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QHIN Conformance Testing Process: Initialization Tests

For Candidate QHIN Conformance Testing

Version History

| Version | Description of Change | Version Date |
|---------|---|-------------------|
| 1.0 | Initial Publication | September 9, 2022 |
| 1.0.1 | Removed reference to spreadsheet, in section 6, for coded values included in XDS metadata. Also, aligned language with the TEFCA Standard Operating Procedures (SOPs) | December 6, 2022 |
| 1.0.2 | Updated Title to include “For Candidate QHIN Conformance Testing” only. | May 31, 2023 |
| 1.1 | Update for alignment with QTF 1.1 and modified test patient demographics. Added zipcode for patient QTFTEST-002 | March 18, 2024 |

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1 INTRODUCTION, SCOPE, ORGANIZATION

Please see *QHIN Conformance Testing Process Overview* for higher level information about the testing environment. That document includes a broad overview of the process, applications and documentation for the QHIN Conformance Testing Process; a list of all QHIN Conformance test cases, documentation; and a description of content tests for the QHIN Conformance Testing Process.

This document, *QHIN Conformance Testing Process: Initialization Tests*, describes tasks to be performed by prospective QHINs to initialize their systems with test data and configuration information.

Test patient demographics and clinical information are based on data from the [Synthea Project](#). Details on provenance of the data and transformations are provided in [Section 4](#).

2 TESTS FOR INITIATING QHIN

2.1 Load Data as Initiating System

| | |
|----------------------------|---|
| Test Case ID: | IG Load Data as Initiating System |
| Title: | Load Patients Known by the Initiating Gateway |
| QTF Function / Technology: | Testing Procedure Supporting Requirements |
| Optionality: | Required |

Purpose/Description

This test describes the mechanism for loading test patients that will be accessed by the Initiating Gateway during the testing process. There is a similar test with different patients for the Responding Gateway. We recommend you read both tests before you begin the process. You will likely find similarities in how you prepare your system.

Preconditions

The RCE has created four separate test patients with clinical records to be used in the testing process. The table below lists the two patients that are used for testing the Initiating Gateway.

| Patient Name | Description |
|-----------------------|---|
| QTFTEST-001, QTF TEST | This patient is used when your system is actively pushing documents using the Message Delivery Scenario. You will load data and/or documents for this test patient so you can push one or more documents when requested. |
| QTFTEST-002, QTF TEST | This patient is used when your system is retrieving documents using the Document Query & Retrieve Scenario. You create this test patient in your system with demographics, but you do not include any of the clinical record associated with the patient. You will be instructed to query for documents and to retrieve them. |

Test Steps

Note: The steps assume a workflow for creating records. You will enter the appropriate data in your gateway and source systems in a way that will prepare you for testing. For example, we might state that you are to create documents. Your network might store individual data items and produce documents on demand.

1. Download the test data [RCE Patient Data 20240318.zip](#). The release data contains equivalent files in CCD documents and csv files.
2. Create a patient history for patient QTFTEST-001, QTF TEST using the demographics and clinical data provided. You need to create enough of a clinical record to be able to push C-CDA documents to the testing system when requested. You will not be tested on specific content, so you do not need to include all clinical data provided. You do need to include the proper patient demographics and not substitute other demographic data.
3. Create a patient demographic record for QTFTEST-002, QTF TEST using the demographics supplied. You need the demographic record because you will perform a patient search of the testing system with those demographics. Do not load the clinical data; you will query for and retrieve documents for this test patient.
4. Email the test manager when this task is complete: testing@sequoiaproject.org.

Assessment

1. Accept the email as proof of completion. If the user did not complete the task, future tests will fail.

Change History

| Date | Changes |
|----------------|---|
| April 1, 2022 | Initial Draft Version |
| March 11, 2024 | Remove reference to numbered requirement from QTF 1.1 |

3 TESTS FOR RESPONDING QHIN

3.1 Load Data as Responding System

| | |
|----------------------------|---|
| Test Case ID: | RG Load Data as Responding System |
| Title: | Load Patients Known by the Responding Gateway |
| QTF Function / Technology: | Testing Procedure Supporting Requirements |
| QTF Requirement: | QTF-107 |
| Optionality: | Required |

Purpose/Description

This test describes the mechanism for loading test patients that will be accessed by the Responding Gateway during the testing process. There is a similar test with different patients for the Initiating Gateway. We recommend you read both tests before you begin the process. You will likely find similarities in how you prepare your system.

