**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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**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-2) FHIR®[[2]](#footnote-3) 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 February 20th, 2020   |  |  | | --- | --- | | FHIR Resource Name | FMM Level | | Questionnaire | 3 | | QuestionnaireResponse | 3 | |

The IHE 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

## Closed Issues

1. We seek feedback on the need to be able to update the results from an assessment. How, for example, should the system operate in cases where the assessment needs to be performed again to correct an error in input? How would we address privacy and security concerns related to update. Call out auth/access control issues out of scope?  
   The profile allows assessment results to be updated. It is up to the system to determine
2. Should PCC-71 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.
3. We seek feedback on storage of assessment content (see section 15.4.1.1) and use of the FHIR create operation in PCC-72 to “return” the results of the assessment instrument. Are these mechanisms acceptable to implementers?
4. 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.
5. 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).
6. 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.
7. 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.
8. 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.
9. 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 Requester 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-71]*** – this transaction enables systems to query 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, and to retrieve the assessment instrument.

***Request Assessment [PCC-72]* –**this transaction establishes the context for, and initiates an assessment for a given patient.

***Report Assessment [PCC-73]* –**this transaction reports on the results of an assessment of a given patient via a restful API.

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 15

# 15 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.

## 15.1 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 15.1-1 shows the actors directly involved in the ACDC Profile and the relevant transaction between them.

**Clinical Knowledge Resource Repository**

**Assessment Requestor**

Query Artifact [PCC-71] ↓

**Artifact Consumer**

**Assessor**

Assess Patient [PCC-72] ↓

Publish Assessment [PCC-73] ↑

Figure 15.1-1: ACDC Actor Diagram

Table 15.1-1 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 15.1-1: ACDC Integration Profile - Actors and Transactions

|  |  |  |  |
| --- | --- | --- | --- |
| Actors | Transactions | Optionality | Reference |
| Clinical Knowledge Resource Repository | Query Artifact [PCC-71] | R | PCC TF-2: 3.71 |
| Artifact Consumer | Query Artifact [PCC-71] | R | PCC TF-2: 3.71 |
| Assessor | Request Assessment [PCC-72] | R | PCC TF-2: 3.72 |
| Report Assessment [PCC-73] | R | PCC TF-2: 3.73 |
| Assessment Requestor | Request Assessment [PCC-72] | R | PCC TF-2: 3.72 |
| Report Assessment [PCC-73] | R | PCC TF-2: 3.73 |

### 15.1.1 Actor Descriptions and Actor Profile Requirements

#### 15.1.1.1 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.

#### 15.1.1.2 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 Requester 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.

#### 15.1.1.3 Assessor

The Assessor in this profile performs an assessment and reports 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.

#### 15.1.1.4 Assessment Requestor

The Assessment Requester 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.

## 15.2 ACDC Actor Options

Options that may be selected for each actor in this profile, are listed in the Table 15.2-1. Dependencies between options when applicable are specified in notes.

Table 15.2-1: ACDC - Actors and Options

| Actor | Option Name | Reference |
| --- | --- | --- |
| Clinical Knowledge Resource Repository | Questionnaire Item Retrieval Option1 | PCC TF-15.2.1.1 |
| Assessor Option1 | PCC TF-15.2.2 |
| EHR Launch Option1 | PCC TF-15.2.3 |
| Artifact Consumer | None Defined | |
| Assessment Requestor | EHR Launch Option | PCC TF-15.2.3 |
| Assessor | EHR Launch Option | PCC TF-15.2.3 |

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

### 15.2.1 Questionnaire Item Retrieval Option

The Questionnaire Item Retrieval option enables systems to interpret the content of the returned Questionnaire resources using their own Questionnaire handling interface.

#### 15.2.1.1 Clinical Knowledge Resource Repository

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.

### 15.2.2 Assessor Option

The Assessor Option enables a Clinical Knowledge Repository to provide Assessment capabilities for applications which cannot provide their user interface to implement the user interactions described by the Questionnaire resource.

