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IHE PCC

Technical Framework Supplement

10

Assessment Curation and Data Collection (ACDC)

15

HL7[®] FHIR[®] STU 4

Using Resources at FMM Levels 3

Revision 1.2 – Trial Implementation

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Please verify you have the most recent version of this document. See [here](#) for Trial Implementation and Final Text versions and [here](#) for Public Comment versions.

Foreword

30 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 March 24, 2020 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Patient Care Coordination Technical Framework. Comments are invited and can be submitted at
35 http://www.ihe.net/PCC_Public_Comments.

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.

<i>Amend Section X.X by the following:</i>
--

40 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.

45 General information about IHE can be found at <http://ihe.net>.

Information about the IHE Patient Care Coordination domain can be found at 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 and <http://ihe.net/Profiles>.

50 The current version of the IHE Patient Care Coordination Technical Framework can be found at 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 domain determines that an emerging standard has high likelihood of industry adoption, and the standard offers significant benefits for the use cases it is attempting to address, the domain may develop IHE profiles based on such a standard. During Trial Implementation, the IHE domain will update and republish the IHE profile as the underlying standard evolves.

Product implementations and site deployments may need to be updated in order for them to remain interoperable and conformant with an updated IHE profile.

This ACDC Profile incorporates content from Release 4 of the emerging HL7[®] FHIR[®] specification. HL7 describes FHIR Change Management and Versioning at <https://www.hl7.org/fhir/versions.html>.

HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through N (Normative). See <http://hl7.org/fhir/versions.html#maturity>.

The FMM levels for FHIR content used in this profile are:

FHIR Content (Resources, Value Sets, etc.)	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.

170

175 **Open Issues and Questions**

None

Closed Issues

- 180 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
- 185 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.
- 190 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?
- 195 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.
- 200 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).
- 205 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.
- 210 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.

215 Provenance is challenging b/c the Assessor 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
220 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
225 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.,
230 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.
235

10. 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.
240

Per joint meeting, we have referred to Section 8 of Appendix Z in the ITI Technical Framework.
245

IHE Technical Frameworks General Introduction

250 The [IHE Technical Framework General Introduction](#) is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

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270 9.1.1 DICOM (Digital Imaging and Communications in Medicine)

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IHE Technical Frameworks General Introduction Appendices

295 The [IHE Technical Framework General Introduction Appendices](#) are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

300 *Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located [here](#).*

Appendix A – Actor Summary Definitions

305 *Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

Actor	Definition
Clinical Knowledge Resource Repository	A Clinical Knowledge Resource Repository stores documents <u>artifacts and metadata providing regarding computable</u> clinical 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

310 *Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
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.

Appendix D – Glossary

315

*Add the following **new or updated glossary** terms to the IHE Technical Frameworks General Introduction Appendix D.*

No new terms.

Volume 1 – Profiles

Domain Specific Additions

None.

320

Add new Section 15

15 Assessment Curation and Data Collection (ACDC) Profile

325 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 https://www.ihe.net/resources/technical_frameworks.