Preconditions

The RCE has created four separate test patients with clinical records to be used in the testing process. The table below lists the two patients that are used for testing the Responding Gateway.

| Patient Name | Description |
|-----------------------|--|
| QTFTEST-003, QTF TEST | This patient is used when your system is accepting documents using the Message Delivery scenario. You will load patient demographics only so you are ready to accept the documents that are submitted to you. |
| QTFTEST-004, QTF TEST | This patient is used when your system is supplying documents using the Document Query & Retrieve scenario. You create this test patient in your system with demographics and sufficient clinical data to respond to document query and document retrieve requests. |

Test Steps

Note: The steps assume a workflow for creating records. You will enter the appropriate data in your gateway and source systems in a way that will prepare you for testing. For example, we might state that you are to create documents. Your network might store individual data items and produce documents on demand.

1. Download the test data [RCE Patient Data 20240318.zip](#). The release data contains equivalent files in CCD documents and csv files.
2. Create a patient demographic record for patient QTFTEST-003, QTF TEST using the demographics provided. You need the demographic record because you will accept documents for this patient that are pushed by the testing system. Do not load the clinical data.
3. Create a patient history for patient QTFTEST-004, QTF TEST using the demographics and clinical data provided. You need to create enough of a clinical record to be able to respond to document query and retrieve requests initiated by the testing system. You will not be tested on specific content, so you do not need to include all clinical data provided. You do need to include the proper patient demographics and not substitute other demographic data.
4. Email the test manager when this task is complete: testing@sequoiaproject.org.

Assessment

1. Accept the email as proof of completion. If the user did not complete the task, future tests will fail.

Change History

| Date | Changes |
|----------------|---|
| April 1, 2022 | Initial Draft Version |
| March 11, 2024 | Remove reference to numbered requirement from QTF 1.1 |

4 DATA PROVENANCE

Test patient demographics and clinical information are based on data from the [Synthea Project](#). From the [Synthea Github repository](#):

Synthea™ is a Synthetic Patient Population Simulator. The goal is to output synthetic, realistic (but not real), patient data and associated health records in a variety of formats.

We used a snapshot of data (November, 2021) published as [Synthea Sample Data](#). The C-CDA zip provided Continuity of Care documents for over 500 synthetic subjects. The CSV zip provided individual data items as CSV files for those same subjects.

We selected four subjects that had patient histories covering a range of data (Encounters, Medications, Allergies/Intolerances, ...) that would be useful for the document types used in testing. We reduced the data for each patient using arbitrary date ranges to reduce the size of the CCD documents as well as the number of data items in the CSV files. We modified the patient names to match the QTF requirements on test data. Other than changing patient names and removing data, we made no other changes to the clinical data from the sample data snapshot. The modified CCD files are included in the test environment.

The Synthea data includes sample Continuity of Care documents but does not include other types of documents used in testing. The [C-CDA-Examples Github repository](#) from HL7 provides examples of the other document types needed for testing. We extracted samples from that project and edited the files by hand to create the files needed in the testing environment. The patient demographic information in these files was modified to match the patient demographics in the CCD files. The clinical information from these files may or may not be consistent with the clinical information in the Synthea-based CCD files.

You will be given instructions in Section 5 about the demographic and clinical information to use for the various test scenarios. In general:

- You will be required to use the patient demographics in order to support Patient Discovery Requests and associated Document Query and Retrieve Document Requests.
- You will not be tested on the clinical data found in the samples. You can use the samples to populate your own test environment, but this is not a requirement. You are welcome to use other clinical data that may exist in your environment as long as you use the defined patient demographics.
- You are required to produce valid C-CDA R2.1 documents, and those will be tested for conformance.

5 PATIENT DATA DETAILS

The test procedures use four separate patients. The origin and provenance of the patient data is described in Section 4 (Data Provenance). The four subsections provide details and guidance on how you will use the data during testing. This table provides a summary of how each patient is used during testing.

| Patient | Actor Tested | Scenario Tested |
|-------------|--------------------|------------------|
| QTFTEST-001 | Initiating Gateway | Message Delivery |
| QTFTEST-002 | Initiating Gateway | Document Query |
| QTFTEST-003 | Responding Gateway | Message Delivery |
| QTFTEST-004 | Responding Gateway | Document Query |

5.1 Patient QTFTEST-001

Patient QTFTEST-001, QTF TEST is used when testing the Initiating Gateway in the Message Delivery Scenario. This is the scenario where you actively push documents to a Responding Gateway.

