IHE Work Item Proposal (Detailed)

# Proposed Work Item: Patient-Centric Data-Element Location Service

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Domain: IT Infrastructure with support from Patient Care Coordination (PCC)

**Summary**

Health information sharing relies on different granularity of exchanges:

* **Document Granularity**: Share and access documents as a composition of various data elements to reflect the information known and produced during a care or administrative workflow step. This granularity is optimum to ensure that contained data has clarity of context and reflects source attestation (responsibility) of clinical data.
* **Data Element Granularity**: Access a specific type of data elements (e.g. diagnostics, medications, etc.). This mode is optimum when list of Data Elements relevant to a “time span” or a set of encounters are of interest. Examples of situations where this granularity of access may of optimum are the access to a list of allergies at the time of medication dispensation, or information reconciliation at the time of hospital admission.

Both of **these modes deliver different benefits and their efficient coexistence is the objective of this profile**. Indeed a patient’s health records is structured and support both coarse-grained and fine grained granularity in location and access should apply to overall patient health record.

IHE has an array of profiles that have considered this integrated approach to health records as distinct use cases that have transactions that can be repurposed as foundation elements in this new profile. Much attention will be placed on the requirements that ensure a smooth combined used of these services in the most valued use cases.

A number of regional and national health information exchange platforms attempted to solve this problem, and many more are expecting such a solution for implementation in the coming one to two years. Vendors have also considered and deployed some approaches. It is a timely opportunity to being these implementation experiences as input and shape a consistent approach.

# The Problem

Records are currently shared for more than 200 Millions patients, on a daily basis, world-wide leveraging the use of:

* the peer-to-peer queries and retrieve between edge systems or community gateways (IHE XCA Profiles)
* the provide documents and queries to a shared document registry (IHE XDS Profile) followed by retrieve from centralized or distributed repositories

IHE has extended the to the above records submission (provide document set) and access (query and retrieve) from mobile devices with the more recent IHE MHD Profile (XDS/XCA on FHIR).

This has demonstrated that the sharing of documents across community/regional/national health information exchange platforms is one of the fundamental granularity of exchange of health records. However, such health information exchange platforms that support document sharing, are often considering extensions by offering cross-document data aggregation. This has been addressed in part with the “On-demand Document” option in XDS/XCA Profile and with the QED Profile that supports the granular access to specific data elements (e.g. list of medications, list of allergies). The QED Profiles was based on HL7 V3, and may likely be superseded by HL7 FHIR (Restful access to specific resources). Such FHIR resources are being standardized by HL7 are maturing with the soon to be released DSTU 3, with input from the US Argonaut group.

Note: on the basis of DSTU 2, HL7/Argonaut has:

**Data Element Query**

**Requirements per Resource Type**

* [Allergies](http://argonautwiki.hl7.org/index.php?title=Allergies) (closed 3/22, 0 open issue)
* [Assessment and Plan of Treatment](http://argonautwiki.hl7.org/index.php?title=Assessment_and_Plan_of_Treatment) (closed 10/4 0 open issue)
* [CareTeam](http://argonautwiki.hl7.org/index.php?title=CareTeam) (review until 6/14, 0 open issue)
* [Goals](http://argonautwiki.hl7.org/index.php?title=Goals) (closed 7/5, 0 open issue)
* [Immunizations](http://argonautwiki.hl7.org/index.php?title=Immunizations) (closed 7/5, 0 open issue)
* [Implantable Devices/UDI](http://argonautwiki.hl7.org/index.php?title=Implantable_Devices/UDI) (closed 7/5, 0 open issue)
* [Laboratory Results](http://argonautwiki.hl7.org/index.php?title=Laboratory_Results) (closed 4/21, 0 open issue)
* [Medications](http://argonautwiki.hl7.org/index.php?title=Medications) (closed 7/5, 0 open issue)
* [Patient](http://argonautwiki.hl7.org/index.php?title=Patient) (closed 3/22, 0 open issue)
* [Problems and Health Concerns](http://argonautwiki.hl7.org/index.php?title=Problems_and_Health_Concerns) (closed 5/31, 0 open issues)
* [Procedures](http://argonautwiki.hl7.org/index.php?title=Procedures) (closed review until 8/2, 0 open issues)
* [Smoking Status](http://argonautwiki.hl7.org/index.php?title=Smoking_Status) (closed 3/31, 0 open issues)
* [Vital Signs](http://argonautwiki.hl7.org/index.php?title=Vital_Signs) (closed 3/31, 0 open issues)

Argonaut is in the process to update to DSTU in the Q1 2017 timeframe.

***This proposal is intended to introduce location discovery and fine grained access to health data to coexist and complement coarse grained (document as a coherent set of fined grained data elements) access.***

# Use Cases

Basic Use Case

Following an encounter of a patient with a family physician, a transfer of care document is shared. The patient is advised by the family physician to make an appointment for a surgery. Then the patient picks up his prescribed medication at the local pharmacy that result in sharing a dispensation document. The patient makes an appointment with the local hospital for a scheduled surgery. Being back at home, the patient uses his smart phone to:

1. **access the recent prescription and recently dispensed medications** to review the posology and take his medication with the right dose. For this, the prescription and dispensation information need to be extracted from these documents and only the prescription information accessed by the consumer app on his smartphone.