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

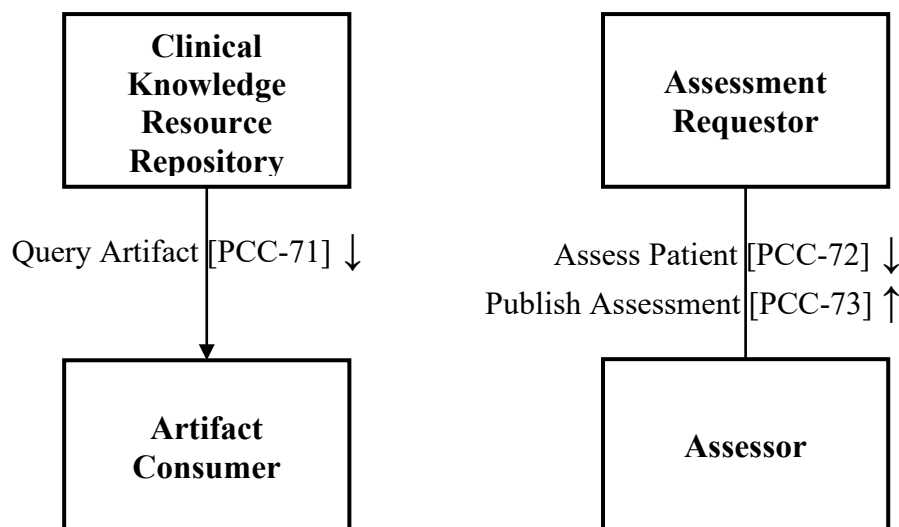


Figure 15.1-1: ACDC Actor Diagram

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:
 - a. 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
 - b. 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.
 - c. 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 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. 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.

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 Option ^{Note1}	PCC TF-1: 15.2.1.1
	Assessor Option ^{Note1}	PCC TF-1: 15.2.2
	EHR Launch Option ^{Note1}	PCC TF-1: 15.2.3
Artifact Consumer	None Defined	
Assessment Requestor	EHR Launch Option	PCC TF-1: 15.2.3
Assessor	EHR Launch Option	PCC TF-1: 15.2.3

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

395 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

400 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

405 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 that is able to perform the assessments it provides.

15.2.3 EHR Launch Option

410 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

415 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

- 420 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

425

15.4 ACDC Overview

- 430 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. HealthMeasures¹ has nearly 750 measures, the Alcohol and Drug Abuse Institute at the University of Washington² lists over 1031 screening instruments, and a search of PubMed³ results in nearly 26,000 articles on different instruments used for patient assessment.

- 435 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 assessments⁴. These are shown in Figure 15.4-1 below.

¹ <http://HealthMeasures.net>

² <http://lib.adai.washington.edu/instruments/>

³ <https://www.ncbi.nlm.nih.gov/pubmed/?term=assessment+instrument>

⁴ Health Assessments in Primary Care, September 2003, AHRQ

Comprehensive Health Assessment Items	CMS Medicare Annual Wellness Visit	CMS Meaningful Use - Stage 1	NCQA HEDIS Measures 2012	NCQA PCMH ¹ 2011	PQRS Measures 2011	The Joint Commission Core Measure Sets	USPSTF "A" or "B" Grade Recs
Alcohol Use	X			X	X	X	X ²
Depression	X			X	X ²		X ²
Fall Risk	X		X ³		X		
Physical Activity	X		X ³				
Tobacco Use	X	X ²		X	X ²	X	X ²

¹ PCMH: Requirement 2C Comprehensive Health Assessment includes "Behaviors affecting health"

² Includes assessment and follow-up action (e.g., referral, counseling, other intervention)

³ Medicare patients only

Figure 15.4-1: Quality Related Assessments

440 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

445 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.

450 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 Estimator⁵. This instrument provides an estimation of a patients' 10-year ASCVD risk. It appears in the figure below.

⁵ See <http://tools.acc.org/ASCVD-Risk-Estimator-Plus>

AMERICAN COLLEGE of CARDIOLOGY ASCVD Risk Estimator Plus Estimate Risk Therapy Impact Advice

Unit of Measure US SI Reset All

App should be used for primary prevention patients (those without ASCVD) only.

Current Age * Sex * Race *

Systolic Blood Pressure (mm Hg) * Diastolic Blood Pressure (mm Hg) *

Total Cholesterol (mg/dL) * HDL Cholesterol (mg/dL) * LDL Cholesterol (mg/dL) *

History of Diabetes? * Smoker? * On Hypertension Treatment? * On a Statin? * On Aspirin Therapy? *

Do you want to refine current risk estimation using data from a previous visit? *

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.

