish data to the SMPI.
- TRFR1-2. (Optional) Patient records MAY be published to an SMPI using an EHR that is connected to an HIE. The HIO SHALL forward the records from its CMPI to an SMPI. An ITI-8 transaction, or a Patient Identity Feed HL7 v3 (ITI-44) transaction for systems using the HL7 v3 supplement, SHALL be used to publish data to the SMPI.
- TRFR1-3. (Optional) A statewide RLS SHALL have the patient document metadata recorded within its registry after the SMPI is updated. An ITI-41 and ITI-42 transaction SHALL be used to record the patient metadata to the statewide RLS.

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>Vendor</b>	The organization providing and operating the EHR or HIE under test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The health information exchange either being tested or utilized to facilitate testing of an EHR.
<b>SMPI</b>	The application with the statewide master patient index which may either be an actual state run application or simulated via a testing tool.

Table 1 - FR1 Patient Publish and Document Publish Test Actors

#### Test Environment Prerequisites

1. EHR has established connectivity to an SMPI.

<sup>5</sup> Reference IHE IT Infrastructure Technical Framework Volume 2B (ITI TF-2b) Transactions Part B Sections 3.29 -3.51. Provide and Register Section 3.41 and Register Document Set-b Section 3.42.

2. EHR has loaded required patient data into the SMPI.

### **Test Step TRFR1-1**

Actors:

Tester, EHR, SMPI

Procedure:

Tester shall query the SMPI via the EHR being tested to confirm Patient #1 is not present in the SMPI. The query may be performed through XCPD which is tested as part of FR-5 referenced in section 4.4.

The tester shall publish a new patient's (Patient #1) to the SMPI.

An update and merge of the patient (Patient #1) shall be published to the SMPI.

Expected Result:

Tester shall verify Patient #1 is not currently present in the SMPI.

After the initial query to verify the patient is not present in the SMPI it is expected the patient will be populated within the SMPI on the publish transaction.

An update and merge of the patient will occur after the update transaction is performed.

Verification Action:

The tester shall document Patient #1 is present within the EHR and confirm demographic data and associated documents.

The tester shall send an initial query to document Patient #1 is not present in the SMPI and verification should be performed through record notes or screen shot proof.

To verify that the patient has been published to the SMPI a query shall be sent to the SMPI for the patient via a PDQ, XCPD query or other local means.

The tester will verify that the update publish transaction and or merge publish transaction has been performed successfully by querying the SMPI through a PDQ, XCPD transaction and verifying the returned data matches what was sent.

### **Test Step TRFR1-2**

Actors:

Tester, EHR, HIE, SMPI

Procedure:

EHR shall establish a connection to SMPI or its HIE and upload demographic data for Patient #1 through patient identity feed (either ITI-8 or ITI-44). If using an HIO, the HIO will be configured to forward to the SMPI.

Expected Result:

Tester shall verify demographic data of Patient #1 is present in the SMPI.

Verification Action:

Tester confirms Patient #1 is now present in SMPI through SMPI audit logs or other means.  
Tester confirms all expected demographic data within SMPI matches demographic data within EHR.

Tester records connection to SMPI either through direct connection or through an HIE.

Tester records the EHR use of either of ITI-8 or ITI-44 for patient identify feed method and use of either ITI-41 or ITI-42 for Provide and Register Document Set-b.

**Test Step TRFR1-3**

Actors:

Tester, EHR, HIE, SMPI, RLS

Procedure:

Testing an EHR:

The tester shall update the demographic data within the EHR for Patient #1 and add an additional document to the patient record.

EHR shall establish a connection to the SMPI or an HIE and update the demographic data for Patient #1 through patient identify feed (either ITI-8 or ITI-44). If the EHR is connected to an HIE, the HIE will be configured to forward the transaction to the SMPI.

The tester shall have the EHR establish a connection to the RLS to upload the new document of Patient #1 through Provide and Register Document Set-b (either by ITI-41 or ITI-42).

Testing an HIE:

Using a simulation tool or an EHR connected to an HIE, the tester shall update the demographic data within the EHR for Patient #1 and add an additional document to the patient record. The RLS will be updated with the new document of Patient #1 through a Provide and Register Document Set-B (either by ITI-41 or ITI-42).

Expected Result:

Tester shall verify demographic data of Patient #1 is updated in SMPI.

Tester shall verify new document of Patient #1 is present in the RLS.

Verification Action:

Testing an EHR:

Tester confirms all expected demographic data within SMPI matches demographic data within the EHR by performing a PDQ or XCPD query to retrieve the patient identity.

Tester confirms the new document of Patient #1 is now present in the RLS by querying the RLS using a NHIN Query for Documents transaction which is based on the IHE Registry Stored Query Transaction for XDS Profile query (ITI-18). It is expected this

query will pass through an HIE for access to the RLS. The response shall list the available metadata which the tester shall confirm matches what was initially sent for the patient.

Tester records the EHR use of either of ITI-8 or ITI-44 for patient identify feed method and use of either ITI-41 or ITI-42 for Provide and Register Document Set-b.

Further testing on linking patients from the EHR to an existing patient as well as testing duplicate merged transaction is outside the scope of these specifications however they should be addressed in compliance testing scripts.

#### Testing an HIE:

Tester shall confirm the demographic data within the SMPI is updated using an ITI-8 or ITI-44. A testing tool or EHR connected to the HIE may be used to initiate the transaction. The transaction must be routed through the HIE for verification purposes. Logging or a validation tool may be used to document verification.

Using a testing tool or EHR connected to the HIE a NHIN Query for Documents transaction which is based on the IHE Registry Stored Query Transaction for XDS Profile query (ITI-18) shall be initiated and routed through the HIE to the RLS. It is expected the HIE will use an NHIN Query for Documents transaction based on the IHE XCA query (ITI-38) when cross communities.

### 3.1.3 Test Data

The vendor will provide patient demographics that correspond to the test procedures documented. It is at the discretion of the compliance body and tester to change this data prior to the test procedures being performed.

### 3.1.4 Conformance Test Tool(s)

The testing facility shall provide an implementation of an SMPI and RLS with audit logs that can be monitored and validated against by the tester. The vendor providing the EHR will need to verify connectivity to the SMPI prior to the testing procedures taking place.

## 3.2 FR-2 Patient Consent

Section left intentionally blank

## 3.3 FR-3 End User Authentication

### 3.3.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

Priority: Required

Description: End users must be authenticated prior to submitting a patient search query by local application.

Purpose: The system shall use XUA to verify the end user's identity prior to accessing the statewide RLS or HIO(s) to query for an existing patient and retrieve record locations.

Derived compliance shall encompass:

- Message communication shall be based on the NHIN Authorization Framework Specification that is in turn based on the IHE XUA profile.
- The EHR shall use single factor (or better) authentication, often paraphrased as “something you know”. The Statewide Patient Data Inquiry Service Technical Specifications mandates the use of FIPS Security Level 2 as a minimum security standard. FIPS Security Level 2 in turn “requires, at a minimum, role-based authentication in which a cryptographic module authenticates the authorization of an operator to assume a specific role and perform a corresponding set of services.” (Security Requirements for Cryptographic Modules, 2001)
- The EHR shall maintain audit logs of authentication corresponding to specifications set forth by the NwHIN Framework.<sup>7</sup> The audit logs will use ATNA logging as specified by the IHE IT Infrastructure Technical Framework Volume 2b.
- All communication between the HIO will use SAML assertions as specified in the NHIN Authorization framework.
  - The SAML assertion must include the following required attributes:
    - Version
    - ID
    - IssueInstant attribute
    - Issuer
    - Subject
      - SubjectConfirmation
  - The Authentication Statement must include the following required attributes:
    - AuthnContext

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<sup>7</sup> Reference NwHIN Authorization Framework Production Specification v2.0 section 1.3.

- AuthnInstant
  - Reference the NHIN Authorization Framework Specification v2.0 for details on required elements and attributes. Further testing shall encompass attribute statement elements, authentication method, and decision statements. Testing should reflect the required SAML assertion rules as detailed in Appendix A.
- ATNA logging shall be employed for audit trails as documented in the XUA integration profile.<sup>8</sup> The ATNA encoding rules for representing the X-User Assertion will follow the guidelines set in the IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) section 3.40.3.2 ATNA Audit encoding. The element at a minimum will ascribe to <"user"@"issuer"> with an optional alias. The user is the content of the assertion subject element and the issuer will be the provider entity id contained within the issuer element. ATNA logging is used authenticate machines and hosts on the network. All machines within the secure node must comply with ATNA requirements as set forth in the IHE Frameworks.

### 3.3.2 Test Procedures

#### Test Requirements

- TRFR3-1. The connection system, usually an EHR or HIE SHALL employ single factor authentication (at a minimum) for initial security login.
- TRFR3-2. SAML assertions as specified in the NHIN Authorization Framework SHALL be used for all message transactions.
- TRFR3-3. ATNA logging SHALL be used for audit security logging.

