**Integrating the Healthcare Enterprise**



**IHE PCC**

**Technical Framework Supplement**

**Assessment Curation and Data Collection (ACDC)**

HL7® FHIR® STU 4

Using Resources at FMM Levels 3

**Rev. 1.0 – Draft for Public Comment**

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**Please verify you have the most recent version of this document.** See [here](http://ihe.net/Technical_Frameworks/) for Trial Implementation and Final Text versions and [here](http://ihe.net/Public_Comment/) for Public Comment versions.

**Foreword**

This is a supplement to the IHE Patient Care Coordination Technical Framework V11.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on April 27, 2019 for public comment. Comments are invited and can be submitted at [http://www.ihe.net/PCC\_Public\_Comments](http://www.ihe.net/PCC_Public_Comments/). In order to be considered in development of the trial implementation version of the supplement, comments must be received by June 25, 2019.

This supplement describes changes to the existing technical framework documents.

“Boxed” instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text bold underline. Where the amendment removes text, make the removed text bold strikethrough. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

General information about IHE can be found at [http://ihe.net](http://ihe.net/).

Information about the IHE Patient Care Coordination domain can be found at [http://ihe.net/IHE\_Domains](http://ihe.net/IHE_Domains/).

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at [http://ihe.net/IHE\_Process](http://ihe.net/IHE_Process/) and [http://ihe.net/Profiles](http://ihe.net/Profiles/).

The current version of the IHE Patient Care Coordination Technical Framework can be found at [http://ihe.net/Technical\_Frameworks](http://ihe.net/Technical_Frameworks/).

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# Introduction to this Supplement

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE committee determines that an emerging standard offers significant benefits for the use cases it is attempting to address and has a high likelihood of industry adoption, it may develop IHE profiles and related specifications based on such a standard.  The IHE committee will take care to update and republish the IHE profile in question as the underlying standard evolves. Updates to the profile or its underlying standards may necessitate changes to product implementations and site deployments for them to remain interoperable and conformant with the profile in question.  This Technical Framework Supplement uses the emerging HL7®[[1]](#footnote-1) FHIR®[[2]](#footnote-2) specification. The FHIR release profiled in this supplement is R4. HL7 describes the STU (Standard for Trial Use) standardization state at [https://www.hl7.org/fhir/versions.html.](https://www.hl7.org/fhir/versions.html)  In addition, HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through 5 (normative ballot ready).The FHIR Maturity Model is described at [http://hl7.org/fhir/versions.html#maturity.](http://hl7.org/fhir/versions.html#maturity)  Key FHIR Release 4 content, such as Resources or ValueSets, used in this profile, and their FMM levels are on April 27th, 2019:   |  |  | | --- | --- | | FHIR Resource Name | FMM Level | | Questionnaire | 3 | | QuestionnaireResponse | 3 | |

The Assessment Curation and Data Collection (ACDC) profile supports the selection of assessment instruments from a repository and the integration of those instruments into a provider workflow for the capture of assessment data for a given patient.

## Open Issues and Questions

1. Should PCC-X1 and PCC-X2 be collapsed into a single transaction that can be used for multiple purposes (finding a resource and acquiring it)? The reason for separating them at this time is that PCC-X2 contains the assessment IP, which may require licensing of the content, and we felt that it was appropriate to keep this as a separate transaction. However, we seek feedback from assessment implementors on whether there are other ways this could be addressed to simplify this profile.
2. We seek feedback on storage of assessment content (see section X.4.1.1) and use of the FHIR create operation in PCC-X3 to “return” the results of the assessment instrument. Are these mechanisms acceptable to implementers?
3. The IHE QRPH Structured Data Capture (SDC) profile addresses the definition of forms that can be used to fill out questionnaires, typically for collecting data for registries. This profile overlaps with that one. We seek feedback on how we should address this overlap.

## Closed Issues

1. Is assessment an option, in that it describes the type of resource returned from the knowledge repository? This anticipates retrieval of other definitional artifacts (i.e., care plan definition) from the clinical knowledge resource repository.  
     
   For now, assessment isn’t an option of this profile, though we might make it one in the future to support access to other definitional resources (e.g., CarePlanDefinition).
2. How should we address authentication / authorization to a) access the repository, and obtain a resource for implementation? Ideally this would allow for use of bearer tokens after authorization to enable repositories to be compatible with SMART on FHIR (SoF). Considerations: Questionnaires are not patient specific resources, so patient/Questionnaire.read is NOT a useful scope. It should be user/Questionnaire.read. What scope would distinguish between search and acquire permissions? Is that outside of the scope of this profile? That would only be a minor challenge, I think b/c user access controls could enforce user capabilities.  
     
   The profile will require user authentication/authorization but will not specify details.
3. How do we handle provenance for QuestionnaireResponse resources? Is that the responsibility of the assessor or the assessment requestor? It would seem to be the responsibility of the latter, b/c we do not actually say what is done with the responses. They could be persisted, or they could be stored as individual observation resources, et cetera, it’s up to the requestor to determine what to do with the data and how to associate it with provenance.  
     
   Provenance is challenging b/c the Assessor actor is requesting the creation of the resource, and the AssessmentRequestor is responsible for creating/storing it. Often, the information system responsible for storage manages provenance and audit resources, preventing clients from being able to create Provenance resources. However, HL7 has defined an extension on the QuestionnaireResponse resource which enables the Assessor to provide a digital signature of the response, enabling validation of the integrity of the assessment content, and so we need not say anything about Provenance resources, but should discuss the signature extension.
4. Do we want repositories to be able to implement assessment logic for an instrument and return the QuestionnaireResponse? In this case, how is the interaction triggered? Yes, this case needs to be supported for some Clinical Knowledge Resource Repositories. We have provided an option and a Clinical Knowledge Resource Repositories to reflect the use of a grouped Assessor.
5. Should there be an option for EHR Launch/Standalone Launch? I think yes, b/c there are some cases where assessment instruments can be executed using separate hardware (i.e., an iPad) that may need to “log in” to the EHR and be assigned to a given patient being seen, whereas there may be other cases where the EHR may simply launch a web page somewhere (in a similar scenario, the EHR application is running in a browser on the iPad and does the launch in its own UI).

We have defined an EHR Launch option which defines the launch parameter identifying the assessment to be performed.

1. ATNA requirements. Questionnaires are not PHI, but they are IP. Do we need to protect transactions using Questionnaire with ATNA? Do we require, or simply recommend ATNA? I think we adopt RESTful ATNA related requirements re: Authentication, encryption and logging, but do not require ATNA completely b/c FHIR already has Audit Event, which is based on ATNA, and we are using SoF standalone and EHR Launch, which enforces encryption and authentication requirements, so they only thing we need to add is a logging requirement.  
     
   Per joint meeting, we have referred to Section 8 of Appendix Z in the ITI Technical Framework.

# General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

# Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

|  |  |
| --- | --- |
| Actor | Definition |
| Clinical Knowledge Resource Repository | A Clinical Knowledge Resource Repository stores ~~documents~~ artifacts and metadata ~~providing~~ regarding computableclinical knowledge and enables access to that information to requesters ~~on demand~~. |
| Artifact Consumer | The artifact consumer is a user-oriented application component that allows an end user (e.g., clinician, informaticist, interface engineer, et cetera) to explore clinical knowledge resources available from a Clinical Knowledge Resource Repository. |
| Assessment Requestor | The assessment requestor is an application component that needs assessment data and can request the capture of assessment information from an assessor. |
| Assessor | An assessor is a user-oriented application that allows a clinician, patient or other party to answer the questions associated with an assessment instrument and obtain a completed response. |

# Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

***Query Artifact [PCC-X1]*** – this transaction uses RESTful API to query identity assessment instruments that meet certain criteria, e.g., by topic, coded concern, procedure, clinical area, et cetera, retrieving the metadata essential to enable the consumer to determine if it wants to know more about the assessment instrument.

The returned result would list the metadata associated with the various Questionnaire resources available but need not contain complete data on items in the instrument.

***Request* *Artifact* *[PCC-X2]* –** this transaction uses RESTful API to requests the complete details of an Assessment Instrument in order to implement it for evaluation or production use.

***Assess Patient [PCC-X3]* –** this this transaction uses RESTful API to execute the assessment and return a QuestionnaireResponse and any data resulting from the Questionnaire (e.g., ClinicalImpression).