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.

### 15.2.3 EHR Launch Option

The EHR Launch Option allows assessments to be performed using the SMART on FHIR EHR Launch workflow from the providers EHR system.

#### 15.2.3.1 EHR Launch Requirements on Clinical Knowledge Resource Repository

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.

#### 15.2.3.2 EHR Launch Requirements on Assessment Requester

An Assessment Requester that implements the EHR Launch option shall initiate a SMART on FHIR EHR Launch protocol via the launch url associated with the assessment.

### 15.2.3.3 EHR Launch Requirements on Assessor

An Assessor that implements the EHR Launch option supports initiation of the assessment via 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.

## 15.3 ACDC Required Actor Groupings

Table 15.3-1: ACDC - Required Actor Groupings

| ACDC Actor | Actor to be grouped with | Reference |
| --- | --- | --- |
| Assessment Requestor | Secure Node or Secure Application | PCC TF-15.6.3 |

## 15.4 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-4) has nearly 750 measures, the Alcohol and Drug Abuse Institute at the University of Washington[[4]](#footnote-5) lists over 1031 screening instruments, and a search of PubMed[[5]](#footnote-6) 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-7). These are shown in figure 15.4-1 below.

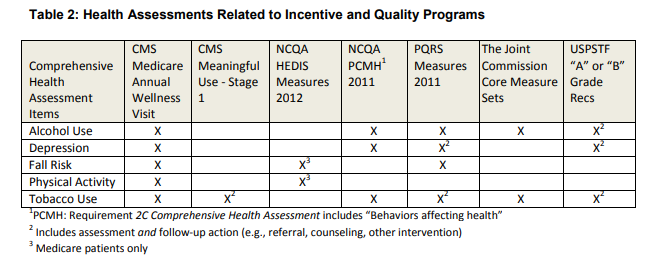


Figure 15.4-1 Quality Related Assessments

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.

### 15.4.1 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-8). This instrument provides an estimation of a patients’ 10-year ASCVD risk. It appears in the figure below.