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>Vendor</b>	The organization providing and operating the EHR or HIE under test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The health information exchange either being tested or utilized to facilitate testing of an EHR.

Table 2 - FR3 End User Authentication Actors

#### Test Environment Prerequisites

1. Vendor has provided details of their security protocol standards, which authentication standard is in use, and the authentication factor (ownership, knowledge, or inherence) for the product undergoing testing.

<sup>8</sup> Reference IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1) section 13.6.1 – Audit Trail and Node Authentication and IHE IT Infrastructure Technical Framework, Volume 2b (ITI TF-2b) section 3.40.4.1.3 – Expected Actions

2. Details of the operating systems of the end user workstation the vendor's software supports or anticipated to be deployed upon shall be provided to the tester.
3. Access to an outbound message log is required. The log must show the entire message that is being sent through the outbound transport.
4. The transport protocol in use for the transmission of the Syslog Protocol, either Syslog Messages over TLS or UDP must be supplied to the tester.

### **Test Step TRFR3-1**

#### Actors:

Tester, Vendor, EHR, HIE

#### Procedure:

##### Testing an EHR:

Tester will login to the EHR using an identified username and password combination.

Tester will login to the EHR with an unknown username and password combination.

Verification of the authentication standard will be performed by the tester if accessible.

Verification of the operating systems used for testing as well as supported operating systems of the EHR will be performed.

##### Testing an HIE:

Tester will login to the EHR (or other portal) using an identified username and password combination and perform a transaction requiring routing through the HIE.

Tester will login to the EHR (or other portal) using a username and password combination that is registered within the EHR (or other portal) but has not been registered as a valid user within the HIE. Details of the test setup are left at the discretion of the tester and the individual components being used.

Verification of the authentication standard will be performed by the tester if available.

#### Expected Result:

##### Testing an EHR:

Login into the EHR will be successful.

Tester will not be successful in logging into the EHR.

The authentication standard of the login will comply with FIPS Security Level 2 standards.

The operating system for the test procedure will be identified by the tester. The vendor will supply details on supported operating systems.

##### Testing an HIE:

The transaction will be routed through the HIE from the EHR or other portal.

The HIE will reject the transaction being sent from the EHR or other portal.

The authentication standard employed by the HIE will comply with FIPS Security Level 2 standards.

Verification Action:

Testing an EHR:

Verification will be completed by the tester recording login status (successful or unsuccessful) to the EHR. The tester shall note the identity factor used to verify login to the EHR and verify this login corresponds to an identity factor associated with published security standards or common industry practices.

The authentication method used will be verified and documented that at a minimum it uses role based authentication in order to comply with FIPS Security Level 2.

The operating system being used for the test procedure as well as identified supported systems will use a comparable level of trust and is certified as EAL2 (at a minimum) evaluation assurance level<sup>9</sup>. The specifics on supported operating systems and the evaluation assurance level will be documented by the tester. For an EHR (or other portal) that is web based, this requirement may be bypassed if identification of the operating system is not deemed feasible.

Testing an HIE:

The tester shall record a successful transaction routing to the HIE through an EHR or other connected portal. Inspection of log files on the HIE or the use of a testing tool may be used for verification.

If available, the tester shall verify the authentication method complies with FIPS Security Level 2 and uses role based authentication. Verification may be confirmed through the inspection of log files or the use of a testing tool.

**Test Step TRFR3-2**

Actors:

Tester, EHR, HIE, SMPI or RLS

Procedure:

Testing an EHR:

From the EHR being tested the tester will login and perform a transaction that requires a message to be sent to the SMPI or the statewide RLS.

Testing an HIE:

The tester will login to an EHR that has a connection to the HIE, or use a testing tool, and perform a transaction that requires a message be sent to the SMPI or statewide RLS via

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<sup>9</sup> Reference National Information Assurance Partnership (NIAP) for details on specific EAL levels per operating system ([http://www.niap-ccevs.org/vpl/?tech\\_name=Operating+System](http://www.niap-ccevs.org/vpl/?tech_name=Operating+System)).

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the HIE. The outbound message sent from the HIE to the SMPI or statewide RLS by the EHR or testing tool shall be identified and monitored.

Expected Result:

A message is sent from the EHR to an HIE that requires cross community access. The message is expected to be forward to the SMPI or RLS from the HIE.

Verification Action:

Verification will be performed by the tester by using a test harness to verify the SAML confirms to the specifications as outlined in the NHIN Authorization Framework and documenting the SAML assertion passes. It is expected the outbound SAML assertion for both an EHR and HIE will be similar and verification actions are applicable to either unless noted. The outbound message shall contain a SAML assertion as required by the XUA profile. The tester shall verify the SAML version is 2.0 by viewing the assertion rule header or use a testing harness that performs the same verification. An ID attribute must be present in the message for verification to pass. The IssueInstant attribute must be present and in the format as xs:dateTame as defined by <http://www.w3.org/TR/xmlschema-2>. Example,

```
<saml: Assertion xmlns="http://www.w3.org/2001/04/xml enc#"
  xmlns:ns2="http://www.w3.org/2000/09/xml dsig#"
  xmlns:ns3="urn:oasis:names:tc:SAML:2.0:assertion"
  ID="ID_4da01c2c-89db-4c79-9278-594555adaaf1"
  IssueInstant="2011-11-24T12:56:43.581Z" Version="2.0">
  <saml: Issuer>...</saml: Issuer>
  <ds: Signature>...</ds: Signature>
  .
  .
  .
</saml: Assertion>
```

Figure 1 - SAML Assertion Header Example

The tester shall verify and document the <Issuer> element is present and populated with initial login user. Example,

```
<saml: Issuer>urn: idp: demo</ns3: Issuer>
```

Figure 2 - SAML Issuer Example

The <Subject> element shall be present in the SAML assertion and is populated with one of the available NameID formats. Example,

```
<saml: NameID Format="urn:oasis:names:tc:SAML:1.1:
  nameid-format:X509SubjectName"> CN=unknown, O=1.1, UID= unk
</ns3: NameID>
```

Figure 3 - SAML Subject Example

Tester shall inspect for an unknown population of the <Subject> element often using in development testing. Per the NHIN Authorization Framework Production Specification the only formats allowable are “X509SubjectName” and “emailAddress” regardless of other formats documented by OASIS. Example,

```
<saml:NameID Format="urn:oasis:names:tc:SAML:1.1:  
nameid-format:unspecified"> ihelocal  
</saml:NameID>
```

Figure 4 - SAML Invalid Subject Example

Tester shall verify and document that the message contains an <AuthnStatement> which indicates the validation and authentication details.

The <AuthnStatement> shall contain one <AuthnContextClassRef> which will identify the method the subject was authenticated.<sup>10</sup> Example,

```
<saml:AuthnContext>  
  <saml:AuthnContextClassRef>  
    urn:oasis:names:tc:SAML:2.0:ac:classes:PreviousSession  
  </saml:AuthnContextClassRef>  
</saml:AuthnContext>
```

Figure 5 - SAML AuthnContextClassRef Example

An <AttributeStatement> element which associates the SAML authority elements with the requesting subject (user) shall be a required element. The tester will validate and document this element is present and that it contains 6 required attributes, Subject ID, Subject Organization, Subject Role, Purpose of Use, Home Community ID, Organization ID. It is expected more than these attributes will be included within the <AttributeStatement> block.

### Test Step TRFR3-3

Actors:

Tester, EHR, HIE

Procedure:

Testing an EHR

To test an unidentified machine on the network, the tester will login to the EHR from a machine that has not been identified to the HIE and perform a transaction. This may not

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<sup>10</sup> Reference NwHIN Authorization Framework Production Specification v2.0 section 3.3.1.1 Authentication Method for the various authentication options.

be testable depending on the deployment model of the HIE and is at the discretion of the tester.

To test normal ATNA logging the tester will login to the EHR from a machine that is known to the network and perform a transaction.

#### Testing an HIE

To test an unidentified machine on the network the tester will login to an EHR that has a connection to the HIE but is not part of its network, or use a testing tool, and perform a transaction.

The tester will login to an EHR that has a valid connection the HIE and is considered part of the network and will perform a transaction that requires a message be sent to the SMPI or statewide RLS.

The outbound message sent from the HIE to the SMPI or statewide RLS by the EHR or testing tool shall be identified and monitored.

Optional for both an EHR and an HIE:

The audit messages will be verified and documented that is in a native format of an XML scheme defined by RFC-3381 created by the Internet Engineering Task Force. Tester shall verify that the audit vocabulary corresponds to the DICOM Audit Message Vocabulary. If a custom format is used this test procedure may be bypassed.

#### Expected Result:

It is expected that the ATNA logs will be populated with transaction recording, warning and error messages.