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

No new terms added.

Volume 1 – Profiles

## Copyright Licenses

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

No new copyright licenses added.

Add new Section X

# X Assessment Curation and Data Collection (ACDC) Profile

The Assessment Curation and Data Collection (ACDC) supports the selection of assessment instruments from a repository and the integration of those instruments into a provider workflow for the capture of the assessment data.

## X.1 ACDC Actors, Transactions and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at <http://www.ihe.net/Technical_Framework/index.cfm>.

Figure X.1-1 shows the actors directly involved in the ACDC Profile and the relevant transaction between them.

**Clinical Knowledge Resource Repository**

**Assessment Requestor**

Query Artifact [PCC-X1] ↓  
Retrieve Artifact [PCC-X2] ↓

**Artifact Consumer**

**Assessor**

Assess Patient [PCC-X3] ↓

Figure X.1-1: ACDC Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the ACDC Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

Table X.1-1: ACDC Integration Profile - Actors and Transactions

|  |  |  |  |
| --- | --- | --- | --- |
| Actors | Transactions | Optionality | Reference |
| Clinical Knowledge Resource Repository | Query Artifact [PCC-X1] | R | PCC TF-2: 3.X1 |
| Retrieve Artifact [PCC-X2] | R | PCC TF-2: 3.X2 |
| Artifact Consumer | Query Artifact [PCC-X1] | R | PCC TF-2: 3.X1 |
| Retrieve Artifact [PCC-X2] | R | PCC TF-2: 3.X2 |
| Assessor | Assess Patient [PCC-X3] | R | PCC TF-2: 3.X3 |
| Assessment Requestor | Assess Patient [PCC-X3] | R | PCC TF-2: 3.X3 |

### X.1.1 Actor Descriptions and Actor Profile Requirements

#### X.1.1.1 Clinical Knowledge Resource Repository

The Clinical Knowledge Resource Repository in this profile responds to FHIR-based queries for one or more clinical knowledge artifacts.

1. Given that a Clinical Knowledge Resource Repository provides an assessment instrument that a healthcare provider can use to assess a given condition or health concern, it must provide a mechanism by which that assessment can be performed on a given patient. This can be implemented in one of three ways:
   1. The Clinical Knowledge Resource Repository implements the Questionnaire Item Retrieval option, which enables the healthcare provider’s Health IT system to execute the assessment instrument with the Assessor of its choice, or
   2. The Clinical Knowledge Resource Repository implements the Assessor option; it must be grouped with an Assessor that the healthcare provider’s Health IT system can use to execute the assessment instrument.
   3. The Clinical Knowledge Resource Repository implements the EHR Launch Option. It must also provide the Launch URL for the SMART on FHIR application that implements the accessor capabilities.

For each assessment instrument that can be accessed by a Clinical Knowledge Resource Repository, it must do at least one of the following:

1. Provide the Questionnaire.item fields that can be used to implement the assessment.
2. Provide at least one Launch URL for a SMART on FHIR application that performs the assessment.
3. Demonstrate that the Assessor actor it is grouped with can be configured to perform the specified assessment with an Assessment Requestor.

#### X.1.1.2 Artifact Consumer

The Artifact Consumer in this profile sends FHIR-based queries to the Clinical Knowledge Resource Repository to search for and obtain one or more clinical knowledge artifacts. Rendering and further processing of these artifacts is defined by the Assessor and Assessment Requestor in this profile.

1. Given that a user with appropriate permissions is operating the provider’s health IT system, when a new assessment instrument is needed, then the user can locate an appropriate assessment instrument, and configure that health IT system to use it to capture an assessment.
2. A healthcare provider’s health IT system must be able to support assessments from a Clinical Knowledge Resource Repository that implements the Questionnaire Retrieval Option.
3. A healthcare provider’s health IT system must be able to support assessments from a Clinical Knowledge Resource Repository that implements the Assessor Option.

#### X.1.1.3 Assessor

The Assessor in this profile performs an assessment and posts the results as a QuestionnaireResponse to the appropriate patient and encounter. It must populate the QuestionnaireResponse resource with the appropriate references to the subject, encounter, author and questionnaire resources. The subject, encounter, and author resources must be obtained from the current context of the Assessor actor. The questionnaire resource should be represented by the canonical url which uniquely identifies the assessment instrument.

#### X.1.1.4 Assessment Requestor

The Assessment Requestor in this profile requests an assessment of an assessor and processes results returned in a QuestionnaireResponse resource. It must accept an assessment as a QuestionnaireResponse resource from the Assessor actor.

## X.2 ACDC Actor Options

Options that may be selected for each actor in this profile, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: QEDm - Actors and Options

| Actor | Option Name | Reference |
| --- | --- | --- |
| Clinical Knowledge Resource Repository | Questionnaire Item Retrieval Option1 | PCC TF-X.2.1.1 |
| Assessor Option1 | PCC TF-X.2.1.2 |
| EHR Launch Option1 | PCC TF-X.2.1.3 |
| Artifact Consumer | None Defined | |
| Assessment Requestor | None Defined | |
| Assessor | EHR Launch Option | PCC TF-X.2.2 |

Note 1: At least one of these options shall be supported by the related actor

### X.2.1 Clinical Knowledge Resource Repository

#### X.2.1.1 Questionnaire Item Retrieval Option

A Clinical Knowledge Resource Repository that implements the Questionnaire Item Retrieval Option shall include the necessary information in Questionnaire.item fields in the returned Questionnaire resource to enable execution of the assessment instrument.

#### X.2.1.3 Assessor Option

A Clinical Knowledge Resource Repository that implements the Assessor Option shall be grouped with an Assessor actor that is able to perform the assessments it provides.

#### X.2.1.3 EHR Launch Option

A Clinical Knowledge Resource Repository that implements the EHR Launch Option shall include at least one launch-url extension in Questionnaire resources to tell the receiver how to launch a SMART on FHIR application that will implement the assessment. That assessor must implement the FHIR EHR Launch Option.

### X.2.2 Assessor EHR Launch Option

An Assessor that implements the EHR Launch option supports the SMART on FHIR EHR Launch protocol and allows specification of the canonical url of the Questionnaire resource in the def parameter of the launch url.

## X.3 ACDC Required Actor Groupings

Table X.3-1: ACDC - Required Actor Groupings

| ACDC Actor | Actor to be grouped with | Reference |
| --- | --- | --- |
| Assessment Requestor | Secure Node or Secure Application | PCC TF-X.6.3 |

## X.4 ACDC Overview

Assessments are the principle means by which numerous forms of data regarding physical function, mental/cognitive status, social determinants of health, and patient reported outcomes are collected. These are variously known as assessments, screening instruments, scales, scores, questionnaires

Many assessment instruments have been automated, but there are thousands of these instruments. HealthMeasures[[3]](#footnote-3) has nearly 750 measures, the Alcohol and Drug Abuse Institute at the University of Washington[[4]](#footnote-4) lists over 1031 screening instruments, and a search of PubMed[[5]](#footnote-5) results in nearly 26,000 articles on different instruments used for patient assessment.

In the US, more than a half dozen quality improvement or recognition programs require documenting or reporting specific information about patients that contain elements that can be obtained from health assessments[[6]](#footnote-6). These are shown in figure X.4-1 below.

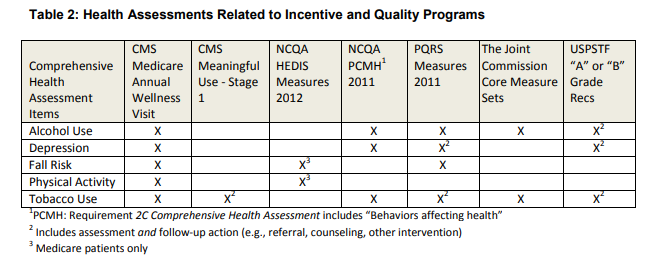


Figure X.4-1 Quality Related Assessments

Many of these instruments can be implemented using technology, as they are simple forms or questionnaires. Some data in these instruments might be automatically populated by the EHR system. However, because there are so many instruments, and so many providers of the instruments, it is challenging to integrate these instruments into provider workflows.