Patient Demographics

The table below contains demographic information for patient QTFTEST-001. The column with the label “Tested” will be marked with an X when that value will be tested at some point during the process. Not all demographic attributes are tested, and you are allowed to substitute different values.

| Attribute | Value | Tested |
|-----------------------|---|--------|
| Family Name | QTFTEST-001 | X |
| Given Name | QTF TEST | X |
| Date of Birth | 19580918 | X |
| Time of Birth | 002251 | |
| Administrative Gender | F (2.16.840.1.113883.5.1) | X |
| Race Code | 2106-3 (2.16.840.1.113883.6.238) | |
| Ethnic Group Code | 2186-5 (2.16.840.1.113883.6.238) | |
| Home Address | 577 Schmeler Frontage road Unit 7 Quincy, MA 02169 | |
| Alias | Gutmann970, Maddie576 (Original Synthea patient name. There is no requirement that you track/include alias information.) | |

Clinical Data Overview

Example clinical data are provided to help you build a patient record with the purpose of sending documents in the Message Delivery Scenario.

1. You will not be tested on the clinical content; that means you can substitute other content if that simplifies your preparation. You do have to create enough of a record in your systems to produce clinical documents.
 - a. The synthetic data for this patient indicates that she died at the age of 51. You are not required to include that fact as you construct a patient record.
2. You will be required to submit example documents for all versions of software and systems in your network. If you have three network participants that create CCD documents with different software, you will be tested for each of those three versions of CCD submission.
3. While you are not tested on clinical content, the metadata used when submitting documents will be tested. Details for each document type are given below.

Clinical Document Types

The QHIN Technical Framework lists requirements and suggestions for different document types (CCD, Progress Note, etc.). This section will not repeat those line items nor provide guidance on the types of documents your network needs to produce. You will have discussions with a Testing Manager to review those requirements. This section provides overall guidance based on document type.

Continuity of Care Document: The original Synthea sample data provides an example CCD that covers a long patient history. We have reduced that document to produce a shorter version that spans a select portion of the patient's life. If you are testing a CCD, we recommend you base that document on a shorter patient history so that you do not create a document larger than needed for testing. We will test the document metadata and general structure of the CCD, but we will not test specific content. There are tests for using code values from proper value sets.

Progress Note: The Synthea sample data did not include a Progress Note nor did we create a sample. As with the Continuity of Care Document, we recommend you create a short Progress Note that meets the C-CDA 2.1 requirements and uses coded values from proper value sets. You do not need to correlate data in the Progress Note with data in the CCD.

Discharge Summary: The Synthea sample data did not include a Discharge Summary. We did create and include an example. You may use the data in the sample as a model or you may use your own clinical data to populate the Discharge Summary. You do not need to correlate data in the Discharge Summary with data in the CCD or data in the Progress Note.

Unstructured Document: The Unstructured Document is assumed to contain a PDF document that can be of any type. We have included a sample Unstructured Document that contains a lab report, but you can include any type of embedded document. Please take care with coded values in both the Unstructured Document itself and XDS metadata.

Other Document Types: The first phase of testing focuses on the document types listed above. If you have other types of documents that you will be sending to a Responding QHIN, please discuss this with the Testing Manager. The testing platform can be extended for other types.

Document Metadata

There are multiple Document Entry metadata attributes to consider. In some cases, the value is fixed by specification. In other cases, the value must be taken from a value set, but a specific value is not required. Other attributes may not be required, and tests for such attributes are not included. Please see Section 7 of this document for a detailed description on document metadata testing.

5.2 Patient QTFTEST-002

Patient QTFTEST-002, QTF TEST is used when testing the Initiating Gateway in the Document Query Scenario. This is the scenario where you retrieve documents to a Responding Gateway.

Patient Demographics

The table below contains demographic information for patient QTFTEST-002.

| Attribute | Value | Tested |
|-----------------------|---|--------|
| Family Name | QTFTEST-002 | |
| Given Name | QTF TEST | |
| Date of Birth | 19931212 | |
| Time of Birth | 091854 | |
| Administrative Gender | F (2.16.840.1.113883.5.1) | |
| Race Code | 2106-3 (2.16.840.1.113883.6.238) | |
| Ethnic Group Code | 2186-5 (2.16.840.1.113883.6.238) | |
| Home Address | 1085 Grant Boulevard Marblehead, MA 01945 | |
| Alias | Stokes453, Oneida64 (Original Synthea patient name. There is no requirement that you track/include alias information.) | |

Clinical Data Overview

You do not have to create a clinical record for this patient. The test procedure will require that you query and retrieve documents. The table below contains the list of documents that are found in the simulated communities.