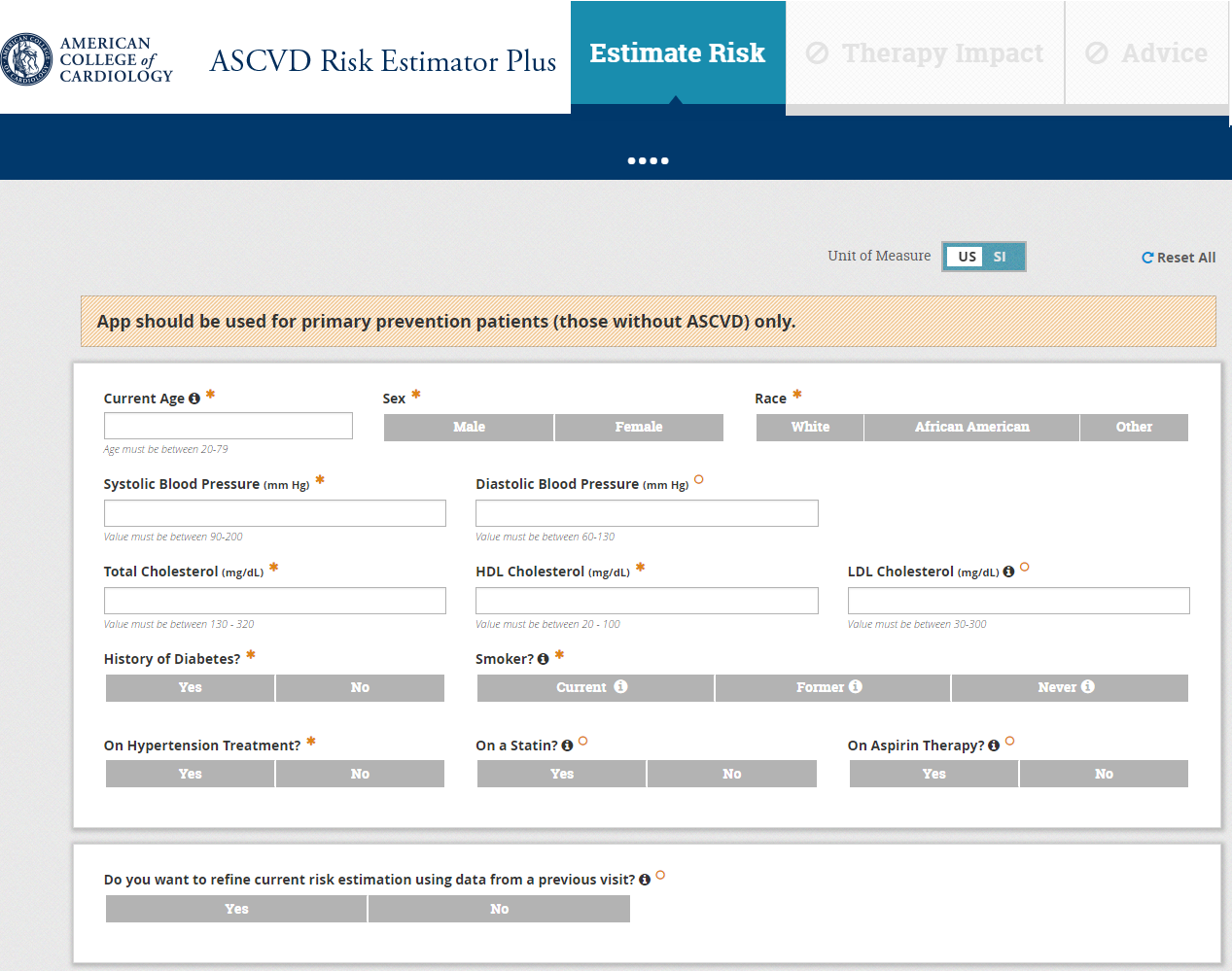


Figure 15.4.1-1 An Assessment Instrument

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-9). 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-10) 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.

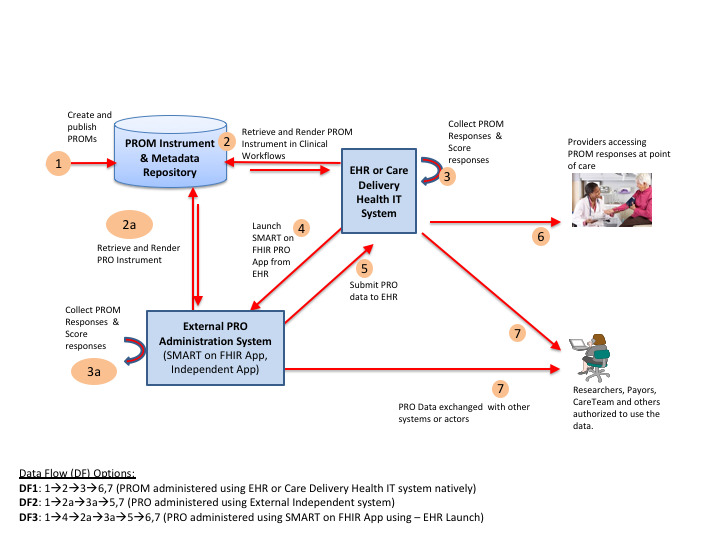


Figure 15.4.1-2 Abstract Model for Basic Questionnaires

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 assessment 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 15.4.1-1, which is the execution of the assessment instrument.

#### 15.4.1.1 Use of Assessment Instrument Results

This profile makes no assumptions about how assessment results are used after they are returned to the Assessment Requester 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-11).

This profile does require that the Assessment Requester actor expose a FHIR endpoint that supports the QuestionnaireResponse create operation. That does not create a commitment on the Assessment Requester 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.