### X.4.1 Concepts

Assessment instruments are tools which enable clinicians to assess a patient’s clinical condition based on certain evaluations or observations performed with the patient. Evaluations may include the recording of clinical data that is captured by other means (e.g., measurement tools) or by simply answering questions based on the clinician or patient’s knowledge. The result is an assessment that will provide both the collected data and an assessment of what that means for the condition being assessed.

Assessments may be used for screening, diagnosis, treatment determination, or reporting of outcomes. Assessment instruments are used to gather data on a wide variety of clinical conditions. One well known example of an assessment instrument is the American College of Cardiology’s ASCVD Risk Estimator[[7]](#footnote-7). This instrument provides an estimation of a patients’ 10-year ASCVD risk. It appears in the figure below.

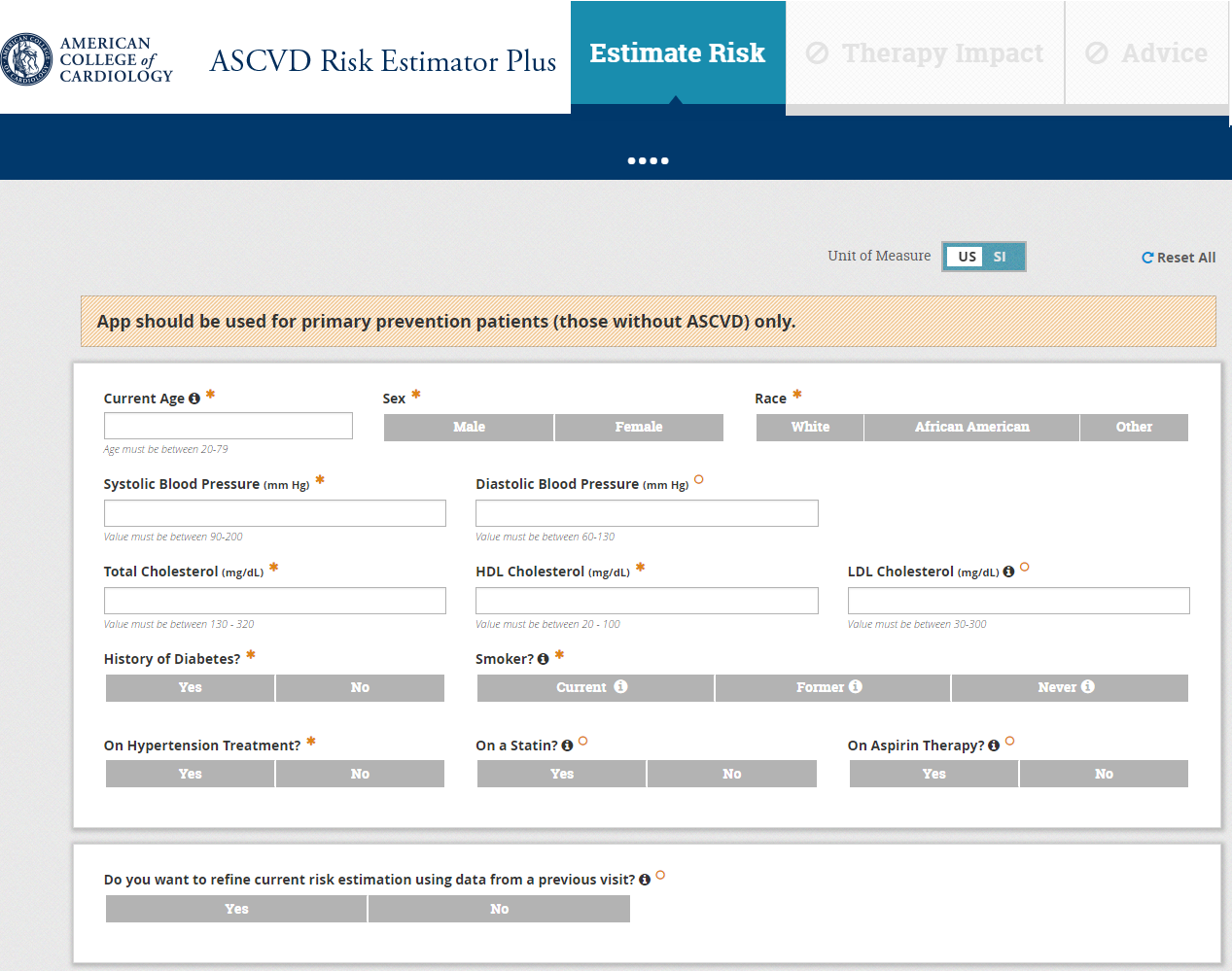


Figure X.4.1-1 An Assessment Instrument

Both the gathered data in the assessment and the resulting assessment can be used for later evaluation, either for clinical care or to support health research.

As a clinical tool used in the delivery of care, assessment instruments often go through evaluation and validation, and include training materials on how the assessment is to be performed[[8]](#footnote-8). Changes to the questions asked, or the possible responses allowed results in a different diagnostic instrument, which may or may not perform as well as the validated instrument. Therefore, developers of assessment instruments often accompany them with intellectual property controls that ensure they are implemented appropriately. Many assessment instruments were originally implemented as paper forms, but with the growth of the web, these are now often implemented as electronic forms. Because of the intellectual property controls, instrument developers may restrict online use to a validated implementation.

This results in a challenge for healthcare providers because each instrument they choose to use may have different user interfaces, different initiation protocols and delivery mechanisms, and require different ways to be integrated into their electronic health record systems. The purpose of this profile is to provide a way for these instruments to be readily integrated into the EHR.

Because many of these instruments rely on data that is already known to the EHR, there is further value in enabling a connection between the EHR and the system delivering the assessment instrument content so that information that is already known to the EHR can be supplied to the assessment instrument delivery system.

In this profile, the assessment instrument is represented as a FHIR Questionnaire resource. The questionnaire resource is designed to support collection of data based on answers from end users and enables detailed control over presentation of the instrument. The responses to the assessment instrument are represented in the FHIR QuestionnaireResponse resource. This resource provides the list of questions, answers and additional data (e.g., assessments, scores, et cetera) determined from the answers to the questions.

The figure below illustrates the abstract implementation model for working with assessments for patient reported outcomes[[9]](#footnote-9) as published in the HL7 FHIR Patient Reported Outcomes Implementation Guide. While this model was developed for patient reported outcome assessments, it can be applied to other forms of assessment as well.

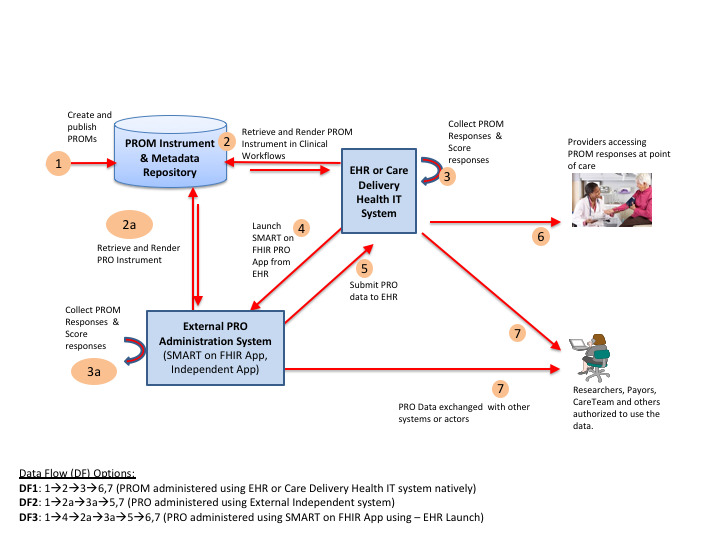


Figure X.4.1-2 Abstract Model for Basic Questionnaires

The ACDC profile focuses on steps 2 through 5 of the model and implements these steps using four different actors. The first use case in this profile, corresponding to step 2 in the diagram above, is to identify the assessment instrument that the healthcare provider wants to integrate into their workflow. The PROM Instrument and Metadata repository in this diagram would support instrument retrieval by implementing the Clinical Knowledge Resource Repository Actor. The External PRO Administration System or EHR or Care Delivery Health IT system could then retrieve instruments by implementing the Artifact Consumer actor. This enables the assessment instrument to be selected by the healthcare provider.