#### Verification Action:

The tester shall view the ATNA logs to ensure that denial from an unknown host machine has occurred. The transaction will not be allowed to complete and will result in an error message. A warning message will not be accepted.

The ATNA logs shall be inspected and documented for verification for that the content is within the guidelines set by the IHE for ATNA logging. The following questions shall be identifiable for each transaction.<sup>11</sup>

- “For some user: which patients’ PHI was accessed?”
- “For some patient PHI: which users accessed it?”
- “What user authentication failures were reported?”
- “What node authentication failures were reported?”

Tester shall verify one of the two specified protocols for ATNA logging is being used. Preferable method logging would entail Syslog Messages over TLS (RFC 5425) with the Syslog Protocol (RFC 5424). A secondary acceptable method would be using UDP (RFC

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<sup>11</sup> Reference IHE IT Infrastructure (ITI) Technical Framework Volume 1 for more details.

5426) with the Syslog Protocol (RFC 5424). The tester should view audit log messages to verify compliance with the Syslog Protocol. The entire message need not be validated however at a minimum the HEADER and PRI should be verified as present. The header must be contained within an 8 bit field. The PRI must have 3-5 characters and be bound with angle brackets as the first and last characters. The priority and facility level code should match with the context of the message. Possible facility values as referenced by RFC-5424 are included in the following table. A situation may exist in which a system is using facility values that are proprietary or exist outside of the RFC. In either case, the tester shall verify that a facility value is present, not that it necessarily conforms to SysLog specifications which are outside the scope of this document.

Numerical Code	Facility
0	Kernel messages
1	User-level messages
2	Mail system
3	System Daemons
4	Security/authorization messages
5	Messages generated internally by syslogd
6	Line printer subsystem
7	Network news subsystem
8	UUCP subsystem
9	Clock daemon
10	Security/authorization messages
11	FTP daemon
12	NTP subsystem
13	Log audit
14	Log alert
15	Clock daemon
16	Local0
17	Local1
18	Local2
19	Local3
20	Local4
21	Local5
22	Local6
23	Local7

Table 3 - Syslog Facility Values<sup>12</sup>

Each PRI message should contain a decimal point indicating the severity level. Tester shall ensure the severity levels are in the range of 0 to 7 with 0 being the most severe message and 7 indicating debug level information.

<sup>12</sup> Table was extracted from RFC 5424 "The Syslog Protocol" published by the Internet Engineering Task Force (IETF)

Numerical Code	Severity
0	Emergency: system is unusable
1	Alert: action must be taken immediately
2	Critical: critical conditions
3	Error: error conditions
4	Warning: warning conditions
5	Notice: normal but significant condition
6	Informational: informational messages
7	Debug: debug-level messages

Table 4 - Syslog Severity Levels

Within the auditing messaging body the following element, alias "<user@issuer>" shall be inspected and documented to be present.

It is optional depending on ATNA logging configuration for the tester to inspect audit messages for compliance with RFC 3381.

### 3.3.3 Test Data

The vendor will provide user authentication details and access to ATNA logs.

### 3.3.4 Conformance Test Tool(s)

Either an EHR (or other portal with access to an initiating gateway) or an HIE (with access to a responding gateway) shall be available in the tool with its logging and authentication details.

## 3.4 FR-4 Node Authentication

### 3.4.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

**Priority:** Required

**Description:** Nodes on a network will be authenticated using Transport Layer Security (TLS) based on NwHIN Production Standards.

**Purpose:** The system shall use node authentication standards to authenticate to other nodes on the statewide network.

Derived compliance shall encompass:

- The X-User Assertion will be authenticated and encrypted by TLS or equivalent to maintain consistency with the NHIN Authorization Framework Production Specification and the IHE XUA Profile (for systems crossing enterprise boundaries).

A digital signature shall be used in the format of a X.509 certificate or equivalent.

### 3.4.2 Test Procedures

#### Test Requirements

- TRFR4-1. The X-User Assertion SHALL be encrypted using TLS as specified by the XUA profile. The TLS protocol SHOULD be employed for all socket layer transmission (i.e. HTTPS or secure SMTP).

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>Vendor</b>	The organization providing and operating the EHR or HIE under test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The health information exchange either being tested or utilized to facilitate testing of an EHR.

*Table 5 - FR4 Node Authentication Test Actors*

#### Test Environment Prerequisites

1. Vendor must provide an X509 certificate (or equivalent) for digital signature. The certificate type must be specified in the <saml:AuthnContext> of the message.

### **Test Step TRFR4-1**

#### Actors:

Tester, EHR or HIE, SMPI, RLS

#### Procedure:

Testing an EHR:

To verify an expired certificate the tester will login to the EHR that possess an expired certificate and attempt to send a transaction to the SMPI or RLS.

Tester shall repeat the process with a revoked certificate.

A valid certificate will be used to test for normal transactions.

Testing an HIE

To verify an expired certificate residing on the HIE the tester will invoke a transaction to an HIE using an EHR or testing tool and send a transaction to the SMPI or RLS.

Tester shall repeat the process with a revoked certificate.

A valid certificate will be used to test for normal transactions.

#### Expected Result:

The transaction will not be allowed to complete and will result in an error message for both test procedures involving an expired and revoked certificate. The following combinations shall be used for testing certificates where applicable.

- EHR to HIE
- EHR to SMPI
- HIE to SMPI
- HIE to RLS

While testing a valid certificate the transaction will be allowed to complete.

#### Verification Action:

To verify expired and revoked certificates the tester shall view the ATNA logs (or other visual confirmation) to inspect and document that a rejection notice was received and monitor the transaction to verify and document that the transaction was not completed. A warning message will not be accepted. The use of a testing tool that provides confirmation of rejected connections is acceptable in lieu of log inspection.

For valid certificate verification the tester shall view the ATNA logs to inspect and document that a digital certificate was included within the message body and can be validated against WS specifications.

The tester shall inspect and document the contents of the ATNA logs to ensure that the authorization type was included within the <saml:AuthnContext> element.

### 3.4.3 Test Data

Vendor will supply test data including a generated test certificate or a production certificate if available.

### 3.4.4 Conformance Test Tool(s)

Either an EHR (or other portal with access to an initiating gateway) or an HIE (with access to a responding gateway) shall be available in the tool with its logging and authentication details.

## 3.5 FR-5 Patient Query

### 3.5.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

**Priority:** Required

**Description:** The local clinical application will send a query for a patient (using Patient Demographic Query (PDQ), Patient Identifier Cross-Referencing (PIX), or XCPD for Patient Discovery).

**Purpose:** The system shall offer the ability for a query to be made to find a patient.

Derived compliance shall encompass:

- A systems ability to send/receive queries for patient demographics via either a Patient Identifier Cross Reference (PIX ITI-9)/Patient Demographics Query (PDQ ITI-21/ITI-22) queries, Patient Identifier Cross-Reference HL7 V3 (PIXV3 ITI-45)/Patient Demographic Query HL7 V3 (PDQV3 ITI-47) or a Cross-Community Patient Discovery (XCPD ITI-55) query.
- A system will support either a SMPI model (PIX/PDQ or PIXV3/PDQV3) or a non-SMPI model (XCPD).
- The required request/response value for an XCPD query.
- Auditing of the request/response messages.

Correct formatting and validating required elements of a PIX/PDQ or XCPD query.

### 3.5.2 Test Procedures

#### Test Requirements

Testing an EHR

- SMPI Model<sup>13</sup> - at least one test requirement is required, all others may be considered optional.

TRFR5-1. (Optional) The initiating system (EHR) SHALL query for patient's using a PIX (ITI-9) query using all valid patient identifier combinations. The initiating system SHALL receive responses to this query and have capabilities to parse the received message.

TRFR5-2. (Optional) The initiating system (EHR) SHALL query for patient's using a PIXV3 (ITI-45) query using all valid patient identifier combinations. The initiating system

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<sup>13</sup> At a minimum at least one transaction is required, PIX, PDQ, PIXV3, or PDQV3. However, in production systems it would be expected that a combination would be implemented, a PIX/PDQ or PIXV3/PDQV3.

SHALL receive responses to this query and have capabilities to parse the received message.

TRFR5-3. (Optional) The initiating system (EHR) SHALL query for patient demographics using a PDQ (ITI-21/ITI-22) query using all valid patient demographic combinations.<sup>14</sup>

TRFR5-4. (Optional) The initiating system (EHR) SHALL query for patient demographics using a PDQV3 (ITI-47) query using all valid patient demographics combinations.

- Non-SMPI Model

TRFR5-5. The initiating system (EHR) SHALL query for patient's using a NHIN Patient Discovery based XCPD (ITI-55) query using all valid patient demographic combinations and have capabilities to parse the response message.

#### Testing an HIE

TRFR5-6. (Optional) The responding system (HIE) SHALL have the capability to receive a PIX (ITI-9) query, parse the query, and generate a response.