### 15.4.2 Use Cases

#### 15.4.2.1 Use Case #1: Finding an Assessment Instrument

##### 15.4.2.1.1 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.

##### 15.4.2.1.2 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 **15.4.2.2 Use Case #2 Executing the Assessment Instrument**.

Query Artifact   
Request [PCC-71]

Clinical Knowledge Resource Repository

Artifact Consumer

Query Artifact

Response [PCC-71]

Figure 15.4.2.1-1: Use Case #1 Process Flow in ACDC Profile

#### 15.4.2.2 Use Case #2: Executing the Assessment Instrument

##### 15.4.2.2.1 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 either manually by the provider or through an integration method not specified by this guide. This application will integrate with the provider’s Health IT system to determine which assessment is to be performed, for which patient and which encounter. It will then collect the data and return it 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 collect data already known about the patient that is stored in the health IT system that will receive the assessment results. When the EHR Launch option is used, this data can be accessed via FHIR resources from the launching EHR system.

##### 15.4.2.2.2 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.

This first step may be implemented via process in which the healthcare provider orders an assessment be performed or may be initiated via a SMART on FHIR EHR Launch flow. At the end of this step, the patient or provider is presented with a user interface that enables them to complete the assessment.

The next step performs the assessment. During this step, the assessor may collect additional data from the receiving health IT system to facilitate completion of the assessment. The software performing the assessment may connect to the user’s health IT system in order to perform queries (e.g., using the IHE QEDm or PDQm profile, or through other methods).

Upon completion of the assessment, the assessor records the results of the assessment in a QuestionnaireResponse resource stored by the Assessment Requester actor and sends it to the Assessment Requestor.

Should there be an error in input, or selection of assessment instrument, the assessment can be subsequently updated to amend the content, or report that it was entered in error. It is up to the Assessment Requester actor to determine the rules about when and by what system an assessment can be updated.

Report Assessment (Update) [PCC-73]

Request Assessment [PCC-72]

Assessor

Assessment Requestor

Report Assessment (Create) [PCC-73]

Figure 15.4.2.2-1: Use Case #2 Process Flow in ACDC Profile

## 15.5 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-12) 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.

## 15.6 ACDC Cross Profile Considerations

### 15.6.1 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 Requester 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 Requester 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 Requester 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.

### 15.6.2 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 Requester to implement the Patient Demographics Supplier Actor and must be able to perform normally if the Assessment Requester does not support some of the additional requested scopes or resources.

The Assessment Requester 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 Requester 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 Requester shall respond with the scopes appropriate for the patient demographics that it supports.

### 15.6.3 ITI ATNA – Audit Trail and Node Authentication

The Assessment Requester 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 3.71

## 3.71 Query Artifact [PCC-71]

This section corresponds to Transaction PCC-71 of the IHE PCC Technical Framework. Transaction PCC-71 is used by the Clinical Knowledge Resource Repository and Artifact Consumer Actors.

### 3.71.1 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.

### 3.71.2 Actor Roles

Clinical Knowledge Resource Repository

Artifact Consumer

Figure 3.71.2-1: Use Case Diagram

Table 3.71.2-1: 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. |

### 3.71.3 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 |

### 3.71.4 Interaction Diagram

Search Artifact Request

Clinical Knowledge Resource Repository

Artifact Consumer

Search Artifact Response

Message 1

Read Artifact Request

Read Artifact Response

Message 1

#### 3.71.4.1 Search 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.

##### 3.71.4.1.1 Trigger Events

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

##### 3.71.4.1.2 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 3.71.4.1.2.1). 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 3.71.4.1.2.1, 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.

###### 3.71.4.1.2.1 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 set of searches:

1. A query based on the content of the Assessment instrument that supports any of the following search parameters:

* \_summary=true
* 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)

1. A query based on the canonical url of the Assessment instrument.
   * url (uri)

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).