However the patients’ condition worsens resulting in an emergency hospitalization. The emergency physician:

1. needs to urgently stabilize the patients’ condition and seeks to ***obtain his current medication list*** (the medications prescribed and dispensed need to be extracted from at least two documents)
2. then decides to complete the patient admission and schedule the intended surgery. For this, he ***needs to retrieve the transfer of care document.***

To prepare the surgery:

1. the anesthesiologist n***eeds to obtain the medication history and the list of known allergies*** (the allergies need to be extracted for the past 10 years from all shared documents for the patient)

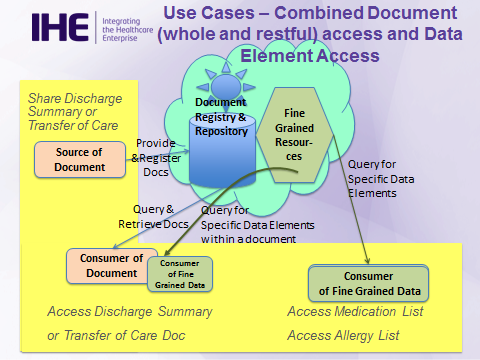
Secondary Use Case

A consumer opens an app on his smart phone, through which he wants to review the discharge summary associated with his surgery from the previous use case (Step 4).

1. ***The consumer app queries the document registry to list the recent documents shared*** for the patient, the patient selects the discharge summary of interest.
2. ***The app choses to retrieve the document content as a set of FHIR resources*** (even if the shared document has been shared as a CDA document).

# Standards & Systems

Several approaches should be analyzed for the first use case (Basic Use Case in Section 3):



Just like documents’ metadata are recorded in a document registry, data elements (or Resources in the cases of HL7 FHIR) could be recorded in a sort of resources registry or a records location service.

The **duality between document-level access and resources (data element) level access** should also be considered to leverage a document registry (a resource in the MHD sense) to be exploded as a composition of resources that make up the document content. This would allow a restful access to a document content (e.g. drilling into a CDA document). This may be considered an extension to MHD, setting relationships, between the document, its composition and individual resources.

This proposed profile needs to be articulated with related profiles addressing complementary but distinct use cases:

## The non-patient centric search for services and end-points offered by APIs

There are some efforts in Argonaut to create a directory that can be used for this. At the minimal end, it is a replacement for a UDDI. The present proposal is not to duplicate this on-going effort for which IHE could get more visibility, so that the international community might become interested.

## Trust Framework

One can't expose patient information until one has a trust-framework. It is only when there is a basis of trust that one should expose any patient specific information. Because documents are easily linked with “encounters” trust frameworks for document sharing have been reasonably easy to establish and form the large majority of trust framework world-wide at regional or national levels (even at cross-border levels such as epSOS in Europe).

The design of this profile should leverage such trust framework to the maximum extended possible for ease of implementation.

## Systems involved in this profile proposal are:

* + Hospital/practice EMR/EHRs
  + Pharmacy IT systems
  + Mobile Consumer and Provider Apps
  + Health Information Exchange Infrastructure at the community, regional or national levels

## Relevant Standards and Transaction from IHE Profiles are:

* + IHE XCA and IHE XDS profile transactions (SOAP-based)
  + IHE MHD profile transactions (REST-based), HL7 FHIR DSTU2-based.
  + IHE RECON transactions, HL7 FHIR (pre-DSTU 2-based)

# Technical Approach

## Use case refinement, key requirements

The dynamic combination of the access with different level granularity using different standards or the same standard within drastically different profiling requires the consistency of document and data element metadata and in particular identifiers. For example, the profile will likely have constrain how from a specific resource identifiers, the attribute needed to access the document from which the resource is extracted. This will have to be performed at the level of actor groupings requirements (See section 5.3), when such actors originate from transactions reused from different profiles.

## Review the PCC RECON profile/transaction

Applicability here is the general process flow enabled by the PCC RECON profile:

Data Providers

Reconciliation Agent

Content Creator /  
Clinical Data Source

Content / Clinical Data Consumer

1. Collect Data

2. Merge Streams

3. Reconcile Data

4. Store

**5. Deliver  
Reconciled Content**

It is important to note that the Profile transactions enable the delivery of “reconciled content” (results from an algorithmic and manual process by clinicians). The selected transactions support the step 5 in the figure above.