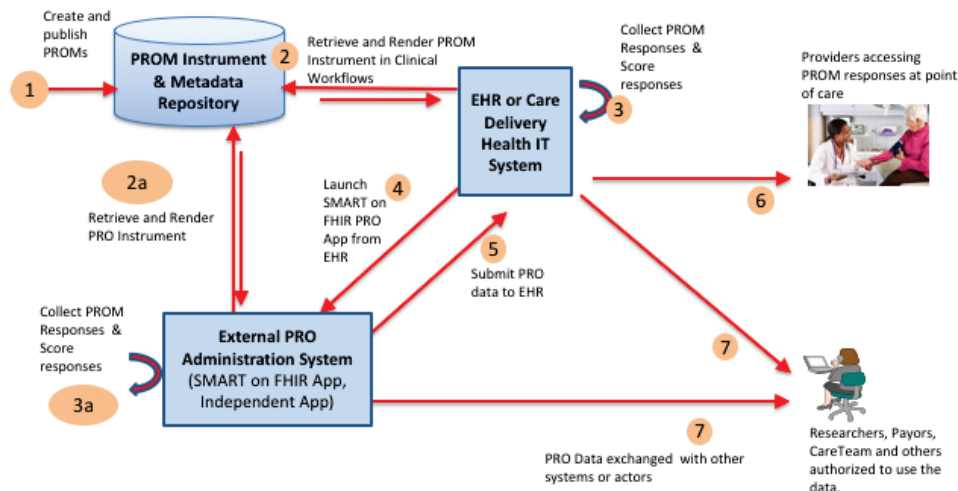
- 460 As a clinical tool used in the delivery of care, assessment instruments often go through evaluation and validation, and include training materials on how the assessment is to be performed⁶. Changes to the questions asked, or the possible responses allowed results in a different diagnostic instrument, which may or may not perform as well as the validated instrument. Therefore, developers of assessment instruments often accompany them with
- 465 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.
- 470 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

⁶ See <https://www.sciencedirect.com/science/article/pii/S0735109718390363?via%3Dihub>

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 outcomes⁷ 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.



Data Flow (DF) Options:

DF1: 1→2→3→6,7 (PROM administered using EHR or Care Delivery Health IT system natively)

DF2: 1→2a→3a→5,7 (PRO administered using External Independent system)

DF3: 1→4→2a→3a→5→6,7 (PRO administered using SMART on FHIR App using – EHR Launch)

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

⁷ FHIR Patient Reported Outcomes Implementation Guide available from <http://hl7.org/fhir/us/patient-reported-outcomes/2019May/pro-overview.html>

Repository. The External PRO Administration System or EHR or Care Delivery Health IT
495 system could then retrieve instruments by implementing the Artifact Consumer. 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

500 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
505 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 profile⁸.

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

515 15.4.2.1 Use Case #1: Finding an Assessment Instrument

15.4.2.1.1 Use Case #1 Description

520 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.

⁸ However, we might recommend simply persisting the QuestionnaireResponse resource returned by the Assessor actor.

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

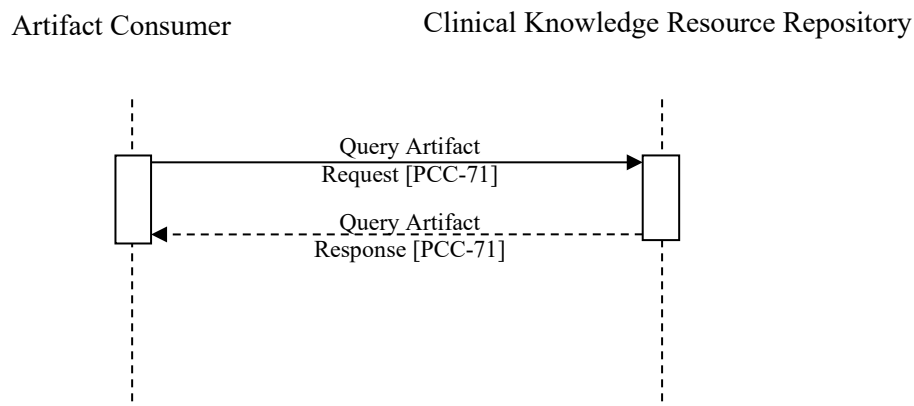


Figure 15.4.2.1.2-1: Use Case #1 Process Flow in ACDC Profile

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.