TRFR5-7. (Optional) The responding system (HIE) SHALL have the capability to receive a PIXV3 (ITI-45) query, parse the query, and generate a response.

TRFR5-8. (Optional) The responding system (HIE) SHALL have the capability to receive a PDQ (ITI-21 or ITI-22) query, parse the query, and generate a response.

TRFR5-9. (Optional) The responding system (HIE) SHALL have the capability to receive a PDQV3 (ITI-47) query, parse the query, and generate a response.

TRFR5-10. The responding system (HIE) SHALL have the capability to receive a NHIN Patient Discovery based XCPD (ITI-55) query, parse the query, and generate a response.

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>Vendor</b>	The organization providing and operating the EHR or HIE under test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The health information exchange either being tested or utilized to facilitate testing of an EHR.

*Table 6 - FR5 Patient Query Test Actors*

<sup>14</sup> Since the ITI-21 and ITI-22 transactions are similar, either one may be used as a PQD query. The extra payload data in the response message of the ITI-22 is not addressed in these specifications.

### Test Environment Prerequisites

1. The vendor shall provide details of the patient's identifiers and domains to be used for testing.
2. Patient data is accessible through the HIE previous to testing.

### Test Step TRFR5-1

#### Actors:

Tester, EHR, HIE, SMPI

#### Procedure

Tester will login in to the EHR and query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) or directly to the SMPI using the Q23 HI7 trigger event. The following QPD combinations shall be tested.

To verify the basic capability to send a PIX query (ITI-9) the following transaction events shall be tested.

1. The initial procedure will test a PIX (ITI-9) query to the responding gateway by specifying the patient id. The tester will login in to the EHR or HIO and query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1 and an assigning authority in QPD-3.4 with the first subcomponent of QPD-3.4 containing a namespace ID.
2. To verify the ability of a system to receive a PIX (ITI-9) query that contains both a patient id and a universal id within the assigning authority subcomponent the following procedure will be performed. The tester will login in to the EHR or HIO and query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1. QPD-3.4 will contain the assigning authority with a universal namespace id entered in the second subcomponent and a universal id type entered in the third subcomponent.
3. This test procedure will verify the capabilities of a system to process a PIX (ITI-9) query that contains a patient id and a universal patient that do not match. The tester will login in to the EHR or HIO and query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1, a universal patient identifier will be entered in QPD-3.2 and a universal ID type will be entered in QPD-3.3. QPD-3.4 will contain the assigning authority. The patient identifier in QPD-3.1 will not match the universal patient identifier or correspond to the same patient as is entered in QPD-3.2.

#### Expected Result:

A PIX query (ITI-9) is expected to be sent for each patient identifier transaction to the HIE.

#### Verification Action:

For each query transaction the tester shall view the outbound message (through system available logs) or use a testing tool to inspect and document the transactions match the test procedure requirements. For positive testing it is expected a RSP^K32 response will be returned with each transaction. For negative testing it is expected an error will be returned.

The tester shall verify that field RCP-1 contains an 'I' indicating immediate priority on the outbound message.

Tester shall verify that a response message to each PIX (ITI-9) query is able to be consumed by the original sending system (EHR). Inspection of the outbound query shall be completed by viewing system logs or using a testing tool; all applicable segments including a query acknowledgment (QAK), original query patient identifiers (QPD), and patient identifier (PID) must be present. The EHR must be able to parse the PID-3 to establish the patient identifier.

The PID-3 segment received shall contain all subcomponents of the assigning authority which includes the namespace ID, universal ID, and the universal ID type. The PID-5 will be empty except for PID-5 component 7 which will contain a value of 'S' in the second repetition.

The system should specifically be able to respond to condition code '204' for unknown key identifier as specified by the use cases.<sup>15</sup>

For tests involving multiple domains the tester will verify that the EHR will process all patient identifiers on response to a PIX query (ITI-9). The EHR will either consume all patient identifiers returned from all domains or ignore all patient identifier responses.

Testing of the PIX (ITI-9) query is not intended to be exhaustive or supplant vendor testing or other compliance testing. Core capabilities are required to adequately address the functional requirements of the Patient Data Inquiry specifications. In all test steps within the procedure a testing tool may be used in lieu of manual inspection of inbound or outbound queries. It is expected that the testing tools validation capabilities would encompass the test requirements as set forth here as well as be more robust and have additional coverage.

1. The tester shall view the system logs (or development logs in lieu) or use a testing tool to ensure that a PIX (ITI-9) message was sent to the recipient system. Tester will ensure that within the QPD segment the QPD-3.1 patient identifier and QPD-3.4 assigning authority delimiters have been populated. The tester will verify that the initiating system (EHR) is able to receive a K23 response message (RSP^K23). The response message from the HIE shall be validated by viewing a log containing the response message or confirming within a testing tool. The tester will inspect and document that this response message contains elements for a query acknowledgment (QAK), original query patient identifiers (QPD) and patient identifier (PID). PID-3 segment shall contain all subcomponents including namespace id, universal id, and universal id type.
2. To verify that an assigning authority may contain a universal id and a universal id type within a PIX (ITI-9) query the tester shall view the system logs or use a testing tool to ensure that a PIX (ITI-9) message was sent to the recipient system. The tester will ensure that within the QPD segment the second and third subcomponents of the QPD-3.4 have been populated. The response message verification will be the same as performed in step 1.

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<sup>15</sup> Reference IHE IT Infrastructure Technical Framework Volume 2a (ITI-TF2a)

3. For this negative test of a patient id and a universal patient id that do not match the tester shall view the ATNA logs or use a testing tool verification to ensure that a PIX (ITI-9) message was sent to the recipient system. The tester will ensure that within the QPD segment the value in QPD-3.1 will not match the universal patient identifier or correspond to the same patient as is entered in QPD-3.2. The response message for this query is expected to contain an error in the form of an 'AE' value in the QAK segment. The tester shall verify that the EHR is able to respond to the specific error code returned in the ERR segment within the QPD.

### **Test Step TRFR5-2**

#### Actors:

Tester, EHR, HIE, SMPI

#### Procedure:

The tester shall login in to the EHR and query the HIE (or SMPI directly) for a patient by using a PIXV3 (ITI-45) query. The response query will not support continuation queries, only a single response mode is allowed.

#### Expected Result:

A PIXV3 query (ITI-45) is expected to be sent for each patient identifier transaction to the HIE or SMPI.

#### Verification Action:

For each query transaction the tester shall view the outbound message (through system available logs) or use a testing tool to inspect and document the transactions match the test procedure requirements.

The tester shall verify by documenting and inspecting the following parameters are present in the outbound query as they are required and/or use a testing tool to confirm successful query transmissions. It is expected that schema validation would be performed when undertaking more stringent compliance testing or using a test script.

1. PatientIdentifier – this parameter is required and shall match the identifier associated with the patient. Only one PatientIdentifier parameter is permissible.
2. DataSource – (optional) specifies the assigning authority of the domain if a domain is selected, otherwise all identifiers are returned from all known patient identity domains. Each DataSource parameter shall contain one DataSource.value parameter. More than one DataSource parameter is allowable.
3. QueryByParameter.responsePriorityCode is required and is fixed to 'I' for immediate.
4. QueryByParameter.statusCode is defaulted to "new".
5. The interactionId shall be set to 'PRPA\_IN201309UV02'.
6. The value of processingModeCode shall be set to 'T'

The response to the query shall be verified by inspecting and documenting the inbound response message. In lieu of manual inspection a testing tool with a verification response

may be used if the testing tools scripts perform the same function. In addition it is expected that schema validation would be performed. The following characteristics shall be verified:

1. The WSDL schema shall be identified as 'PRPA\_IN201310UV02'.
2. A *Patient* class shall be present with at least one of the requested patient ID attributes are present in the Patient.id attribute. More than one Patient.id attributes may be in the response message.
3. A *Person* class containing the name of the patient shall be present for further verification.
4. (Optional) A *Provider* class may be present which identifies the provider organization where this person is a patient. The provider organization will be identified by an id at least one of the following attributes, address, telephone, or contact person.
5. (Optional) An *OtherIDs* class may be present which provides further identification of the patient (driver's license number, social security number etc). This information may be included in the *Patient* class and therefore not present. The OtherIDs.id attribute shall be included within the OtherIDs class. More than one OtherIDs.id attributes may be sent in the response message.
6. No other classes are permissible in the response message.

### Test Step TRFR5-3

#### Actors:

Tester, EHR, HIE

#### Procedure:

A tester shall login in to the EHR and query the HIE for a patient by transmitting a PDQ (ITI-21) query to the recipient PIX manager (HIE) using the Q22 HI7 trigger event (QBP^Q22). To verify the basic capability to send a PDQ query (ITI-21) the following transaction events shall be tested. Existing testing scripts, tools or certification may be used to accomplish verification (i.e., IHE PDQ tests) and is left at the discretion of the tester.