5.3 Patient QTFTEST-003

Patient QTFTEST-003, QTF TEST is used when testing the Responding Gateway in the Message Delivery Scenario. This is the scenario where documents are pushed to your Responding Gateway. Your Responding Gateway will also be tested using Patient Discovery queries for this patient.

Patient Demographics

The table below contains demographic information for patient QTFTEST-003. The column with the label “Tested” will be marked with an X when that value will be tested at some point during the process.

| Attribute | Value | Tested |
|-----------------------|---|--------|
| Family Name | QTFTEST-003 | X |
| Given Name | QTF TEST | X |
| Date of Birth | 19730402 | X |
| Time of Birth | 143232 | |
| Administrative Gender | F (2.16.840.1.113883.5.1) | X |
| Race Code | 2028-9 (2.16.840.1.113883.6.238) | |
| Ethnic Group Code | 2186-5 (2.16.840.1.113883.6.238) | |
| Home Address | 239 Upton Walk Lowell, MA 01852 | |
| Alias | Murphy561, Terrilyn343 (Original Synthea patient name. There is no requirement that you track/include alias information.) | |

5.4 Patient QTFTEST-004

Patient QTFTEST-004, QTF TEST is used when testing the Responding Gateway in the Document Query Scenario. This is the scenario where your Responding Gateway responds to Find Document and Retrieve Document requests. Your Responding Gateway will also be tested using Patient Discovery queries for this patient.

Patient Demographics

The table below contains demographic information for patient QTFTEST-004. The column with the label “Tested” will be marked with an X when that value will be tested at some point during the process.

| Attribute | Value | Tested |
|-----------------------|--|--------|
| Family Name | QTFTEST-004 | X |
| Given Name | QTF TEST | X |
| Date of Birth | 20110115 | X |
| Time of Birth | 084507 | |
| Administrative Gender | F (2.16.840.1.113883.5.1) | X |
| Race Code | 2106-3 (2.16.840.1.113883.6.238) | |
| Ethnic Group Code | 2186-5 (2.16.840.1.113883.6.238) | |
| Home Address | 359 Schmitt Track Unit 80 Somerville, MA 02155 | |
| Alias | Barton704, Eustolia154 (Original Synthea patient name. There is no requirement that you track/include alias information.) | |

Clinical Data Overview

Please read *Clinical Data Overview* in Section 5.1 (Patient QTFTEST-001). Because you are responding to requests for documents, the same guidance applies to your system. You will need to generate documents and appropriate metadata based on the participants in your network.

Clinical Document Types

Please read *Clinical Document Types* in Section 5.1 (Patient QTFTEST-001).

Document Metadata

Please read *Document Metadata* in Section 5.1 (Patient QTFTEST-001). Your Responding Gateway needs to provide accurate metadata when responding to Find Document requests. Your system also needs to be able to filter responses based on metadata values in those Find Document Requests.

6 VALUE SETS

Coded values included in XDS metadata must be selected from value sets provided by the RCE. This is both a testing issue and an interoperability issue when in production. One can download the file *codes.xml* from the NIST XDS software to see the values configured in that tool.

7 DOCUMENT METADATA – MESSAGE DELIVERY SCENARIO

Table 4.3.1-2 in IHE ITI TF 3:4.3.1 Defines requirements for document metadata as part of a submission process. The sections below describe the metadata values that will be tested, considering the document type and baseline requirements (R, R2, O).

- Some attributes will be tested for specific values
- Some attributes will be tested to ensure they are taken from a defined value set (not a specific value).
- The values of some attributes are not tested (author, creation time) even if that attribute is required.
- Optional attributes are not tested.

7.1 Document Entry Metadata Testing – Message Delivery

| Metadata Attribute | Optionality (Initiating Gateway) | Testing Notes |
|---------------------|----------------------------------|--|
| Author | R2 | If present, suggested values; see below |
| availabilityStatus | O | Not tested |
| classCode | R | Depends on document type; see below |
| comments | O | Not tested |
| confidentialityCode | R | Must be from confidentialityCode Value Set |
| creationTime | R | Suggested range; see below |