The second use case in this profile addresses steps 3 through 5 in Figure X.4.1-1, which is the execution of the assessment instrument.

#### X.4.1.1 Use of Assessment Instrument Results

This profile makes no assumptions about how assessment results are used after they are returned to the Assessment Requestor application. The results may be stored in the provider’s health IT system, they may be used to produce other information that is stored in the patient’s chart, data may be extracted from the assessment to produce a care plan, they may be discussed with the patient, et cetera. There is no responsibility on the receiving system to persist or store the results or otherwise make them accessible for future use, they may simply be discarded after being produced and acted upon. There may be some requirements in the providers jurisdiction that requires that the data used in the assessment be persisted in some way, that is outside of the scope of this profile[[10]](#footnote-10).

This profile does require that the Assessment Requestor actor expose a FHIR endpoint that supports the QuestionnaireResponse create operation. That does not create a commitment on the Assessment Requestor actor to expose endpoints supporting the read or search operations. It is simply a convenience used to enable a stateless application to be launched and “return” results from its operations.

### X.4.2 Use Cases

#### X.4.2.1 Use Case #1: Finding an Assessment

##### X.4.2.1.1 Use Case #1 Description

In the first use case, a care provider organization is seeking information about assessment instruments to address a specified condition or health concern. Their goal is to identify instruments and eventually acquire instruments which could be used to capture information essential to management of the care of patients having that condition. Their EHR will be able to perform the assessment once it has been acquired.

##### X.4.2.1.2 Use Case #1 Process Flow

The Query Artifact transaction is used to request lists of one or more artifacts that match the users search criteria. The metadata for the artifacts matching the criteria is returned so that the user can further explore these artifacts to consider acquisition of them for use in their health information system.

After identifying an artifact for implementation, the user can either retrieve the full artifact so that it can be implemented in their health information system, or a link to where it has been externally implemented so that they integrated it the collected data into their system, which is described in more detail in **X.4.2.2 Use Case #2 Executing the Assessment Instrument**.

Query Artifact   
Request [PCC-X1]

Clinical Knowledge Resource Repository

Artifact Consumer

Query Artifact

Response [PCC-X1]

Retrieve Artifact   
Request [PCC-X2]

Retrieve Artifact

Response [PCC-X2]

Figure X.4.2.1-1: Use Case #1 Process Flow in ACDC Profile

#### X.4.2.2 Use Case #2: Executing the Assessment Instrument

##### X.4.2.2.1 Use Case #2 Description

In the second use case, the care provider organization wants to assess a patient using the retrieved or identified assessment in their health IT system and be able to collect the results of this assessment for a given patient. This process may be initiated through the user’s EHR, a separate application or device, a patient portal, et cetera.

In this use case, there are several possible ways the assessment data can be collected.

1. The provider’s Health IT system can invoke a separate application that can interpret the assessment instrument and collect data on the patient, returning it to the health IT solution.
2. A separate application can be launched which integrates with the provider’s Health IT system. The application determines which assessment is to be performed, for which patient and which encounter, and then collects the data and return the EHR attached to the correct patient and encounter.
3. The provider’s Health IT system can initiate data capture on its own forms, using the data describing the assessment instrument. To implement this option, the health IT system needs to correctly interpret instrument description, collect the data and do what it deems necessary with the data that was collected (e.g., create observations or other resources, store a questionnaire response, et cetera). Because this case can be completely managed by the provider’s Health IT system when the questionnaire items are provided, it is not addressed within this profile.

During the execution of this use case, the software performing the assessment may wish to collect data already known about the patient that is stored in the health IT system that will receive the assessment results.

##### X.4.2.2.2 Use Case #2 Process Flows

In this use case, the first step is to associate the assessment instrument with a context available in the health IT system (shown below as the Assessment Requestor) that will receive the assessment results. The context at a minimum establishes the subject of the assessment: the patient being assessed, and the user information that might be associated with any provenance for the assessment. The context might also include the provider requesting the assessment, and the encounter in which the assessment is performed.

The next step performs the assessment. During this step, the assessor may also collect data from the receiving health IT system to facilitate completion of the assessment.

Upon completion of the assessment, the assessor records the results of the assessment in a QuestionnaireResponse resource stored by the Assessment Requestor actor. For this to be possible, the software performing the assessment will need to make a connection to the user’s health IT system in order to perform queries (e.g., using QEDm or PDQm or other methods).

Assess Patient Request  
[PCC-X3]

Message 1

Assessor

Assessment Requestor

Assess Patient Response  
[PCC-X3]

Message 1

Figure X.4.2.2-1: Use Case #2 Process Flow in ACDC Profile

## X.5 ACDC Security Considerations

See ITI TF-2.x Appendix Z.8 “Mobile Security Considerations” for general background on “Mobile” security considerations, and recommendations regarding security.

The ACDC profile provides an API for accessing data element level details that are identifiable to a specific patient. All the data communicated, including the query parameters, should be considered patient identifiable information (PII). Assessments may also include information protected about other individuals and should be considered individually identifiable information (III). The grouping with IUA, or some similar user authentication and authorization solution, is critical for enforcing privacy and security requirements. All accesses to this data should be recorded as audit log for security surveillance and privacy reporting. These topics are discussed in Appendix Z.8 with recommendations.

Some data being exchanged in this profile represent the execution of an assessment, a validated instrument, for a patient. The data in this can affect decision treatments, and so may need additional protection against data integrity and data authenticity risks. To mitigate data integrity and data authenticity risks, the Assessor may include a questionnaireresponse-signature[[11]](#footnote-11) extension on the QuestionnaireResponse, or on selected QuestionnaireResponse.item elements.

Assessment instruments are intellectual property which owners may wish to protect in various ways, e.g., licensing agreements, copyright restrictions, et cetera. As such the content of the assessment instrument should be encrypted during exchange. Accessors of assessment instruments may need to authenticate themselves in some way before being able to access assessment instruments. Access to specific assessment instrument content that may be implemented by a user can have financial or contractual ramifications for that user (e.g., incur charges), and should therefore be logged by both the owner and receiver of the content.

A Health IT system that is configured to support a new assessment instrument has had a significant change in functionality that should be logged.

This profile makes use of the SMART on FHIR EHR Launch protocol, and some implementations may also use the SMART on FHIR Standalone Launch protocol. Use of these protocols relies on OAuth2, HTTPS and TLS communications, ensuring authentication, authorization and encryption during exchanges involving PHI or III.

## X.6 ACDC Cross Profile Considerations

### X.6.1 PCC QEDm – Query for Existing Data for Mobile

An Assessor may be grouped with a Clinical Data Consumer actor from the QEDm profile to enable it to access data from the requesting system. This grouping enables data that is already known to the requesting system to be accessed.

Given that an Assessor is grouped with the Clinical Data Consumer actor, when the authorization process is performed, the Assessor shall negotiate for the additional scopes that it desires access to via the Clinical Data Consumer actor in order to perform the assessment. The Assessor Actor shall not require the Assessment Requestor to implement the Clinical Data Source Actor and must be able to perform normally if it does not support some of the additional requested scopes or resources.

The Assessment Requestor may be grouped with a Clinical Data Source actor from the QEDm profile to enable it to respond to requests for data access from the requesting system. This grouping enables data that is already known to the requesting system to be accessed during the assessment process. Given the Assessment Requestor Actor is grouped with a Clinical Data Source from the QEDm profile, when the Assessor requests additional scopes to access clinical data, the Assessment Request shall respond with the scopes appropriate for the clinical data options that it supports.

### X.6.2 ITI PDQm – Patient Demographics Query for Mobile

An Assessor may be grouped with a Patient Demographics Consumer actor from the PDQm profile to enable it to access data about the patient from the requesting system. This grouping enables demographics data that is already known to the requesting system to be accessed.

Given that an Assessor is grouped with the Patient Demographics Consumer actor, when the authorization process is performed, the Assessor shall negotiate for the additional scopes that it desires access to via the Patient Demographics Consumer actor in order to perform the assessment. The Assessor Actor shall not require the Assessment Requestor to implement the Patient Demographics Supplier Actor and must be able to perform normally if the Assessment Requestor does not support some of the additional requested scopes or resources.