###### 3.71.4.1.2.2 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.

##### 3.71.4.1.3 Expected Actions

1. The Artifact Consumer shall send a query to a Clinical Knowledge Resource Repository.
2. 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. 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.
4. On success, the Clinical Knowledge Resource Repository will return a Bundle of zero or more Questionnaire resources conforming to the FHIR Profile described in section PCC TF-3: 6.6.107.1 ACDC Questionnaire.

###### 3.71.4.2.2.2 Resource Bundling

The Query Artifact Response message shall be a FHIR Bundle Resource containing zero or more Questionnaire resources conforming to the ACDC Questionnaire profile in 6.6.107.1. The response shall adhere to the FHIR Bundle constraints specified in ITI TF-2x: Appendix Z.1.

#### 3.71.5 Read Artifact Request message

This message uses the HTTP GET method to retrieve an individual FHIR Questionnaire Resource. This transaction performs a FHIR read request on Questionnaire resources.

##### 3.71.4.1.1 Trigger Events

When the Artifact Consumer needs to read Questionnaire Resources it issues a Read Artifact message.

##### 3.71.4.1.2 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. The syntax of the FHIR read is:

GET [base]/Questionnaire/{id}

where {id} is the internal identifier of the Questionnaire resource as known by the Clinical Knowledge Resource Repository.

###### 3.71.4.1.2.2 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.

##### 3.71.4.1.3 Expected Actions

1. The Artifact Consumer shall send read artifact request to a Clinical Knowledge Resource Repository.
2. 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).
3. On success, the Clinical Knowledge Resource Repository will return a Questionnaire resource conforming to the FHIR Profile described in section PCC TF-3: 6.6.107.1 ACDC Questionnaire.

#### 3.71.4.3 Capability Statement Resource

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

### 3.71.5 Security Considerations

The retrieved content contains IP that shall be protected. See the general Security Considerations in PCC TF-1: 15.5.

#### 3.71.5.1 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-71] is a Query sInformation 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-71”, “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-71”, “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 3.72

## 3.72 Request Assessment [PCC-72]

This section corresponds to Transaction PCC-72 of the IHE PCC Technical Framework. Transaction PCC-72 is used by the Assessment Requester and Assessor Actors.

### 3.72.1 Scope

The Request Assessment transaction is used to request the assessment defined in a Questionnaire resource. The result of this transaction is the display of, and interaction with a user in order to complete an assessment.

### 3.72.2 Actor Roles

Assessment Requestor

Assessor

Figure 3.72.2-1: Use Case Diagram

Table 3.72.2-1: 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. |

### 3.72.3 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 |

### 3.72.4 Interaction Diagram

Establish Context

Assessor

Assessment Requestor

Launch  
Assessment

#### 3.72.4.1 Establish Context message

When the EHR Launch option is not used, the EHR system or user will establish the context for performing the assessment through a mechanism not specified in this profile. This may be by placing an order, launching and configuring a web application for the patient being assessed, or through some other mechanism.

When the Assessment Requester actor implements the EHR Launch option, this message uses a SMART on FHIR EHR Launch sequence to establish the context and launch the assessment for a given patient with the specified Questionnaire resource.

##### 3.72.4.1.1 Trigger Events

An assessment is requested for a patient.

##### 3.72.4.1.2 Message Semantics

When used without the EHR Launch option, the user or system that launches the Assessor instrument must first establish the patient and encounter context with the Assessor.

When used with the EHR Launch option, the patient context is established with a SMART on FHIR application through the EHR launch sequence. The Assessment Requester actor corresponds to the EHR actors described in SMART on FHIR. The Assessor actor corresponds to the App actor described in SMART on FHIR. 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-13).

##### 3.72.4.1.3 Expected Actions

The Assessment Requester and Assessor actors establish 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.

When the EHR Launch option is used, the Assessment Requester shall launch the Assessor as specified by the SMART on FHIR EHR Launch sequence.

#### 3.72.4.2 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.

#### 3.72.4.2.1 Trigger Events

This message is triggered by launching the Assessor.

#### 3.72.4.2.2 Semantics

The user or patient (or patient representative) is provided with a series of prompts or questions and responds to them. The user responses are collected in a FHIR QuestionnaireResponse resource.