| Metadata Attribute | Optionality (Initiating Gateway) | Testing Notes |
|----------------------------|----------------------------------|--|
| entryUUID | R | Generated by IG; tested for format |
| eventCodeList | O | Not tested |
| formatCode | R | Depends on document type; see below |
| hash | O | If present, tested for correct value |
| healthcareFacilityTypeCode | R | Must be from healthcareFacilityTypeCode Value Set |
| homeCommunityId | O | If present, tested for value; see below |
| languageCode | R | Must be from languageCode Value Set |
| legalAuthenticator | O | Not tested. |
| limitedMetadata | X | Does not apply; not tested |
| contentType | R | Depends on document type; see below |
| objectType | R | Tested for one value defined by specification; see below |
| patientId | R | Must match value provided by test system |
| practiceSettingCode | R | Must be from practiceSettingCode Value Set |
| referenceIdList | O | |
| repositoryUniqueId | O | If present, tested for format |
| serviceStartTime | R2 | Suggested range; see below |
| serviceStopTime | R2 | Suggested range; see below |
| size | O | If present, tested for correct value. |
| sourcePatientId | R | Tested for format |
| sourcePatientInfo | O | Not tested |
| title | O | Not tested |
| typeCode | R | Depends on document type; see below |
| uniqueId | R | Generated by Initiating Gateway; tested for format |
| URI | O | Not tested |

Any attribute below with the label Suggested Value will not be tested for those values. Use the suggested value or another of your choosing.

author suggested values: Lincoln^Miranda, Grant^Jonas

classCode: The value for classCode is defined for CCD, Progress Note and Discharge Summary documents as listed in the table below. The value for classCode for an Unstructured Document will depend on the content of the document.

| Document Type | Required classCode |
|-----------------------|--|
| CCD | 34133-9 (2.16.840.1.113883.6.1) |
| Progress Note | 11506-3 (2.16.840.1.113883.6.1) |
| Discharge Summary | 18842-5 (2.16.840.1.113883.6.1) |
| Unstructured Document | Will depend on the content of the document |

creationTime: Please use different values that are on or after 2000.01.01. That will demonstrate realistic values and that they are not hard coded in your system.

formatCode: The value for formatCode is deterministic. In the context of this QHIN Conformance Testing Process:

| formatCode | Trigger Rules |
|--|---|
| urn:hl7-org:sdwg:ccda-structuredBody:2.1 | Required for C-CDA 2.1 documents with a structured body. Examples include CCD, Progress Note, Discharge Summary. |
| urn:hl7-org:sdwg:ccda-nonXMLBody:2.1 | Required for C-CDA 2.1 documents where the body is not structured. That is, the body is an embedded document in another format such as PDF. |

homeCommunityId: The attribute DocumentEntry.homeCommunityId is optional when the Initiating Gateway sends a document. If the value is included, it must match the value that is provided in the simulated environment with one or more Responding Gateways, corresponding to one or more communities.

mimeType: The value for mimeType is deterministic. In the context of this QHIN Conformance Testing Process:

| mimeType | Trigger Rules |
|----------|---|
| text/xml | Required for all C-CDA 2.1 documents, including those with structured bodies and unstructured bodies (non XML). |

objectType: When submitting a document in the Message Delivery Scenario, the required value for objectType indicates a stable Document Entry:

urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1

serviceStartTime: Similar to creationTime, please use different values for different documents to demonstrate that your system is not hard coding values. There are no constraints on time range as you are documenting actual events/observations in patient history and not the time the document was created.

serviceStopTime: See comments for serviceStartTime. The value for serviceStopTime must be on or after the value for serviceStartTime.

typeCode: The value for typeCode depends on the document that is submitted and is not always deterministic. See the table below. Recommendations for typeCode values are found in this document:

https://s3.amazonaws.com/ceq-project/wp-content/uploads/2019/04/11013830/20190201_Improve_C-CDA_Joint_Content_WG_IHE_v1.1_Final.pdf

| C-CDA 2.1 Document | Values / Notes |
|-----------------------|---|
| CCD | Fixed: 34133-9 (2.16.840.1.113883.6.1) |
| Progress Note | The preferred LOINC document type code is 11506-3, Provider-unspecified Progress note, although systems may send more specific codes from the ProgressNoteDocumentTypeCode urn:oid:2.16.840.1.113883.11.20.8.1 value set. |
| Discharge Summary | The preferred LOINC document type code is 18842-5, Discharge Summary note, although systems may send more specific codes from the DischargeSummaryDocumentTypeCode value set urn:oid:2.16.840.1.113883.11.20.4.1. |
| Unstructured Document | Can be any value from the typeCode Value Set |

7.2 Submission Set Metadata – Message Delivery

| Metadata Attribute | Optionality (Initiating Gateway) | Testing Notes |
|--------------------|----------------------------------|---------------|
| author | R2 | |
| availabilityStatus | O | |
| comments | O | |
| contentTypeCode | R | |
| entryUUID | R | |
| homeCommunityId | O | |
| intendedRecipient | R2 | |
| limitedMetadata | X | |
| patientId | R | |
| sourceId | R | |
| submissionTime | R | |
| title | O | |
| uniqueId | R | |