1. The initial procedure will send a PDQ query (ITI-21) with QPD-3 containing a number of multiple PID attributes from the IHE profile required PID attribute list.
2. A following procedure will send a PDQ query (ITI-21) with a single attribute contained within the QPD-3 from the IHE profile required PID attribute list. It is expected that this single PID attribute will return multiple patients and should be constructed as such. A single known domain will be contained within QPD-8.
3. To test for unknown domains, the previous procedure will be repeated with a single unknown domain within QPD-8.
4. The tester will send a PDQ query (ITI-21) with a single attribute within QPD-3 and multiple known domains within QPD-8.
5. The previous test shall be repeated by the tester however multiple known and at least one unknown domains will be contained within QPD-8.
6. To test quantity limit requests the tester shall send a PDQ query (ITI-21) with QPD-3 containing a single PID attribute that is known to return a large number of patients. A quantity limit request will be specified in the RCP-2 segment. To test quantity limits this number shall be smaller than the number of patients returned.

7. The tester will resend the query from the previous procedure however placing a continuation pointer within the DSC segment.
8. (Optional) Cancellations of a query shall be handled by sending a HL7 J01 trigger event. The tester shall invoke a function from within the EHR product, or using a testing tool trigger a cancellation event.<sup>16</sup>

Expected Result:

A PDQ query (ITI-21) is expected to be sent for each transaction to the HIE.

Verification Action:

For each query transaction the tester shall view the outbound message (through system available logs) to inspect and document the transactions match the test procedure requirements or use a testing tool to ensure successful transmission and validation of the query.

To verify the outbound message tester shall verify that the system is able to send a query with each of the attributes and tester shall also verify fields <seg><field no><component no> are correct within the HL7 message by cross referencing with the HL7 protocol specifications.<sup>17 18</sup> QPD-1 will specify IHE PDQ Query for the QPD-1 message query name. QPD-8 will not be populated. QPD-3 will contain at least one of the following required attributes.

PID.3	Patient Identifier List
PID.5	Patient Name
PID.7	Date/Time of Birth
PID.8	Administrative Sex
PID.11	Patient Address
PID.18	Patient Account Number

*Table 7 - QPD-3 fields required to be supported<sup>19</sup>*

For the response message the tester shall view the inbound message and verify and document correct message format and that the system is able to parse the message. Tester shall check for valid values within the QAK segment such as OK or AE and within the MSA segment values such as AA or AE.

The following characteristics shall match the test procedures described above.

<sup>16</sup> Test procedure is optional if the cancellation function is not readily available from within the product or a testing tool.

<sup>17</sup> Reference IHE IT Infrastructure Technical Framework Volume 2a (ITI TF-2a) section 3.21.4.1.2.2.1 "Populating QPD-3-Demographic Fields"

<sup>18</sup> Reference HL7 Messaging Standard Version 2.5 – An Application Protocol for Electronic Data Exchange in Healthcare Environments

<sup>19</sup> If the system supports the Pediatric Demographic profile option within the PDQ query PID.6 – Mother's Maiden name and PID.13 – Phone Number Home will be included as optional fields.

1. A successful response is expected to be received by the initiating system (EHR). The tester shall inspect and document the response message and verify the EHR is able to process this message. QAK segment is expected to return a value of OK.
2. A successful response is expected to be received by the initiating system (EHR) for this message. Inspection and documentation of the response message shall be performed by the tester including verifying the ability to parse the returned PID segment with multiple known patients as well as the assigning authority of the domain of the patient located in component 4 of the PID-3. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
3. An error is expected to occur and be received by the initiating system (EHR) for this message. Tester shall inspect the inbound message and verify correct message format and that the initiating system is able to parse the message. MSA-1 and QAK-2 shall contain a value of AE. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
4. A successful response is expected to be received. Tester shall view the inbound message and verify correct message format and that the system is able to parse the message. MSA-1 shall contain a value of AA and QAK-2 shall contain a value of OK. The initiating system shall be verified that it is able to parse the returned PID segment with multiple known patients as well as the assigning authority of the domain of the patient located in component 4 of the PID-3. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
5. An error is expected to occur and be received by the initiating system (EHR) for this message. Tester shall view the inbound message and verify correct message format and that the initiating system is able to parse the message. MSA-1 and QAK-2 shall contain a value of AE. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
6. A successful response is expected to be received by the initiating system (EHR) for this message. The tester shall view the inbound message and verify correct message format and that the system is able to parse the message. Tester shall ensure the inbound message possesses a DSC segment and that the return patient identifier's is able to be parsed. The next increment value, the continuation pointer in the DSC segment shall be captured. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
7. A successful response is expected to be received by the initiating system (EHR) for this message. The tester shall view the inbound message and verify correct message format and that the system is able to parse the continuation of patient's from the previous inbound/outbound message combination. Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.
8. The tester shall inspect and document that the cancellation process is successful. The system will stop receiving messages after the J01 HL7 cancellation trigger event has been sent and the previous received patient identifiers shall be shown to the user.

Verification may be completed by a testing tool validating the response (if robust enough) or through visual inspection of the returned result displayed within the EHR.

#### **Test Step TRFR5-4**

Actors:

Tester, EHR, HIE

Procedure:

The tester shall login in to the EHR and query the HIE for a patient by using a PDQV3 (ITI-47) query.

Expected Result:

A PDQV3 query (ITI-47) is expected to be sent for each patient identifier transaction to the HIE or SMPI.

Verification Action:

For each query transaction the tester shall view the outbound message (through system available logs) or use a testing tool to inspect and document the transactions match the test procedure requirements.

The tester shall verify by documenting and inspecting the following parameters are present in the outbound query as they are required and/or use a testing tool to confirm successful query transmissions. It is expected that schema validation would be performed when undertaking more stringent compliance testing or using a test script.

1. Each parameter may have only one value attribute.
2. QueryByParameter.responsePriorityCode is required and is fixed to 'I' for immediate.
3. QueryByParameter.responseModalityCode is required and is fixed to 'R' for real time.
4. QueryByParameter.statusCode is defaulted to "new".
5. The interactionId shall be set to 'PRPA\_MT201306UV02'.

The response to the query shall be verified by inspecting and documenting the inbound response message. In lieu of manual inspection a testing tool with a verification response may be used if the testing tools scripts perform the same function. In addition it is expected that schema validation would be performed. The following characteristics shall be verified:

1. The WSDL schema shall be identified as 'PRPA\_MT201310UV02'.
2. A *Patient* class shall be present containing the primary record for the focal person.
3. A *Person* class containing the name or id of the patient shall be present for further verification.

#### **Test Step TRFR5-5**

Actors:

Tester, EHR, HIE

Procedure:

The tester shall verify the ability to send a constrained NwHIN XCPD message to the responding gateway by inspecting and documenting the outbound message to the responding gateway.

Expected Result:

A NHIN Patient Discovery based XCPD (ITI-55) query is sent from the EHR to the HIE. A response message to the ITI-55 request query is expected to be received from the responding gateway (HIE).

Verification Action:

The tester shall verify the following attributes of the outbound message sent from the initiating gateway (EHR) by sending one or more queries to the HIE. A testing tool may be used to perform verification of validation of the data elements. It is expected that a test script leveraged against a production environment or compliance testing would check the following values within a larger set of validation requirements. The use of schema validation and schematron validation would be expected.

1. The tester will verify the transaction mode(s) corresponds to the vendor identified mode, either demographic query only or demographic query and feed. Shared national patient identifier query and feed is not supported and demographic query only mode is only allowed with the responding gateway is a consumer of data but not a supplier.
2. A homeCommunityId element shall be present in the outbound message and this element corresponds to the vendor identified required data.
3. The outbound message shall contain a community patient id assigning authority which will only contain one root element.
4. The LivingSubjectName element has been specified in the message.
5. The LivingSubjectName.value element has been specified in the message and only sends the value of 'PN'.
6. The tester shall verify the sending system (initiating gateway) is able to send multiple names within the LivingSubjectName element.
7. The LivingSubjectAdministrativeGender parameter is present.
8. The LivingSubjectBirthTime element has been specified in the message as an exact date/time.
9. The LivingSubjectBirthTime element has been specified in the message as an approximate date.
10. The LivingSubjectBirthTime element has been specified in the message as a date range.
11. (Optional) The LivingSubjectId element has been specified in the message. Optionally this element may be specified as the patient identifier.
12. The transmission wrapper will include a value of 'MCCI\_MT000300UV01' to indicate a send application acknowledgement.
13. The values of interactionId shall be set to 'PRPA\_IN201306UV02', processingModeCode shall be set to 'T', acceptAckCode shall be set to 'NE'.
14. The value of responsePriorityCode is set to 'I' for immediate. Deferred transactions will not be supported.