#### 3.72.4.2.3 Expected Actions

1. 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.
2. The assessor will prompt the user (e.g., provider or patient) and enables them to respond.
3. The user completes the assessment.
4. Upon completion the Assessor will transmit the results by performing the PCC-73 transaction.

#### 3.72.4.4 Capability Statement Resource

Assessor and Assessment Requester actors implementing this transaction shall provide a CapabilityStatement Resource as described in ITI TF-2x: Appendix Z.3.

When the EHR Launch option is support, this capability statement shall provide the required information to support a SMART on FHIR EHR Launch.

### 3.72.5 Security Considerations

The posted content contains PHI and potentially III that shall be protected. See the general Security Considerations in PCC TF-1: 15.5.

#### 3.72.5.1 Security Audit Considerations

When the EHR Launch option is used and the actors are grouped with the Secure Node or Secure Application actor, the Assessment Requestor and Assessor actors both generate an Application Start Audit Event consistent with ATNA. The message shall comply with the following pattern:

* Event
* EventID = EV 110100, Application Activity, “Audit event: Application Activity has taken place.”)
* EventTypeCode = EV(110120, Application Start, “Audit event: Application Entity has started.”)
* EventActionCode = “X” (Execute)
* Application Launcher (1..1)
* UserID = The Assessment Requestor actor system identity
* RoleIDCode = EV(110151, DCM, “Application”)
* Patient (1..1)
* The identity of the patient being assessed.
* 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
* Application (1..1)
* Asessor actor system identity
* RoleIDCode = EV(110150, DCM, “Application”)
* Audit Source (1..1)
* not specified

When the assessment is complete, the Assessor shall issue an Application Stop audit event. The message shall comply with the following pattern:

* Event
* EventID = EV 110100, Application Activity, “Audit event: Application Activity has taken place.”)
* EventTypeCode = EV(110121, Application Stop, “Audit event: Application Entity has stopped.”)
* EventActionCode = “X” (Execute)
* Application Launcher (1..1)
* UserID = The Assessment Requestor actor system identity
* RoleIDCode = EV(110151, DCM, “Application Launcher”)
* Patient (1..1)
* The identity of the patient being assessed.
* 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
* Application (1..1)
* Asessor actor system identity
* RoleIDCode = EV(110150, DCM, “Application”)
* Audit Source (1..1)
* not specified

Add Section 3.73

## 3.73 Report Assessment [PCC-73]

This section corresponds to Transaction PCC-73 of the IHE PCC Technical Framework. Transaction PCC-73 is used by the Assessment Requester and Assessor Actors.

### 3.73.1 Scope

The Report Assessment transaction is used to report the results of an assessment. The result of this transaction is the production of a FHIR QuestionnaireResponse Resource that contains the results of the assessment.

### 3.73.2 Actor Roles

Assessment Requestor

Assessor

Figure 3.73.2-1: Use Case Diagram

Table 3.73.2-1: 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. |

### 3.73.3 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 |

### 3.73.4 Interaction Diagram

Assessor

Assessment Requestor

Create Assessment

Update Assessment

#### 3.73.4.1 Create Assessment message

The Assessor reports the results of the assessment in a QuestionnaireResponse to the Assessment Requester as a QuestionnaireResponse.

##### 3.73.4.1.1 Trigger Events

When an assessment is complete the Assessor will send the Create Assessment Message to the Assessment Requester actor.

##### 3.73.4.1.2 Message Semantics

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 Assessment Requester be able to support the read, search or update transactions on the “created” QuestionnaireResponse.

Implementations should document what is done with the QuestionnaireResponse.

The semantics of the QuestionnaireResponse are treated as an update to a previously recorded assessment. There is no expectation from this transaction that the results are persisted permanently within the patient chart. The assessment 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 Assessment Requester be able to support the read, search or update transactions on the “created” QuestionnaireResponse.