- 550 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
555 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.

560 **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
565 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
570 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).

575 Upon completion of the assessment, the assessor records the results of the assessment in a QuestionnaireResponse resource stored by the Assessment Requester 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
580 Assessment Requester to determine the rules about when and by what system an assessment can be updated.

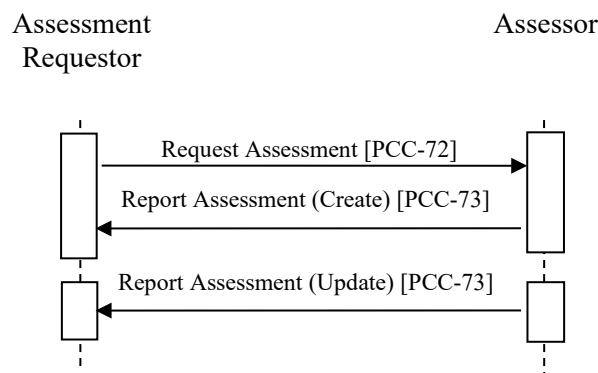


Figure 15.4.2.2-1: Use Case #2 Process Flow in ACDC Profile

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`⁹ 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

⁹ See <http://hl7.org/fhir/StructureDefinition/questionnaireresponse-signature>

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.

- 610 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

615 15.6.1 PCC QEDm – Query for Existing Data for Mobile

An Assessor may be grouped with a Clinical Data Consumer 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.

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

- 625 The Assessment Requester may be grouped with a Clinical Data Source 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 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.
- 630

15.6.2 ITI PDQm – Patient Demographics Query for Mobile

An Assessor may be grouped with a Patient Demographics Consumer 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.

- 635 Given that an Assessor is grouped with the Patient Demographics Consumer, when the authorization process is performed, the Assessor shall negotiate for the additional scopes that it desires access to via the Patient Demographics Consumer in order to perform the assessment. The Assessor shall not require the Assessment Requester to implement the Patient Demographics Supplier and must be able to perform normally if the Assessment Requester does not support some of the additional requested scopes or resources.
- 640

645 The Assessment Requester may be grouped with a Patient Demographics Supplier 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 is grouped with a Patient Demographics Supplier 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

650 The Assessment Requester 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 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

655 *Add Section 3.71*

3.71 Query Artifact [PCC-71]

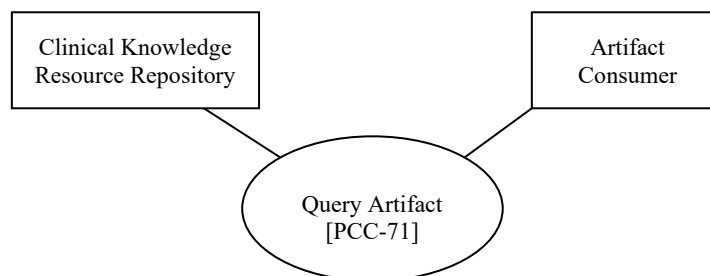
This corresponds to transaction [PCC-71] of the IHE PCC Technical Framework. Transaction [PCC-71] is used by the Clinical Knowledge Resource Repository and Artifact Consumer Actors.

660 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.

665 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



670 **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 RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