## Test Step TRFR5-6

### Actors:

Tester, HIE, EHR or simulation tool, SMPI

### Procedure

The tester shall send a PIX query using an EHR, or simulation tool, connected to an HIE or directly to an SMPI.

To verify the basic capability to receive and parse a PIX query (ITI-9) the following transaction events shall be tested.

1. The initial procedure will test a PIX (ITI-9) query to the responding gateway by specifying the patient id. The tester will use a connected EHR or simulation tool and query the HIE for a patient by transmitting a PIX query (ITI-9) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1 and an assigning authority in QPD-3.4.
2. This procedure will test a PIX (ITI-9) query by specifying the universal patient id. The tester will use a connected EHR or simulation tool to query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A universal patient identifier will be entered in QPD-3.2 and a universal ID type will be entered in QPD-3.3. QPD-3.4 will contain the assigning authority.
3. To verify the ability of a system to receive a PIX (ITI-9) query that contains both a patient id and a universal patient id the following procedure will be performed. The tester will use a connected EHR or simulation tool to query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1, a universal patient identifier will be entered in QPD-3.2 and a universal ID type will be entered in QPD-3.3. QPD-3.4 will contain the assigning authority.
4. This test procedure will verify the capabilities of a system to process a PIX (ITI-9) query that contains a patient id and a universal patient that do not match. The tester will use a connected EHR or simulation tool to query the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1, a universal patient identifier will be entered in QPD-3.2 and a universal ID type will be entered in QPD-3.3. QPD-3.4 will contain the assigning authority. The patient identifier in QPD-3.1 will not match the universal patient identifier or correspond to the same patient as is entered in QPD-3.2.
5. Known domains specified within the PIX (ITI-9) query will be tested by the tester using a connected EHR or simulation tool and querying the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1. QPD-3.4 will contain the assigning authority. QPD-4 will be populated with a known domain that contains information about the patient. Systems that are incapable of submitting a CX data type delimiter within the QPD segment may bypass this test requirement.
6. Unknown domains specified within the PIX (ITI-9) query will be tested by the tester using a connected EHR or simulation tool and querying the HIE for a patient by transmitting a PIX query (ITI-9) to the recipient PIX manager (HIE) using the Q23 HI7 trigger event. A patient identifier will be entered in QPD-3.1. QPD-3.4 will contain the assigning authority. QPD-4 will be populated with a known domain that contains information about the patient.

Systems that are incapable of submitting a CX data type delimiter within the QPD segment may bypass this test requirement.

Expected Result:

A PIX query (ITI-9) is expected to be received for each patient identifier transaction to the HIE and a response sent to the initiating system.

Verification Action:

For each query transaction the tester shall view the outbound message (through system available logs) to inspect and document the transactions match the test procedure requirements or use a testing tool with validation responses for verification. For positive testing it is expected a RSP^K32 response will be returned with each transaction. For negative testing it is expected an error will be returned. The tester shall verify that field RCP-1 contains an 'I' indicating immediate priority on the outbound message.

Tester shall verify that a response message to each PIX (ITI-9) query is able to be sent to the initiating system. Inspection of the outbound query shall be completed by viewing system logs; all applicable segments including a query acknowledgment (QAK), original query patient identifiers (QPD), and patient identifier (PID) must be present.

The PID-3 segment received shall contain all subcomponents of the assigning authority which includes the namespace ID, universal ID, and the universal ID type. The PID-5 will be empty except for PID-5 component 7 which will contain a value of 'S' in the second repetition.

The system should specifically be able to respond to condition code '204' for unknown key identifier as specified by the use cases.<sup>20</sup>

Testing of the PIX (ITI-9) query is not intended to be exhaustive or supplant vendor testing or other compliance testing. Core capabilities are required to adequately address the functional requirements of the Patient Data Inquiry specifications.

1. The tester shall view the ATNA logs (or development logs in lieu) or use a testing tool for validation to ensure that a PIX (ITI-9) message was sent to the initiating system. The tester will verify and document that the responding system (HIE) is able to send a K23 response message (RSP^K23).
2. The response message from the HIE shall be validated by viewing a log containing the response message or use a testing tool for validation of the response. The tester will inspect and document that this response message contains elements for a query acknowledgment (QAK), original query patient identifiers (QPD) and patient identifier (PID). PID-3 segment shall contain all subcomponents including namespace id, universal id, and universal id type.
3. The response message verification will be the same as performed in step 2.
4. The response message for this query is expected to contain an error in the form of an 'AE' value in the QAK segment. The tester shall verify that the HIE is able to

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<sup>20</sup> Reference IHE IT Infrastructure Technical Framework Volume 2a (ITI-TF2a)

send a specific error code in the ERR segment within the QPD. Manual inspection of the response message may be performed or a testing tool may be used for validation.

5. Known domain verification will occur by the tester viewing the ATNA logs or using a testing tool for validation to ensure that a PIX (ITI-9) message was sent to the initiating system. A positive response is expected to be received by the EHR from the responding gateway (HIE). Inspection and documentation is the same as described in test step 2.
6. It is expected that an error message will be sent to the EHR from the responding gateway (HIE). Verification is to be completed as is described in test step 4.

### **Test Step TRFR5-7**

#### Actors:

Tester, HIE, EHR or simulation tool

#### Procedure:

The tester shall send a PIXV3 (ITI-45) query using an EHR, or simulation tool, connected to the HIE.

#### Expected Result:

A PIXV3 query (ITI-45) is expected to be received for each patient identifier transaction to the HIE and a response sent to the initiating system.

#### Verification Action:

For each query transaction the tester shall view the inbound message (through system available logs) or use a testing tool with validation capabilities to inspect and document the HIE is able to parse the request.

The response message shall be inspected by the tester to verify and document correct message format or a testing tool with validation capabilities may be used.

Schema validation and schematron validation is expected to be used for testing.

The tester shall ensure the major components of the query are present in the message (either through manual inspection or using a testing tool).

1. The PatientIdentifier parameter shall be present. Reference Appendix E of the IHE Patient Identifier Cross-Reference HL7 V3 (PIXV3) and Patient Demographic Query HL7 V3 (PDQV3) for reference to data types of patient identifiers.
2. If the DataSource parameter is present the assigning authority of the domain shall be represented and validation of a valid domain is expected.
3. Restrictions made to the base RMIM shall be verified (reference the restrictions in the IHE specifications referenced in #1 of this verification action as well the reference to the original base RMIM):
  - a. Exactly one PatientIdentifier parameter shall be present.
  - b. Exactly one PatientIdentifier.value attribute shall be present.
  - c. If one or more DataSource parameters are present, each shall contain exactly one DataSource.value parameter.

- d. The optional attributes ParameterList.id, QueryByParameter.responseElementGroupId, QueryByParameter.modifyCode, and QueryByParameter.executionAndDeliveryTime were removed from the model.
  - e. QueryByParameter.responsePriorityCode is required and is fixed to I (Immediate).
  - f. QueryByParameter.statusCode is defaulted to “new”.
4. If the DataSource parameter is not specified, all patient identifiers for all domains shall be returned.

### Test Step TRFR5-8

#### Actors:

Tester, HIE, EHR or simulation tool

#### Procedure

The tester shall use an EHR, or simulation tool, connected to the HIE to send a PDQ query (ITI-21). To verify the basic capability to respond to a PDQ query (ITI-21) the following transaction events shall be tested.

1. The initial procedure will send a PDQ query (ITI-21) with QPD-3 containing a number of multiple PID attributes from the IHE profile required PID attribute list.
2. A following procedure will send a PDQ query (ITI-21) with a single attribute contained within the QPD-3 from the IHE profile required PID attribute list. It is expected that this single PID attribute will return multiple patients and should be constructed as such. A single known domain will be contained within QPD-8.
3. To test for unknown domains, the previous procedure will be repeated with a single unknown domain within QPD-8.
4. The tester will send a PDQ query (ITI-21) with a single attribute within QPD-3 and multiple known domains within QPD-8.
5. The previous test shall be repeated by the tester however multiple known and at least one unknown domains will be contained within QPD-8.
6. To test quantity limit requests the tester shall send a PDQ query (ITI-21) with QPD-3 containing a single PID attribute that is known to return a large number of patients. A quantity limit request will be specified in the RCP-2 segment. To test quantity limits this number shall be smaller than the number of patients returned.
7. The tester will resend the query from the previous procedure however placing a continuation pointer within the DSC segment.
8. (Optional) Cancellations of a query shall be handled by sending a HL7 J01 trigger event. The tester shall invoke a function from within the EHR product, or using a testing tool trigger a cancellation event.<sup>21</sup>

#### Expected Result:

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<sup>21</sup> Test procedure is optional if the cancellation function is not readily available from within the product or a testing tool.

A PDQ query (ITI-21) is expected to be sent for each transaction to the HIE.

Verification Action:

For each query transaction the tester shall view the inbound message (through system available logs) or use a testing tool with validation capabilities to inspect and document the HIE is able to parse the request.