Implementations should document what is done with the QuestionnaireResponse.

##### 3.73.4.1.3 Expected Actions

The Assessor performs a create operation on the QuestionnaireResponse endpoint of the Assessment Requester with a body of the transaction containing the QuestionnaireResponse resource as constrained in the QuestionnaireResponse profile described in section 6.6.Y2. The value of Questionnaire.status in this request shall be "completed".

This is an HTTP or HTTPS POST of a QuestionnaireResponse resource, as constrained by this profile. See <http://hl7.org/fhir/R4/http.html#create>. The request shall specify the Content-Type (either application/xml or application/json) in the Content-Type header.

An example message is given below.

POST [base]/QuestionnaireResponse  
Content-Type: application/json

{

{ "resourceType": "QuestionnaireResponse" },

{ "status": "completed" },

∶

}

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

Upon success, the Assessment Requester shall include a Location header that specifies the URL associated with the assessment. This URL may be used with a subsequent Update Assessment message.

An example response is given below:

HTTP 200 Ok

Location: [base]/QuestionnaireResponse/523ede5e-fe46-4d11-8c29-ae36ee64e730

#### 3.73.4.1 Update Assessment message

The Assessor reports the results of the updated assessment in a QuestionnaireResponse to the Assessment Requester as a QuestionnaireResponse.

##### 3.73.4.1.1 Trigger Events

When an assessment is updated, the Assessor will send the Update Assessment Message to the Assessment Requester actor.

##### 3.73.4.1.2 Message Semantics

The semantics of the QuestionnaireResponse are treated as an update to a previously recorded assessment. There is no expectation from this transaction that the results are persisted permanently within the patient chart.

##### 3.73.4.1.3 Expected Actions

The Assessor performs an update operation on the QuestionnaireResponse endpoint of the Assessment Requester with a body of the transaction containing the QuestionnaireResponse resource as constrained in the QuestionnaireResponse profile described in section 6.6.Y2. The Assessor shall set the value of Questionnaire.status in this request to "amended" or "entered-in-error".

This is an HTTP or HTTPS PUT of a QuestionnaireResponse resource. See <http://hl7.org/fhir/R4/http.html#update>. The request shall specify the Content-Type (either application/xml or application/json) in the Content-Type header.

An example message is given below.

PUT [base]/QuestionnaireResponse  
Content-Type: application/json

{

{ "resourceType": "QuestionnaireResponse" },

{ "status": "amended" },

∶

}

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

Upon success, the Assessment Requester should include a Location header that specifies the URL associated with the assessment.

An example response is given below:

HTTP 200 Ok

Location: [base]/QuestionnaireResponse/523ede5e-fe46-4d11-8c29-ae36ee64e730

#### 3.73.5 Capability Statement Resource

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

### 3.73.6 Security Considerations

The posted content contains PHI and potentially III that shall be protected. See the general Security Considerations in PCC TF-1: 15.5.

#### 3.73.6.1 Security Audit Considerations

When grouped with the Secure Node or Secure Application actor, the Assessor actor generates a “Export” Audit Message and the Assessment Requester generates an “Import” Audit Message, which is consistent with ATNA. The Report Assessment [PCC-73] 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-73”, “IHE Transactions”, “Report Assessment”)
* EventActionCode = “R” (Read)
* Event *for the Assessment Requestor*
* EventID = EV (110107, DCM, "Import")
* EventTypeCode = EV(“PCC-73”, “IHE Transactions”, “Report Assessment”)
* EventActionCode = “C” (Create)
* Source of the request (1..1)
* UserID = The Assessor actor system identity
* RoleIDCode = EV(110153, DCM, “Source”)
* Patient (1..1)
* *No additional constraints*
* 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#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 Requester actor system identity
* RoleIDCode = EV(110152, DCM, “Destination”)
* Audit Source (1..1)
* not specified

Volume 3 – Content Modules

## 6.6 HL7 FHIR Content Modules

### 6.6.107.1 ACDC Questionnaire

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

Table 6.6.107.1-1: 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.