The Assessment Requestor may be grouped with a Patient Demographics Supplier actor from the PDQm profile to enable it to respond to requests for patient demographic data from the requesting system. This grouping enables data that is already known to the requesting system to be accessed during the assessment process. Given the Assessment Requestor Actor is grouped with a Patient Demographics Supplier actor from the PDQm profile, when the Assessor requests additional scopes to access patient demographics, the Assessment Requestor shall respond with the scopes appropriate for the patient demographics that it supports.

### X.6.3 ITI ATNA – Audit Trail and Node Authentication

The Assessment Requestor actor in this profile must be grouped with a Secure Node or Secure Application actor. All other actors in this profile may be grouped with the Secure Node or Secure Application actors. The Assessor actor should be grouped with the Secure Node or Secure Application actor. The Clinical Knowledge Resource Repository and Artifact Consumer actors may also be grouped with the Secure Node or Secure Application actors.

Volume 2 – Transactions

Add Section 3.X1

## 3.X1 Query Artifact [PCC-X1]

This section corresponds to Transaction PCC-X1 of the IHE PCC Technical Framework. Transaction PCC-X1 is used by the Clinical Knowledge Resource Repository and Artifact Consumer Actors.

### 3.X1.1 Scope

The Query Artifact transaction is used to query for assessment instruments in Questionnaires that satisfy a set of parameters by using the FHIR framework. The result of the query is a FHIR Bundle containing FHIR clinical data Resources that match the query parameters.

The ACDC Profile assumes that categories and codes referenced by these FHIR Resources need to be defined at the time of deployment. The specification of these FHIR Resources make recommendations on categories and codes, that should be considered.

### 3.X1.2 Actor Roles

Clinical Knowledge Resource Repository

Artifact Consumer

Figure 3.X1.2-1: Use Case Diagram

Table 3.X1.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | Artifact Consumer |
| **Role:** | Queries the Clinical Knowledge Resource Repository for assessment instrument content requested by the Artifact Consumer. |
| **Actor:** | Clinical Knowledge Resource Repository |
| **Role:** | Responds to query, supplying the FHIR Questionnaire Resources representing the assessment instrument content that match the search criteria provided by the Artifact Consumer. |

### 3.X1.3 Referenced Standards

|  |  |
| --- | --- |
| HL7 FHIR | HL7® FHIR® standard R4: <http://www.hl7.org/fhir/R4/index.html> |
| IETF RFC 2616 | Hypertext Transfer Protocol – HTTP/1.1 |
| IETF RFC 7540 | Hypertext Transfer Protocol – HTTP/2 |
| IETF RFC 3986 | Uniform Resource Identifier (URI): Generic Syntax |
| IETF RFC 4627 | The application/json Media Type for JavaScript Object Notation (JSON) |
| IETF RFC 6585 | Additional HTTP Status Codes |

### 3.X1.4 Interaction Diagram

Query Artifact Request

Clinical Knowledge Resource Repository

Artifact Consumer

Query Artifact Response

Message 1

#### 3.X1.4.1 Query Artifact Request message

This message uses the HTTP GET method parameterized query to retrieve FHIR Questionnaire Resources representing assessment instruments matching search parameters in the GET request. This transaction performs a FHIR search request on Questionnaire resources.

ACDC does not mandate any additional extended or custom method.

##### 3.X1.4.1.1 Trigger Events

When the Artifact Consumer needs to discover Questionnaire Resources matching various search parameters it issues a Query Artifact message.

##### 3.X1.4.1.2 Message Semantics

The Artifact Consumer executes an HTTP GET against the proper Clinical Knowledge Resource Repository’s ACDC URL.

The search target follows the FHIR http specification ([http://hl7.org/fhir/R4/http.html](http://hl7.org/fhir/STU3/http.html)), addressing the proper FHIR Resource type, according to the supported query options (see Section 3.X1.4.1.2.1). The syntax of the FHIR query is:

GET [base]/Questionnaire?summary=true&{[parameters]}

with the following constraints:

* The [base] represents the Service Base URL
* The [parameters] represents a series of encoded name-value pairs representing the filter for the query, as specified in Section 3.X1.4.1.2.1, as well as control parameters to modify the behavior of the Clinical Knowledge Resource Repository such as response format, or pagination. See ITI TF-2x: Appendix Z.6 for more details on response format.

The Questionnaire resources returned by this transaction shall conform to FHIR requirements associated with the IHE and need only include fields in the Questionnaire resource marked as being for summaries.

###### 3.X1.4.1.2.1 Query Search Parameters

All query parameter values shall be appropriately encoded per RFC 3986 “percent” encoding rules. Note that percent encoding does restrict the character set to a subset of ASCII characters which is used for encoding all other characters used in the URL.

The Clinical Knowledge Resource Repository must support any combination of the following parameters:

* code (token)
* At least one of context (token), context-quantity (quantity), context-type (token), context-type-quantity (composite), context-type-value (composite)
* date (date)
* description (string)
* name (string)
* publisher (string)
* status (token)

The Clinical Knowledge Resource Repository may choose to support additional query parameters beyond the subset defined by the profiling listed below, if done according to the core FHIR specification. Such additional parameters are considered out of scope for this transaction. The Clinical Knowledge Resource Repository may ignore any additional parameter not specified in this transaction. See [http://hl7.org/fhir/R4/search.html#errors](http://hl7.org/fhir/STU3/search.html#errors).

###### 3.X1.4.1.2.2 Populating Expected Response Format

The FHIR standard provides encodings for responses as either XML or JSON. The Clinical Knowledge Resource Repository shall support both message encodings, whilst the Artifact Consumer shall support one and may support both.

See ITI TF-2x: Appendix Z.6 for details.

##### 3.X1.4.1.3 Expected Actions

The Clinical Knowledge Resource Repository shall process the query to discover Questionnaire FHIR Resource entries (the assessment instruments) that match the search parameters given and shall use a FHIR Bundle resource to collect the matching entries to be returned.

The Clinical Knowledge Resource Repository shall respond with a Mobile Artifact Query Response synchronously (i.e., on the same connection as was used to initiate the request).

See ITI TF-2x: Appendix Z.6 for more details on response format handling. See ITI TF-2x: Appendix Z.7 for handling guidance for Access Denied.

#### 3.X1.4.2 Query Artifact Response message

The Clinical Knowledge Resource Repository returns an HTTP Status code appropriate to the processing as well as a list of the matching clinical data FHIR Resources.

##### 3.X1.4.2.1 Trigger Events

The Clinical Knowledge Resource Repository completed processing of the Query Artifact Request message.

##### 3.X1.4.2.2 Message Semantics

Based on the query results, the Clinical Knowledge Resource Repository will either return an error or success. The guidance on handling Access Denied related to use of 200, 403 and 404 can be found in ITI TF-2x: Appendix Z.7 (reproduced here for readability).

When the Clinical Knowledge Resource Repository needs to report an error, it shall use HTTP error response codes and should include a FHIR OperationOutcome with more details on the failure. See FHIR [http://hl7.org/fhir/R4/http.html](http://hl7.org/fhir/STU3/http.html) and [http://hl7.org/fhir/R4/operationoutcome.html](http://hl7.org/fhir/STU3/operationoutcome.html).

If the Query Artifact request message is processed successfully, whether or not Questionnaire Resources are found, the HTTP status code shall be 200.   
The Query Artifact Response message shall be a FHIR Bundle Resource containing zero or more Questionnaire resources. If the Clinical Knowledge Resource Repository is sending warnings, the Bundle Resource shall also contain an OperationOutcome Resource that contains those warnings.

The response shall adhere to the FHIR Bundle constraints specified in ITI TF-2x: Appendix Z.1.

###### 3.X1.4.2.2.2 Resource Bundling

Resource Bundling shall comply with the guidelines in ITI TF-2x: Appendix Z.1.

The Clinical Knowledge Resource Repository shall include all resources to be returned as a contained resource. This means that the query shall return resource data contained in the FHIR Bundle as entries.

##### 3.X1.4.2.3 Expected Actions

The Artifact Consumer Actor processes the bundle of resources, received in Transaction PCC-X1 according to the capabilities of its application. These capabilities are not specified by IHE.

If an Artifact Consumer cannot automatically recover from an error condition, it should offer a means to make the error accessible to the query initiator (e.g. user, system).