675

3.71.4 Messages

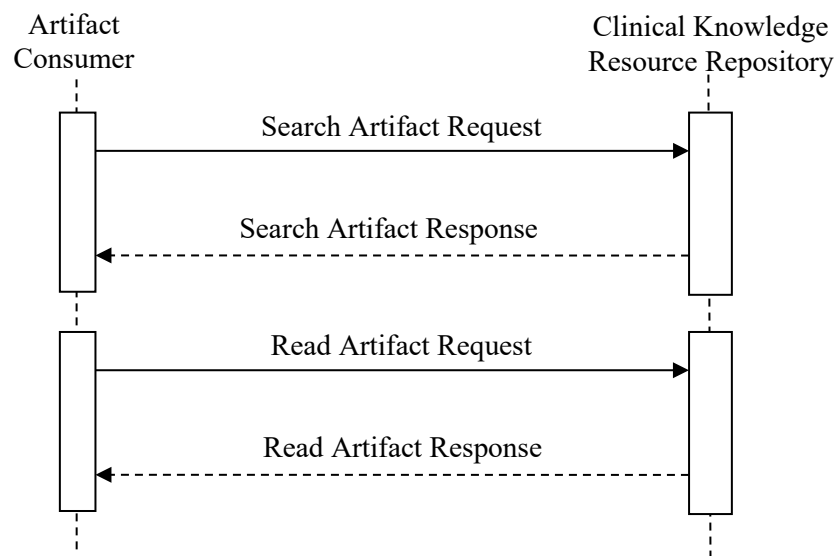


Figure 3.71.4-1: Interaction Diagram

3.71.4.1 Search Artifact Request Message

680 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

685 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.

690 The search target follows the FHIR http specification (<http://hl7.org/fhir/R4/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:

- 695 • 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.

700 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

705 All query parameter values shall be appropriately encoded per RFC3986 “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:

- 710
 - `_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)
- 715
 - `description` (string)
 - `name` (string)
 - `publisher` (string)
 - `status` (token)
- 2. A query based on the canonical url of the Assessment instrument.
- 720
 - `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>.

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.

- 730 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.
- 735 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.
- 740 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).

745 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> and <http://hl7.org/fhir/R4/operationoutcome.html>.

750 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 PCC TF-3: 6.6.107.1 ACDC Questionnaire.

3.71.4.1.3.1 Resource Bundling

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

3.71.4.2 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.

3.71.4.2.1 Trigger Events

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

3.71.4.2.2 Message Semantics

765 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>), addressing the proper FHIR Resource type. The syntax of the FHIR read is:

```
GET [base]/Questionnaire/{id}
```

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

3.71.4.2.2.1 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.

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

3.71.4.2.3 Expected Actions

1. The Artifact Consumer shall send read artifact request to a Clinical Knowledge Resource Repository.
- 780 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 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

795 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.

800 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 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
- 805
 - 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 system identity
 - 810 ○ 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)
 - 815 ○ Clinical Knowledge Resource Repository system identity
 - RoleIDCode = EV(110152, DCM, “Destination”)
- Audit Source (1..1)
 - not specified
- Query Parameters (1..1)
 - 820 ○ ParticipantObjectTypeCode = “2” (system object)
 - ParticipantObjectTypeCode Role = “24” (query)
 - ParticipantObjectIDTypeCode = EV(“PCC-71”, “IHE Transactions”, “Query Artifact”)
 - 825 ○ 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

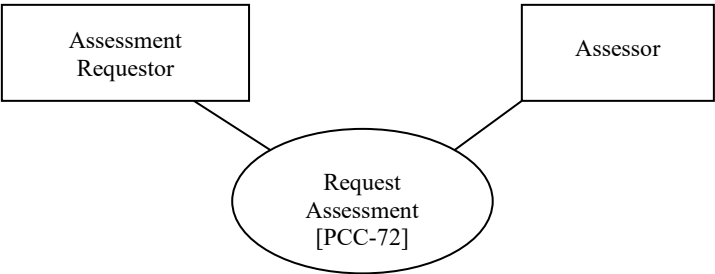


Figure 3.72.2-1: Use Case Diagram

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 RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

3.72.4 Messages

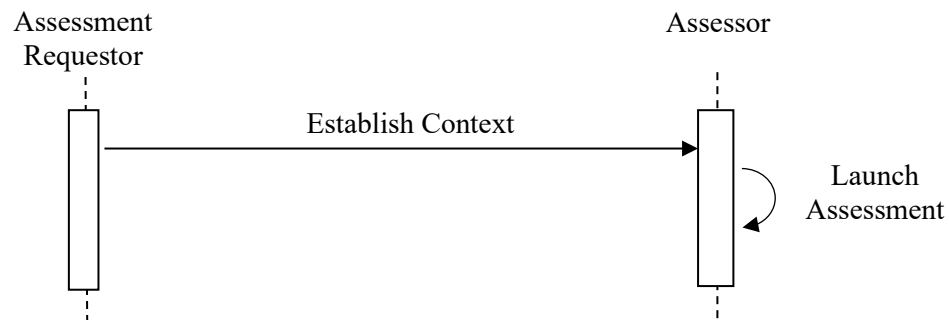


Figure 3.74.4-1: Interaction Diagram

845 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.