### 6.6.108.1 ACDC 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 |  |
| ... contained |  | 0..\* |  |  |
| .... Questionnaire |  | 0..1 | Questionnaire |  |
| ..... id |  | 1..1 | id |  |
| … extension |  | 0..\* | questionnaireresponse-signature | A signature[[13]](#footnote-14) on the QuestionnaireResponse content. |
| ... questionnaire | Σ | **1**..1 | canonical(Questionnaire) | The questionnaire being answered must be provided. |
| .... extension |  | 0..1 | containedquestionnaire-reference | This is an extension to the canonical reference data type providing a reference to a copy of the resource contained in the response. This extension must be present when contained.Questionnaire is present. |
| ..... url |  | 1..1 | *TBD* | This extension supports a reference to a contained copy of the questionnaire resource. It is needed to ensujre that the reference |
| ..... valueReference |  | 1..1 | Reference | The reference must start with # and be followed by the id of the contained Questionnaire resource. |
| ... status | ?!Σ | 1..1 | code | status may have any value other than in-progress |
| ... subject | Σ | **1**..1 | Reference(**Patient**) | The subject shall be present, and must be a reference to a Patient resource. |
| ... 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.

## 6.7 HL7 FHIR Extensions

### 6.7.3 Launch URL Extension

The Launch URL extension is defined in the table below.

Table 6.7.3.1-1: Launch URL Extension

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [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) | http://ihe.net/fhir/StructuredDefinition/questionnaire-launchurl Represents the launch url of a SMART on FHIR application where the assessment can be performed.  Use on Element ID Questionnaire |

### 6.7.4 Contained Questionnaire Reference Extension

The Contained Questionnaire Reference extension is defined in the table below.

Table 6.7.4-1: Contained Questionnaire Extension

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [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) |
| [containedquestionnaire-reference](http://www.hl7.org/fhir/extension-questionnaireresponse-signature-definitions.html#extension.signature) |  | 1..1 | [Reference](http://www.hl7.org/fhir/datatypes.html#Signature) | http://ihe.net/fhir/StructuredDefinition/[containedquestionnaire-reference](http://www.hl7.org/fhir/extension-questionnaireresponse-signature-definitions.html#extension.signature)  Provides a reference to a copy of the questionnaire stored as a contained resource in the response.  Use on QuestionnaireResponse.questionaire |

1. HL7 is the registered trademark of Health Level Seven International. [↑](#footnote-ref-2)
2. FHIR is the registered trademark of Health Level Seven International. [↑](#footnote-ref-3)
3. <http://HealthMeasures.net> [↑](#footnote-ref-4)
4. <http://lib.adai.washington.edu/instruments/> [↑](#footnote-ref-5)
5. <https://www.ncbi.nlm.nih.gov/pubmed/?term=assessment+instrument> [↑](#footnote-ref-6)
6. Health Assessments in Primary Care, September 2003, AHRQ [↑](#footnote-ref-7)
7. See <http://tools.acc.org/ASCVD-Risk-Estimator-Plus> [↑](#footnote-ref-8)
8. See <https://www.sciencedirect.com/science/article/pii/S0735109718390363?via%3Dihub> [↑](#footnote-ref-9)
9. FHIR Patient Reported Outcomes Implementation Guide available from <http://hl7.org/fhir/us/patient-reported-outcomes/2019May/pro-overview.html> [↑](#footnote-ref-10)
10. However, we might recommend simply persisting the QuestionnaireResponse resource returned by the Assessor actor. [↑](#footnote-ref-11)
11. See <http://hl7.org/fhir/StructureDefinition/questionnaireresponse-signature> [↑](#footnote-ref-12)
12. See http://hl7.org/fhir/smart-app-launch/index.html#smart-authorization-sequence [↑](#footnote-ref-13)
13. See <http://www.hl7.org/fhir/extension-questionnaireresponse-signature.html> [↑](#footnote-ref-14)