The response message shall be inspected by the tester to verify and document correct message format or a testing tool with validation capabilities may be used.

The tester shall check for valid values within the QAK segment such as OK or AE and within the MSA segment values such as AA or AE.

The following characteristics shall match the test procedures described above.

1. A successful response is expected to be sent by the responding system (HIE). The tester shall inspect and document the response message against the inbound request message to ensure the values returned match the request. QAK segment is expected to return a value of OK.
2. A successful response is expected to be sent by the responding system (HIE) for this message. Inspection and documentation of the response message shall be performed by the tester including verifying the ability to parse the inbound message segments including the PID segment with multiple known patients as well as the assigning authority of the domain of the patient located in component 4 of the PID-3. The response message shall be inspected to ensure its return values match the requested patient.
3. An error is expected to occur and be sent by the responding system (HIE) for this message. The tester shall inspect the inbound message and verify correct message format and that the responding system is able to parse the message. The response message sent to the initiating system (EHR) shall be inspected and documented for correct format. MSA-1 and QAK-2 shall contain a value of AE.
4. A successful response is expected to be received. The tester shall view the inbound message and verify correct message format and that the system is able to parse the message. The response message shall be inspected and documented. MSA-1 shall contain a value of AA and QAK-2 shall contain a value of OK.
5. An error is expected to occur and be sent by the responding system (HIE) for this message. The tester shall view the inbound message and verify correct message format and that the initiating system is able to parse the message. The response message shall be inspected and documented against the specifications. MSA-1 and QAK-2 shall contain a value of AE.
6. A successful response is expected to be sent by the responding system (HIE) for this message. The tester shall view the inbound message and verify correct message format and that the system is able to parse the message. Tester shall ensure the outbound message possesses a DSC segment and that the return patient identifier's is able to be parsed. The next increment value, the continuation pointer in the DSC segment shall be captured.
7. A successful response is expected to be sent by the responding system (EHR) for this message. The tester shall view the inbound message and verify correct message format and that the system is able to parse the continuation of patient's from the previous inbound/outbound message combination.

8. The tester shall inspect and document that the cancellation process is successful. The HIE will stop sending messages after the J01 HL7 cancellation trigger event has been sent.

### Test Step TRFR5-9

Actors:

Tester, HIE, EHR or simulation tool

Procedure:

The tester shall login in to the EHR or testing tool and query the HIE for a patient by using a PDQV3 (ITI-47) query.

Expected Result:

A PDQV3 query (ITI-47) is expected to be sent for each patient identifier transaction to the HIE.

Verification Action:

For each query transaction the tester shall view the inbound message (through system available logs) or use a testing tool with validation capabilities to inspect and document the HIE is able to parse the request.

The response message shall be inspected by the tester to verify and document correct message format or a testing tool with validation capabilities may be used.

Schema validation and schematron validation is expected to be used for testing.

Successful roundtrip communication is the primary verification method for both the request and response message.

The tester shall ensure the major components of the query are present in the message (either through manual inspection or using a testing tool).

1. Each parameter may have only one value attribute.
2. QueryByParameter.responsePriorityCode is required and is fixed to 'I' for immediate.
3. QueryByParameter.responseModalityCode is required and is fixed to 'R' for real time.
4. QueryByParameter.statusCode is defaulted to "new".
5. The interactionId shall be set to 'PRPA\_MT201306UV02'.

The response to the query shall be verified by inspecting and documenting the inbound response message. In lieu of manual inspection a testing tool with a verification response may be used if the testing tools scripts perform the same function. In addition it is expected that schema validation would be performed. The following characteristics shall be verified:

1. The WSDL schema shall be identified as 'PRPA\_MT201310UV02'.
2. A *Patient* class shall be present containing the primary record for the focal person.
3. A *Person* class containing the name or id of the patient shall be present for further verification.

## Test Step TRFR5-10

### Actors:

Tester, HIE, EHR or testing simulation tool,

### Procedure:

The ability of an HIE to send, receive and respond to a constrained NwHIN XCPD message request shall be verified by inspecting and documenting both the consumption and response of the HIE. A simulation tool may be used to send XCPD requests to the HIE in lieu of a partner EHR system.

### Expected Result:

A NHIN Patient Discovery based XCPD (ITI-55) query is received from an EHR or testing tool for processing within the HIE. A response message is expected to be sent back to the initiating system (EHR).

### Verification Action:

The tester shall verify the ability of the HIE to send, receive and respond to a constrained NwHIN Patient Discovery based XCPD (ITI-55) query. The following characteristics of the response message are expected to be verified by documenting and inspecting the message contents by sending one or more requests.

A testing tool may be used to perform verification of validation of the data elements. It is expected that a test script leveraged against a production environment or compliance testing would check the following values within a larger set of validation requirements.

Schema validation and schematron validation would be expected to be used in testing the ability to send, receive and responds to a constrained NwHIN Patient Discovery.

For outbound messages crossing gateways:

1. The tester will verify the transaction mode(s) corresponds to the vendor identified mode, either demographic query only or demographic query and feed. Shared national patient identifier query and feed is not supported and demographic query only mode is only allowed with the responding gateway is a consumer of data but not a supplier.
2. A homeCommunityId element shall be present in the outbound message and this element corresponds to the vendor identified required data.
3. The outbound message shall contain a community patient id assigning authority which will only contain one root element.
4. The LivingSubjectName element has been specified in the message.
5. The LivingSubjectName.value element has been specified in the message and only sends the value of 'PN'.
6. The tester shall verify the sending system (initiating gateway) is able to send multiple names within the LivingSubjectName element.
7. The LivingSubjectAdministrativeGender parameter is present.
8. The LivingSubjectBirthTime element has been specified in the message as an exact date/time.

9. The LivingSubjectBirthTime element has been specified in the message as an approximate date.
10. The LivingSubjectBirthTime element has been specified in the message as a date range.
11. (Optional) The LivingSubjectId element has been specified in the message. Optionally this element may be specified as the patient identifier.
12. The transmission wrapper will include a value of 'MCCI\_MT000300UV01' to indicate a send application acknowledgement.
13. The values of interactionId shall be set to 'PRPA\_IN201306UV02', processingModeCode shall be set to 'T', acceptAckCode shall be set to 'NE'.
14. The value of responsePriorityCode is set to 'I' for immediate. Deferred transactions will not be supported.

For inbound messages the HIE shall send a response:

1. Tester shall view the inbound message and verify the message in SOAP format roughly corresponding to an XCPD profile message. If the inbound message is not viewable through logs a testing tool with validation capability should be used.
2. Schema validation and schematron validation is expected to be performed using a schema validation and schematron validation tools for verification.

### 3.5.3 Test Data

The vendor will provide patient demographics that correspond to the test procedures documented. It is at the discretion of the compliance body and tester to change this data prior to the test procedures being performed.

### 3.5.4 Conformance Test Tool(s)

Either an EHR (or other portal with access to an initiating gateway) or an HIE (with access to a responding gateway) shall be made available in the tool.

## 3.6 FR-6 Document Query

### 3.6.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

Priority: Required

Description: Document request from the Initiating Gateway or local clinical application will be sent either directly to the Responding Gateway or to the RLS to retrieve a list of all available documents for the matched patient. A list of available documents will be presented to the end user to retrieve.

Purpose: The system shall allow the ability for a query to be made for all available document(s) for the matched patient.

Derived compliance shall encompass:

“IHE Cross Community Access (XCA) profile supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/enterprises that have agreed to work together using a common set of policies for the purpose of sharing clinical information via an established mechanism.”

### 3.6.2 Test Procedures

#### Test Requirements

- TRFR6-1. The initiating system (EHR) SHALL retrieve a list of documents using an NHIN Query for Documents transaction which is based on IHE Registry Stored Query Transaction for XDS Profile (ITI-18).
- TRFR6-2. The responding system (HIE) shall return a list of documents upon receiving an NHIN Query for Documents transaction which is based on IHE Registry Stored Query Transaction for XDS Profile (ITI-18).

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>Vendor</b>	The organization providing and operating the EHR or HIE under test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The document viewer either built within the portal or an associated application.

## Test Environment Prerequisites

1. Vendor must establish patient identity feeds prior to document query.

## Test Step TRFR6-1

### Actors:

Tester, Vendor, EHR, HIE

### Procedure:

To verify the retrieval of available documents the tester will login in to the EHR and query the responding gateway using an NHIN Query for Documents XCA based query to retrieve a list of available documents. The transaction is expected to pass through an HIE to the available gateway.

(Optional) To verify error codes the tester will initiate a response message using a testing tool to simulate an error message from the responding gateway (HIE) to the EHR. The tester will ensure that error codes returned from the responding gateway can be processed. Reference the NHIN Query for Documents Web Services Specification for details on specific error codes.