- 850 When the Assessment Requester 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.

855 **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.

860 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 corresponds to the EHR actors described in SMART on FHIR. The Assessor 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 Sequence¹⁰.

3.72.4.1.3 Expected Actions

865 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.

870 **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.

875 **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

- 880
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.

¹⁰ See <http://hl7.org/fhir/smart-app-launch/index.html#smart-authorization-sequence>

- 885 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

890 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

895 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, the Assessment Requestor and Assessor Actors both generate an Application Start Audit Event consistent with ATNA. The message shall comply with the following pattern:

- 900 • Event
- EventID = EV 110100, Application Activity, “Audit event: Application Activity has taken place.”)
 - EventTypeCode = EV(110120, Application Start, “Audit event: Application Entity has started.”)
 - 905 ○ EventActionCode = “X” (Execute)
- Application Launcher (1..1)
 - UserID = The Assessment Requestor system identity
 - RoleIDCode = EV(110151, DCM, “Application”)
 - Patient (1..1)
 - 910 ○ 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)
 - 915 ○ Assessor system identity

- RoleIDCode = EV(110150, DCM, “Application”)
- Audit Source (1..1)
 - not specified

920 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.”)
 - 925 ○ EventTypeCode = EV(110121, Application Stop, “Audit event: Application Entity has stopped.”)
 - EventActionCode = “X” (Execute)
- Application Launcher (1..1)
 - UserID = The Assessment Requestor system identity
 - RoleIDCode = EV(110151, DCM, “Application Launcher”)
- 930 • 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
- 935 • Application (1..1)
 - Assessor system identity
 - RoleIDCode = EV(110150, DCM, “Application”)
- Audit Source (1..1)
 - not specified

940

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

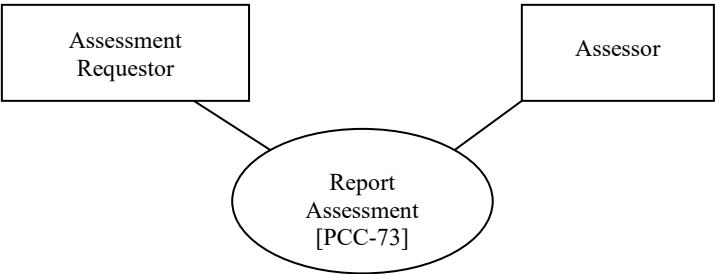


Figure 3.73.2-1: Use Case Diagram

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 RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

955 3.73.4 Messages

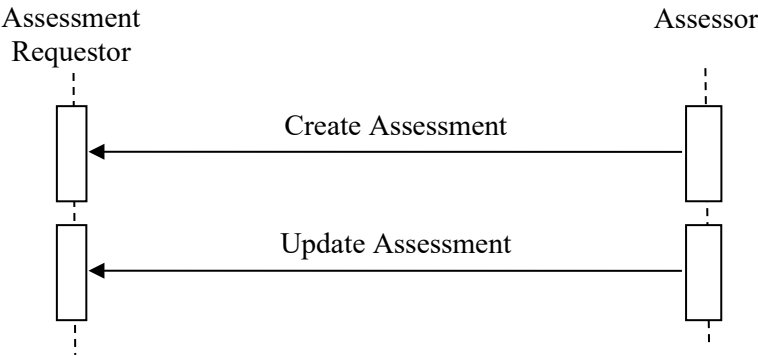


Figure 3.73.4-1: Interaction Diagram

3.73.4.1 Create Assessment message

960 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.