#### 3.X1.4.3 Capability Statement Resource

Clinical Knowledge Resource Repositories implementing this transaction should provide a CapabilityStatement Resource as described in ITI TF-2x: Appendix Z.3 indicating the query operation for the Resources have been implemented and shall include all the supported query parameters.

### 3.X1.5 Security Considerations

The retrieved content contains IP that shall be protected. See the general Security Considerations in PCC TF-1: X.5.

#### 3.X1.5.1 Security Audit Considerations

Grouping a Clinical Knowledge Resource Repository with an ATNA Secure Node or Secure Application is recommended. Grouping an Artifact Consumer with an ATNA Secure Node or Secure Application is recommended.

The Artifact Consumer may be considered overburdened to fully implement the requirements of a Secure Node or Secure Application. The Clinical Knowledge Resource Repository is likely a more robust application and should generate audit messages.

When grouped with the Secure Node or Secure Application actor, both actors generate a ”Query” Audit Message, which is consistent with ATNA. The Query Artifact [PCC-X1] is a Query Information event as defined in Table ITI TF-2:3.20.4.1.1.1-1. The message shall comply with the following pattern:

* Event
* EventID = EV(110112, DCM, “Query”)
* EventTypeCode = EV(“PCC-X1”, “IHE Transactions”, “Query Artifact”)
* EventActionCode = “E” (Execute)
* Source of the request (1..1)
* UserID = The Artifact Consumer actor system identity
* RoleIDCode = EV(110153, DCM, “Source”)
* Human Requestor (0..n)  one for each know User
* UserID = Identity of the human that initiated the transaction.
* RoleIDCode = Access Control role(s) the user holds that allows this transaction
* Destination of the request (1..1)
* Clinical Knowledge Resource Repository actor system identity
* RoleIDCode = EV(110152, DCM, “Destination”)
* Audit Source (1..1)
* not specified
* Query Parameters (1..1)
* ParticipantObjectTypeCode = “2” (system object)
* ParticipantObjectTypeCode Role = “24” (query)
* ParticipantObjectIDTypeCode = EV(“PCC-X1”, “IHE Transactions”, “Query Artifact”)
* ParticipantObjectQuery = Requested URL including query parameters, base64 encoded
* ParticipantObjectDetail = HTTP Request Headers contained in the query (e.g., Accept header)

Add Section 3.X2

## 3.X2 Retrieve Artifact [PCC-X2]

This section corresponds to Transaction PCC-X2 of the IHE PCC Technical Framework. Transaction PCC-X2 is used by the Clinical Knowledge Resource Repository and Artifact Consumer Actors.

### 3.X2.1 Scope

The Retrieve Artifact transaction is used to query for assessment instruments in Questionnaires that satisfy a set of parameters by using the FHIR framework. The result of the query is a FHIR Bundle containing FHIR Questionnaire Resources that match the query parameters.

The ACDC Profile assumes that the URIs used by the Questionnaire Resources have been defined at the time of deployment.

### 3.X2.2 Actor Roles

Clinical Knowledge Resource Repository

Artifact Consumer

Figure 3.X2.2-1: Use Case Diagram

Table 3.X2.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | Artifact Consumer |
| **Role:** | Requests the Clinical Knowledge Resource Repository for assessment instrument content identified by the Artifact Consumer. |
| **Actor:** | Clinical Knowledge Resource Repository |
| **Role:** | Responds to request, supplying the identified FHIR Questionnaire Resources representing the assessment instrument content that match the search criteria provided by the Artifact Consumer. |

### 3.X2.3 Referenced Standards

|  |  |
| --- | --- |
| HL7 FHIR | HL7® FHIR® standard R4: <http://www.hl7.org/fhir/R4/index.html> |
| IETF RFC 2616 | Hypertext Transfer Protocol – HTTP/1.1 |
| IETF RFC 7540 | Hypertext Transfer Protocol – HTTP/2 |
| IETF RFC 3986 | Uniform Resource Identifier (URI): Generic Syntax |
| IETF RFC 4627 | The application/json Media Type for JavaScript Object Notation (JSON) |
| IETF RFC 6585 | Additional HTTP Status Codes |

### 3.X2.4 Interaction Diagram

Query Artifact Request

Clinical Knowledge Resource Repository

Artifact Consumer

Query Artifact Response

#### 3.X2.4.1 Retrieve Artifact Request message

This message uses the HTTP GET method parameterized query to retrieve FHIR Questionnaire Resources representing assessment instruments matching search parameters in the GET request. This transaction performs a FHIR search request on Questionnaire resources.

ACDC does not mandate any additional extended or custom method.

##### 3.X2.4.1.1 Trigger Events

When the Artifact Consumer needs to access a Questionnaire Resources matching the canonical url of a Questionnaire it issues a Retrieve Artifact message.

##### 3.X2.4.1.2 Message Semantics

The Artifact Consumer executes an HTTP GET against the proper Clinical Knowledge Resource Repository’s ACDC URL.

The search target follows the FHIR http specification ([http://hl7.org/fhir/R4/http.html](http://hl7.org/fhir/STU3/http.html)), addressing the proper FHIR Resource type, according to the supported query options (see Section 3.X2.4.1.2.1). The syntax of the FHIR query is:

GET [base]/Questionnaire?{[parameters]}

with the following constraints:

* The [base] represents the Service Base URL
* The [parameters] represents a series of encoded name-value pairs representing the filter for the query, as specified in Section 3.X2.4.1.2.1, as well as control parameters to modify the behavior of the Clinical Knowledge Resource Repository such as response format, or pagination. See ITI TF-2x: Appendix Z.6 for more details on response format.

###### 3.X2.4.1.2.1 Query Search Parameters

All query parameter values shall be appropriately encoded per RFC 3986 “percent” encoding rules. Note that percent encoding does restrict the character set to a subset of ASCII characters which is used for encoding all other characters used in the URL.

The Clinical Knowledge Resource Repository must support the following parameters:

* url (uri)

The Clinical Knowledge Resource Repository may choose to support additional query parameters beyond the subset defined by the profiling listed above, if done according to the core FHIR specification. Such additional parameters are considered out of scope for this transaction. The Clinical Knowledge Resource Repository may ignore any additional parameter not specified in this transaction. See [http://hl7.org/fhir/R4/search.html#errors](http://hl7.org/fhir/STU3/search.html#errors).

###### 3.X2.4.1.2.2 Populating Expected Response Format

The FHIR standard provides encodings for responses as either XML or JSON. The Clinical Knowledge Resource Repository shall support both message encodings, whilst the Artifact Consumer shall support one and may support both.

See ITI TF-2x: Appendix Z.6 for details.

##### 3.X2.4.1.3 Expected Actions

The Clinical Knowledge Resource Repository shall process the query to discover Questionnaire FHIR Questionnaire Resource entries (the assessment instruments) that match the search parameters given and shall use a FHIR Bundle resource to collect the matching entries to be returned.

The Clinical Knowledge Resource Repository shall respond with a Retrieve Artifact Response synchronously (i.e., on the same connection as was used to initiate the request).

See ITI TF-2x: Appendix Z.6 for more details on response format handling. See ITI TF-2x: Appendix Z.7 for handling guidance for Access Denied.

#### 3.X2.4.2 Retrieve Artifact Response message

The Clinical Knowledge Resource Repository returns an HTTP Status code appropriate to the processing as well as a list of the matching clinical data FHIR Resources.

##### 3.X2.4.2.1 Trigger Events

The Clinical Knowledge Resource Repository completed processing of the Retrieve Artifact Request message.

##### 3.X2.4.2.2 Message Semantics

Based on the query results, the Clinical Knowledge Resource Repository will either return an error or success. The guidance on handling Access Denied related to use of 200, 403 and 404 can be found in ITI TF-2x: Appendix Z.7 (reproduced here for readability).

When the Clinical Knowledge Resource Repository needs to report an error, it shall use HTTP error response codes and should include a FHIR OperationOutcome with more details on the failure. See FHIR [http://hl7.org/fhir/R4/http.html](http://hl7.org/fhir/STU3/http.html) and [http://hl7.org/fhir/R4/operationoutcome.html](http://hl7.org/fhir/STU3/operationoutcome.html).