### Expected Result:

A list of available documents is to be returned to the EHR.

### Verification Action:

For verification the tester shall inspect and document the outbound message and confirm the outbound query is in the correct format according to specifications detailed in the NHIN Query for Documents. The tester will inspect and document the outbound message to ensure the homeCommunityId is specified in the XCA query and this id corresponds to the homeCommunityId returned from the patient identity query as required in FR-5. The same will be done for the patient id as this id must match the initial patient identifier retrieved as part of the pre-requisites. In lieu of manual inspection a testing tool with validation capabilities may be used.

To verify the basic required elements of an XCA query from the initiating gateway the tester shall continue to inspect the outbound message to the responding gateway. The namespace and schema location shall correspond to 'urn:oasis:names:tc:ebxml-regrep:xsd:query:3.0' and 'query.xsd'.

The tester will ensure the auditing on the initiating gateway is compliant with specifications detailed in the NHIN Query for Documents.

(Optional) If a testing tool that can simulate error codes generated by the HIE is available further testing can be performed to verify the ability of the EHR to receive error codes from the HIE. The tester shall verify the initiating gateway can process error codes returned by the responding gateway by sending invalid requests conforming to the error codes mentioned in the NHIN Query for Documents Web Services Specifications. Verification of errors may be performed using log entries or visual inspection of the user interface. Specifics of error verification require implementation details which is outside of scope.

## Test Step TRFR6-2

### Actors:

Tester, HIE, RLS

### Procedure:

To verify the ability of the HIE to return a list of available documents, the tester will use an EHR or simulation tool connected to the HIE to send a query based on the NHIN Query for Documents XCA. The HIE is expected to retrieve a list of documents from the RLS using an NHIN Query for Documents XCA query.

### Expected Result:

The HIE returns a list of documents to the initiating system.

### Verification Action:

The ability of the HIE to retrieve a document from either its own community or a cross enterprise community shall be verified by the tester.

If a testing tool is available the tester shall initiate a query to the HIE simulating an EHR sending a request for documents by simulating a NHIN Query for Documents. The response message will be verified by inspecting and documenting query response from the responding gateway (HIE). The tester will ensure the patient identifier returned in the query response is the same as the initiating query and is in the appropriate elements of the returned message. If the element is missing the initiating gateway is expected to return an XDSMissingHomeCommunityId to the original responding gateway for routing.

The tester will ensure the auditing on the responding gateway is compliant with specifications by inspecting and documenting the log files if available. When a Cross Gateway Query is received it shall perform the same auditing as if it were a document registry except for the event code specifying this was an ITI-38 transaction. If this responding gateway interacts with a local document registry it shall in addition audit as if it were a document consumer with an ITI-38 transaction.

## 3.6.3 Test Data

The vendor will provide patient's that have known documents to exist in an accessible document registry.

## 3.6.4 Conformance Test Tool(s)

An initiating gateway (EHR or other portal) and a responding gateway (HIE) that has accessible documents registered within a document repository shall be available in the tool.

## 3.7 FR-7 Record Retrieval

### 3.7.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

Priority: Required

Description: Retrieval of patient records from all connected entities once they have been identified.

Purpose: The system shall support retrieval of patient records from across all connected entities directly by an end user's EHR application or a request made by an EHR application routed through the end user's local HIO.

Derived compliance shall encompass:

Delivery of requested registered documents from a document repository either within a single community or cross-community.

### 3.7.2 Test Procedures

#### Test Requirements

TRFR7-1. The initiating system (EHR) SHALL retrieve a document using an NHIN Retrieve Documents specification which is based on the IHE Cross Community Access (XCA) ITI-39 transaction.<sup>22</sup>

TRFR7-2. The responding system (HIE) SHALL retrieve a document and return this document to the initiating system using an NHIN Retrieve Documents specification which is based on the IHE Cross Community Access (XCA) ITI-39 transaction.

#### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>EHR</b>	The electronic health record system under test.
<b>HIE</b>	The document viewer either built within the portal or an associated application.

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<sup>22</sup> Aggregated CCD will not be addressed as a test specification as this is an optional feature of the functional requirements and the format and content is at the discretion of the vendor and/or state.

### Test Environment Prerequisites

1. EHR has established patient identity feeds prior to document query.
2. EHR must register (or know of) a document within the document registry and identify the document id and associated metadata.

### Test Step TRFR7-1

Actors:

Tester, EHR, HIE

Procedure:

To verify that a record may be retrieved a tester will first establish the available documents by sending a request from the EHR using a NHIN Request for Documents XCA (ITI-38) transaction to retrieve a list of available documents from the HIE as described in Functional Requirement FR-6. After the available document list has been established the tester will query the responding gateway using an NHIN Retrieve Documents constrained XCA query (ITI-39) to retrieve a document using a single document id.

Expected Result:

A record will be received by the EHR from the responding gateway.

Verification Action:

The tester shall inspect and document that the EHR (or testing tool if testing an HIE) displays a list of available documents that may be retrieved. Upon selection the EHR will begin the retrieve of a single document. The tester shall view the ATNA logs (or development logs in lieu) to verify that the homeCommunityId parameter is present and in the correct format of 'urn:oid:n.n.n.n'.<sup>23</sup> The tester shall document that the repositoryUniqueld and documentUniqueld elements that are identified with the repository from the document query set and selected document that was retrieved as pre-condition is contained within the query.

A testing tool may be used to validate the query, response and document retrieval if available in lieu of manual inspection of messages. Tester shall verify document retrieval within the initiating application.

### Test Step TRFR7-2

Actors:

Tester, HIE

Procedure:

Using a simulation tool or an EHR the tester will retrieve a document from the HIE using a single document id within an NHIN Retrieve Documents constrained XCA query (ITI-39).

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<sup>23</sup> Unlike the base transaction ITI-43 this parameter is required.

The HIE will retrieve the document from its community or perform a cross community retrieve. The tester may need to retrieve a list of available documents using a NHIN Request for Documents XCA (ITI-38) transaction if using an EHR or simulation tool connected to the HIE for testing.

Expected Result:

A record will be sent to the initiating system from the HIE.

Verification Action:

The tester shall view the ATNA logs (or development logs in lieu) to verify that the homeCommunityId parameter is present and in the correct format of 'urn:oid:n.n.n.n'. The tester shall document that the record's repositoryUniqueId and documentUniqueId corresponds to the record being sent to the initiating system.

### 3.7.3 Test Data

The vendor will provide patient's that have known documents to exist in an accessible document registry and repository.

### 3.7.4 Conformance Test Tool(s)

An initiating system (EHR or other portal) and an initiating and responding gateway(s) (HIE) that has accessible documents registered within a document repository shall be available in the tool.

## 3.8 FR-8 Record Viewing

### 3.8.1 Compliance Criteria

This compliance criterion is derived from the Statewide Patient Data Inquiry Service Functional Specification and the Statewide Patient Data Inquiry Service Technical Specification published by the Multi-State/Multi-Vendor Electronic Health Record (EHR)/Health Information Exchange (HIE) Interoperability Workgroup.

Priority: Required

Description: Once selected documents are retrieved, they can be viewed by the user through their local clinical application.

Purpose: The system shall support viewing of patient records within the end user's local clinical application.

Derived compliance shall encompass:

The ability for a requesting system (EHR or other portal) is able to view requested documents within the EHR, portal, or other document viewer.

### 3.8.2 Test Procedures

#### Test Requirements

TRFR8-1. The system SHALL provide the capability for the requesting user to view a requested document retrieved from a document repository.

### Test Actors

Actor	Description
<b>Tester</b>	The individual administering the test.
<b>EHR</b>	The electronic health record system under test.
<b>Document Viewer</b>	The document viewer either built within the portal or an associated application.

### Test Environment Prerequisites

1. EHR has established patient identity feeds prior to document query.
2. EHR must register (or know of) a document within the document registry and identify the document id and associated metadata.
3. EHR will send a request from the initiating gateway using an NHIN Request for Documents XCA (ITI-38) transaction to retrieve a list of available documents as described by Functional Requirement FR-6.

### Test Step TRFR8-1

Actors:

Tester, EHR, Document Viewer

Procedure:

The tester shall login into the EHR and query the initiating gateway using a NHIN Retrieve Documents constrained XCA query (ITI-39) to retrieve a document using a single document id. The document to be retrieved shall be ensured to be viewable prior to the retrieve.

Verification Action:

To verify that this document is viewable the tester shall launch a function that will show the document within the EHR application or it is expected at a minimum to launch an associated application to view the document.

### 3.8.3 Test Data

The vendor will provide patient's that have known documents to exist in an accessible document registry and repository.

### 3.8.4 Conformance Test Tool(s)

An initiating gateway (EHR or other portal) and a responding gateway (HIE) that has accessible documents registered within a document repository. A document viewer accessible to the initiating system either contained within or available outside, is available to the system in the tool.