3.73.4.1.2 Message Semantics

965 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

970 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.

975 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

980 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 6.6.108.1. The value of `Questionnaire.status` in this request shall be "completed".

985 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.

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

{
  { "resourceType": "QuestionnaireResponse" },
  { "status": "completed" },
  :
}
```

995 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.

1000 An example response is given below:

HTTP 200 Ok

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

3.73.4.2 Update Assessment message

1005 The Assessor reports the results of the updated assessment in a QuestionnaireResponse to the Assessment Requester as a QuestionnaireResponse.

3.73.4.2.1 Trigger Events

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

3.73.4.2.2 Message Semantics

1010 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.

3.73.4.2.3 Expected Actions

1015 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 6.6.108.1. The Assessor shall set the value of `Questionnaire.status` in this request to "amended" or "entered-in-error".

1020 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.

1025

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

{
  { "resourceType": "QuestionnaireResponse" },
  { "status": "amended" },
  :
}
```

1030 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:

1035

HTTP 200 Ok

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

3.73.5 Capability Statement Resource

1040

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.

1045

3.73.6.1 Security Audit Considerations

When grouped with the Secure Node or Secure Application Actor, the Assessor 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:

1050

- *Event for the Assessor*
 - EventID = EV (110106, DCM, "Export")
 - EventTypeCode = EV(“PCC-73”, “IHE Transactions”, “Report Assessment”)
 - EventActionCode = “R” (Read)

1055

- *Event for the Assessment Requestor*
 - EventID = EV (110107, DCM, "Import")
 - EventTypeCode = EV(“PCC-73”, “IHE Transactions”, “Report Assessment”)
 - EventActionCode = “C” (Create)

1060

- Source of the request (1..1)
 - UserID = The Assessor system identity
 - RoleIDCode = EV(110153, DCM, “Source”)
- Patient (1..1)
 - *No additional constraints*
- Participating Object

- 1065
- ParticipantObjectTypeCode = 2 (system)
 - ParticipantObjectTypeCodeRole = 4 (other)
 - ParticipantObjectIDTypeCode = EV ("QuestionnaireResponse", FHIR, "QuestionnaireResponse")
 - ParticipantObjectID = *QuestionnaireResponse.identifier*
- 1070
- 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 system identity
- 1075
- RoleIDCode = EV(110152, DCM, "Destination")
 - Audit Source (1..1)
 - not specified

1080

Volume 3 – Content Modules

6.6 HL7 FHIR Content Modules

6.6.107.1 ACDC Questionnaire

1085

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	ΣS	0..1	questionnaire-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	http://ihe.net/fhir/ACDC/StructureDefinition/questionnaire-launchurl	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.

1090 **6.6.108.1 ACDC QuestionnaireResponse**

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

Table 6.6.108.1-1: 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 ¹¹ on the QuestionnaireResponse content.
... questionnaire	Σ	1..1	canonical(Questionnaire)	The questionnaire being answered must be provided.
.... extension		0..1	ihe-acdc-contained-questionnairereference	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	http://ihe.net/fhir/ACDC/StructureDefinition/questionnaire-launchurl	This extension supports a reference to a contained copy of the questionnaire resource. It is needed to ensure 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	ΣS	0..1	Reference(Encounter)	The encounter shall be present when known.

¹¹ See <http://www.hl7.org/fhir/extension-questionnaireresponse-signature.html>

Name	Flags	Card.	Description & Constraints	(Profile) Comments
... 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	ΣS	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.

- 1095 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.

1100 **Table 6.7.3.1-1: Launch URL Extension**

Name	Flags	Card.	Type	Description & Constraints
launchurl		0..*	uri	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	Flags	Card.	Type	Description & Constraints
containedquestionnaire-reference		1..1	Reference	http://ihe.net/fhir/StructuredDefinition/containedquestionnaire-reference Provides a reference to a copy of the questionnaire stored as a contained resource in the response. Use on QuestionnaireResponse.questionnaire

1105