In particular, if a Clinical Knowledge Resource Repository Actor receives a Artifact Query transaction for a resource related to a ACDC Option not supported, it shall return an operationoutcome.issue.code valued as: ‘not-supported’ and a an operationoutcome.issue.details valued as: MSG\_NO\_MATCH No Resource found matching the query "%s"

If the Retrieve Artifact request message is processed successfully, whether or not Questionnaire Resources are found, the HTTP status code shall be 200.   
The Retrieve Artifact Response message shall be a FHIR Bundle Resource containing zero or more Questionnaire Resources. If the Clinical Knowledge Resource Repository is sending warnings, the Bundle Resource shall also contain an OperationOutcome Resource that contains those warnings.

The response shall adhere to the FHIR Bundle constraints specified in ITI TF-2x: Appendix Z.1.

###### 3.X2.4.2.2.2 Resource Bundling

Resource Bundling shall comply with the guidelines in ITI TF-2x: Appendix Z.1.

The Clinical Knowledge Resource Repository shall include all resources to be returned as a contained resource. This means that the query shall return resource data contained in the FHIR Bundle as entries.

##### 3.X2.4.2.3 Expected Actions

The Artifact Consumer Actor processes the bundle of resources, received in Transaction PCC-X2 according to the capabilities of its application. These capabilities are not specified by IHE.

If an Artifact Consumer cannot automatically recover from an error condition, it should offer a means to make the error accessible to the query initiator (e.g. user, system).

#### 3.X2.4.3 Conformance Resource

Clinical Knowledge Resource Repositories implementing this transaction should provide a Conformance Resource as described in ITI TF-2x: Appendix Z.3 indicating the query operation for the Resources have been implemented and shall include all the supported query parameters.

### 3.X2.5 Security Considerations

The retrieved content contains IP that shall be protected.

See the general Security Considerations in PCC TF-1: X.5.

#### 3.X2.5.1 Security Audit Considerations

Grouping a Clinical Knowledge Resource Repository with an ATNA Secure Node or Secure Application is recommended. Grouping an Artifact Consumer with an ATNA Secure Node or Secure Application is recommended.

The Artifact Consumer may be considered overburdened to fully implement the requirements of a Secure Node or Secure Application. The Clinical Knowledge Resource Repository is likely a more robust application and should generate audit messages.

Both actors generate a ”Query” Audit Message, which is consistent with ATNA. The Retrieve Artifact [PCC-X2] is a Query Information event as defined in Table ITI TF-2:3.20.4.1.1.1-1. The message shall comply with the following pattern:

* Event
* EventID = EV(110112, DCM, “Query”)
* EventTypeCode = EV(“PCC-X2”, “IHE Transactions”, “Retrieve Artifact”)
* EventActionCode = “E” (Execute)
* Source of the request (1..1)
* UserID = The Artifact Consumer actor system identity
* RoleIDCode = EV(110153, DCM, “Source”)
* Human Requestor (0..n)  one for each know User
* UserID = Identity of the human that initiated the transaction.
* RoleIDCode = Access Control role(s) the user holds that allows this transaction
* Destination of the request (1..1)
* Clinical Knowledge Resource Repository actor system identity
* RoleIDCode = EV(110152, DCM, “Destination”)
* Audit Source (1..1)
* not specified
* Query Parameters (1..1)
* ParticipantObjectTypeCode = “2” (system object)
* ParticipantObjectTypeCode Role = “24” (query)
* ParticipantObjectIDTypeCode = EV(“PCC-X2”, “IHE Transactions”, “Retrieve Artifact”)
* ParticipantObjectQuery = Requested URL including query parameters, base64 encoded
* ParticipantObjectDetail = HTTP Request Headers contained in the query (e.g., Accept header)

Add Section 3.X3

## 3.X3 Assess Patient [PCC-X3]

This section corresponds to Transaction PCC-X3 of the IHE PCC Technical Framework. Transaction PCC-X3 is used by the Assessment Requestor, Assessor and Artifact Consumer Actors.

### 3.X3.1 Scope

The Assess Patient transaction is used to perform the assessment defined in a Questionnaire resource. The result of this transaction is a FHIR QuestionnaireResponse Resource that contains the results of the assessment.

### 3.X3.2 Actor Roles

Assessment Requestor

Assessor

Figure 3.X3.2-1: Use Case Diagram

Table 3.X3.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | Assessment Requestor |
| **Role:** | Requests an assessment be performed using the specified FHIR Questionnaire Resource for the patient and encounter in the current context. |
| **Actor:** | Assessor |
| **Role:** | Responds to request, by creating a FHIR QuestionnaireResponse Resource for the patient and encounter in the current context representing the execution of the assessment instrument provided. |

### 3.X3.3 Referenced Standards

|  |  |
| --- | --- |
| HL7 FHIR | HL7® FHIR® standard R4: <http://www.hl7.org/fhir/R4/index.html> |
| HL7 SMART on FHIR | HL7® FHIR® SMART Application Launch Framework Implementation Guide Release 1.0.0 <http://hl7.org/fhir/smart-app-launch/index.html> |
| IETF RFC 2616 | Hypertext Transfer Protocol – HTTP/1.1 |
| IETF RFC 7540 | Hypertext Transfer Protocol – HTTP/2 |
| IETF RFC 3986 | Uniform Resource Identifier (URI): Generic Syntax |
| IETF RFC 4627 | The application/json Media Type for JavaScript Object Notation (JSON) |
| IETF RFC 6585 | Additional HTTP Status Codes |

### 3.X3.4 Interaction Diagram

Launch Assessment

Assessor

Assessment Requestor

Record Assessment

Assess Patient  
Activity

#### 3.X3.4.1 Launch Assessment message

This message uses a SMART on FHIR EHR Launch sequence to initiate an assessment for a given patient with the specified Questionnaire resource. It is used by the Assessment Requestor that implements the EHR Launch option.

##### 3.X3.4.1.1 Trigger Events

When the Assessment Requestor implementing the EHR Launch option needs to have a patient assessed it issues a Launch Assessment message.

##### 3.X3.4.1.2 Message Semantics

A patient context is established with a SMART on FHIR application through the EHR launch sequence. The Assessment Requestor actor corresponds to the EHR actors described in SMART on FHIR. The Assessor actor corresponds to the App actor described in SMART on FHIR.

When the EHR Launch sequence is used, the questionnaire to use for the assessment is recorded in the context returned by the EHR Authorization Server in the SMART on FHIR in the SMART Authorization Sequence[[12]](#footnote-12).

{

"access\_token": "i8hweunweunweofiwweoijewiwe",

"token\_type": "bearer",

"expires\_in": 3600,

"scope": "patient/Observation.read patient/Patient.read",

"intent": "client-ui-name",

"patient": "123",

"encounter": "456",

"questionnaire":"*questionnaire-canonical-uri*"

}

##### 3.X3.4.1.3 Expected Actions

The Assessment Requestor and Assessor actors have established a context in which they agree upon the assessment instrument, the patient, the encounter and the user performing the assessment, and the assessment is ready to be performed.

#### 3.X3.4.2 Assess Patient Activity message

This is a user interface action performed by the assessor to capture the assessment data from the user and to provide additional assessment information.

#### 3.X3.4.2.1 Trigger Events

This message is triggered when the assessment is ready to be performed.

#### 3.X3.4.2.2 Semantics

*Not applicable*.

#### 3.X3.4.2.3 Expected Actions

The Assessor will display enough context information to ensure patient safety and data integrity (e.g., the patient name, gender, birthdate, and MRN, the encounter, et cetera), and will display the title of the assessment and user interface to capture data needed for the assessment. The user can complete the assessment and tell the assessor to transmit the results.

#### 3.X3.4.3 Record Assessment message

The Assessor posts the results of the assessment as a QuestionnaireResponse to the Assessment Requestor for it to act upon.

##### 3.X3.4.3.1 Trigger Events

When the user performing indicates that the assessment is complete the Assessor will send the Record Assessment Message to the Assessment Requestor actor.

##### 3.X3.4.3.2 Message Semantics

This is an HTTP or HTTPS POST of a QuestionnaireResponse resource, as constrained by this profile.

The base URL for this is: [base]/QuestionnaireResponse

Where the body of the transaction contains the QuestionnaireResponse resource.

See <http://hl7.org/fhir/R4/http.html#create>

The semantics of the QuestionnaireResponse are treated as the returned result from an assessment request. There is no expectation from this transaction that the results are necessarily persisted permanently within the patient chart. The results may be used to further refine treatment plans, record observations in the patient chart, or be used for purposes other than being stored. There is no requirement in this profile that the AssessmentRequestor be able to support the read, search or update transactions on the “created” QuestionnaireResponse.

Implementations should document what is done with the QuestionnaireResponse.

##### 3.X3.4.3.3 Expected Actions

The Assessment Requestor responds, with success or error, as defined by the FHIR RESTful create interaction. See <http://hl7.org/fhir/R4/http.html#create>.

#### 3.X3.4.4 Capability Statement Resource

Assessor and Assessment Requestor actors implementing this transaction should provide a CapabilityStatement Resource as described in ITI TF-2x: Appendix Z.3 indicating the create operation for the QuestionnaireResponse have been implemented and shall include all the supported parameters.

### 3.X3.5 Security Considerations

The posted content contains PHI and potentially III that shall be protected. See the general Security Considerations in PCC TF-1: X.5.

#### 3.X3.5.1 Security Audit Considerations

When grouped with the Secure Node or Secure Application actor, the Assessor actor generates a “Export” Audit Message and the Assessment Requestor generates an “Import” Audit Message, which is consistent with ATNA. The Assess Patient [PCC-X3] is a PHI Export/PHI Import event pair as defined in Table ITI TF-2:3.20.4.1.1.1-1. The message shall comply with the following pattern:

* Event *for the Assessor*
* EventID = EV (110106, DCM, "Export")
* EventTypeCode = EV(“PCC-X3”, “IHE Transactions”, “Assess Patient”)
* EventActionCode = “R” (Read)
* Event *for the Assessment Requestor*
* EventID = EV (110107, DCM, "Import")
* EventTypeCode = EV(“PCC-X3”, “IHE Transactions”, “Assess Patient”)
* EventActionCode = “C” (Create)
* Source of the request (1..1)
* UserID = The Assessor actor system identity
* RoleIDCode = EV(110153, DCM, “Source”)
* Participating Object
* ParticipantObjectTypeCode = 2 (system)
* ParticipantObjectTypeCodeRole = 4 (other)
* ParticipantObjectIDTypeCode = EV [("QuestionnaireResponse", FHIR, "QuestionnaireResponse")](http://dicom.nema.org/medical/dicom/current/output/chtml/part16/chapter_D.html" \l "DCM_110180)
* ParticipantObjectID = *QuestionnaireResponse.identifier*
* Human Requestor (0..n)  one for each known User
* UserID = Identity of the human that initiated the transaction.
* RoleIDCode = Access Control role(s) the user holds that allows this transaction
* Destination of the request (1..1)
* Assessment Requestor actor system identity
* RoleIDCode = EV(110152, DCM, “Destination”)
* Audit Source (1..1)
* not specified

Volume 3 – Content Modules

## 6.6 HL7 FHIR Content Module

### 6.6.Y1 Questionnaire

The following table shows the IHE constraints on the Questionnaire resource used with the ACDC profile.

Table 6.6.Y1-1: Questionnaire resource

| Name | Flags | Card. | Description & Constraints | (Profile) Comments |
| --- | --- | --- | --- | --- |
| .. Questionnaire | ITU |  | DomainResource | A structured set of questions |
| ... extension | Σ**S** | 0..1 | launchurl | If items are not present, then the question must report the launch url of an Assessor that can perform the assessment. |
| ... url | Σ | **1**..1 | uri | Canonical identifier for this questionnaire, represented as a URI (globally unique) |
| ... name | ΣI | **1**..1 | string | Name for this questionnaire (computer friendly) |
| ... title | Σ | **1**..1 | string | Name for this questionnaire (human friendly) |
| ... date | Σ | **1**..1 | dateTime | Date last changed |
| ... publisher | Σ | **1**..1 | string | Name of the publisher (organization or individual) |
| ... description |  | **1**..1 | markdown | Natural language description of the questionnaire |

A FHIR Questionnaire StructureDefinition can be found in implementation materials – see ITI TF-2x: Appendix W for instructions on how to get to the implementation materials.

#### 6.6.Y2.1 Launch URL Extension

The Launch URL extension is defined in the table below.

Table 6.6.Y1-2: Questionnaire resource

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [Name](http://www.hl7.org/fhir/formats.html#table) | [Flags](http://www.hl7.org/fhir/formats.html#table) | [Card.](http://www.hl7.org/fhir/formats.html#table) | [Type](http://www.hl7.org/fhir/formats.html#table) | [Description & Constraints](http://www.hl7.org/fhir/formats.html#table) |
| [launchurl](http://www.hl7.org/fhir/extension-questionnaireresponse-signature-definitions.html#extension.signature) |  | 0..\* | [uri](http://www.hl7.org/fhir/datatypes.html#Signature) | URL = http://hl7.org/fhir/StructureDefinition/questionnaire-launchurl launchurl: Represents the launch url of a SMART on FHIR application where the assessment can be performed.  Use on Element ID Questionnaire |

### 6.6.Y2 QuestionnaireResponse

The following table shows the IHE constraints on the QuestionnaireResponse resource used with the ACDC profile.

Table 6.6.Y2-1: QuestionnaireResponse resource

| Name | Flags | Card. | Description & Constraints | (Profile) Comments |
| --- | --- | --- | --- | --- |
| .. QuestionnaireResponse | TU |  | DomainResource |  |
| ... signature |  | 0..\* | questionnaireresponse-signature | A signature[[13]](#footnote-13) on the QuestionnaireResponse content. |
| ... questionnaire | Σ | **1**..1 | canonical(Questionnaire) | The questionnaire being answered must be provided. |
| ... status | ?!Σ | 1..1 | code | status may have any value other than in-progress |
| ... subject | Σ | **1**..1 | Reference(Any) | The subject shall be present. |
| ... encounter | Σ**S** | 0..1 | Reference(Encounter) | The encounter shall be present when known. |
| ... authored | Σ | **1**..1 | dateTime | Date the answers were gathered shall be provided. |
| ... author | Σ | **1**..1 | Reference(Device | Practitioner | PractitionerRole | Patient | RelatedPerson | Organization) | Person who received and recorded the answers shall be provided. |
| ... source | Σ**S** | 0..1 | Reference(Patient | Practitioner | PractitionerRole | RelatedPerson) | The person who answered the questions shall be provided when known. |
| ... item | I | **1**..\* | BackboneElement | At least one item shall be present unless status is entered-in-error or stopped. |

A FHIR QuestionnaireResponse StructureDefinition can be found in implementation materials – see ITI TF-2x: Appendix W for instructions on how to get to the implementation materials.

1. HL7 is the registered trademark of Health Level Seven International. [↑](#footnote-ref-1)
2. FHIR is the registered trademark of Health Level Seven International. [↑](#footnote-ref-2)
3. <http://HealthMeasures.net> [↑](#footnote-ref-3)
4. <http://lib.adai.washington.edu/instruments/> [↑](#footnote-ref-4)
5. <https://www.ncbi.nlm.nih.gov/pubmed/?term=assessment+instrument> [↑](#footnote-ref-5)
6. Health Assessments in Primary Care, September 2003, AHRQ [↑](#footnote-ref-6)
7. See <http://tools.acc.org/ASCVD-Risk-Estimator-Plus> [↑](#footnote-ref-7)
8. See <https://www.sciencedirect.com/science/article/pii/S0735109718390363?via%3Dihub> [↑](#footnote-ref-8)
9. FHIR Patient Reported Outcomes Implementation Guide available from <http://hl7.org/fhir/us/patient-reported-outcomes/2019May/pro-overview.html> [↑](#footnote-ref-9)
10. However, we might recommend simply persisting the QuestionnaireResponse resource returned by the Assessor actor. [↑](#footnote-ref-10)
11. See <http://hl7.org/fhir/StructureDefinition/questionnaireresponse-signature> [↑](#footnote-ref-11)
12. See http://hl7.org/fhir/smart-app-launch/index.html#smart-authorization-sequence [↑](#footnote-ref-12)
13. See <http://www.hl7.org/fhir/extension-questionnaireresponse-signature.html> [↑](#footnote-ref-13)