These transactions are focused on the delivery of the “reconciliation facts” along with other clinical data already defined in two transactions from other profile/standards:

* + The way to convey reconciliation results in any document (HL7 CDA)
  + The way to convey reconciliation results in any a Query for Existing Data [PCC-2] transaction (HL7 V3)
  + The way to convey reconciliation results in any Share List [PCC-16] transaction (HL7 FHIR)

Clinical Data Consumer

Clinical Data Source

Actor DEF

The proposed conclusions from this quick analysis that will need to be confirmed:

* + 1. The Share List [PCC-16] transaction from the IHE RECON profile cannot be reused as such.
    2. FHIR Operations upon which the Share List [PCC-16] transaction is designed can be reused, but one will have to restart from FHIR STU3 as RECON was based on a pre-DSTU2
    3. The reconciliation automated logic from RECON can be reused as such, as a valuable option for the Clinical Data Source Actor.

## Actor Grouping between doc sharing and query for data elements

* **Draft Actor Diagram**

Clinical Data Source

Actor DEF

Document

Repository

Actor DEF

Document Recipient

Actor DEF

Clinical Data Consumer

Document Source

Document Consumer

Document Registry

Actor DEF

Document Responder

Actor DEF

It is proposed to plan for a follow-on step (not within this year proposal) to address the cross-community variation, possibly along the following:

Clinical Data Source

Actor DEF

Clinical Data Consumer

Initiating Gateway

Actor DEF

Responding Gateway

Actor DEF

Document Consumer

* **New actors**

No new Actors needed

* **Existing actors**

Document Source, Document Consumer, Document Registry/Repository (XDS)

Initiating Gateway, Responding Gateway (XCA)

Document Recipient/Document Responder (MHD)

Clinical Data Consumer Clinical Data Source (RECON)

* **New transactions (standards used)**

There is only one new transaction needed, called initially: Query for List.

See the discussion about RECON [PCC-16] in Section 9.2.

This transaction should be based on the FHIR Resource List (See current STU3 Build at : <http://build.fhir.org/list.html>)

* **Points of consistency between transactions**

One of the key value add of this proposed profile is to ensure that the health data exchanged at different level of granularity. Three points of consistency seem to be most important:

* 1. When an item is accessed by a Clinical Data Consumer Actor and found relevant, one need to offer a simple way to extract “identifiers” from the item to access or one or more documents in which this item was initially shared.
  2. When a document is accessed by a Document Consumer and some element found relevant, one need to offer a simple way to extract identifiers from the document where the element was found relevant to access “like” items that may have been shared.
  3. When relevant documents are queried and a list of matching documents is returned, rather than retrieving the set of documents, one may want to access the content by type of content (See also Section 9.4)
  4. Some of those ‘identifiers” may also be needed for clinical decision traceability.

## Access to Resources within a document

When accessing fine-grained data elements, one may scope the query in various ways:

* 1. A certain type of data element across all available health data
  2. A certain type of data element for a certain type period and across all available health data
  3. A certain type of data element shared since the last query and across all available health data
  4. A certain type of data element within one or more documents
  5. All data elements within one document

## Document content and data elements extractions.

The intent of this profile is to enable the sharing of all types of health record content. The mapping of clinical data between different formatting standards is necessary to deploy this profile is assumed to be possible and supported. However, this level of content management specification is out of scope. This profile proposal is precisely the setting of the infrastructure where document sharing and data elements access and location can be addressed. On that powerful health information exchange infrastructure, such mapping and in particular the HL7 CDA Content to FHIR Resources mapping can be deployed and operationalized. One should note that the CDA to FHIR mapping is not specified within this profile and is out of scope.

## Health Information Location Service approach

In term of health data location services, document sharing and XDS have demonstrated their dominance as the most effective approach to solving this challenge. With the development of the RESTful world with http operations through URLs, it is not clear if a new paradigm needed. **The development of this profile proposal takes an approach where data location is aligned with the document repository that would support both document based retrieve and data-element query, thus making locating documents and data elements considered jointly.**



The starting point is to use two complementary routes:

* 1. document query as locator for documents, and from this coarse grain location, that seem to have some efficiency advantages, move to the retrieve of specific documents (and access their fine-grained content), or aggregation through on-demand documents
  2. document query as locator for documents, and from this coarse grain location, that seem to have some efficiency advantages, aggregation through selection of lists of fine-grained data elements

## Style of documentation for the profile

* **Impact on existing integration profiles**

This profile will reference transactions from existing profiles: XDS, XCA, and MHD.

* **New integration profiles needed**

This proposal will be a new profile.

The creation of a new profile based on FHIR Query List may be considered, but should not be necessary.

* **Breakdown of tasks that need to be accomplished**

The breakdown of tasks proposed is reflected by the structure of the section 5.

# Risks

Given the work done by Argonaut on query of key data element (Per US meaningful use data set), the emergence of a query for fine-grained data elements in FHIR should reach maturity in 2017, to eliminate most risks for this proposed profile.

# Open Issues

To be completed

# Effort Estimates

IHE ITI, possibly with collaboration with PCC, is the best venue to address this use case.

It is indeed strategic to introduce such a service, not only as a new profile to be deployed stand-alone, but also as a companion profile to MHD (XDS/XCA on FHIR) and to XDS/XCA.

This effort includes only three work components:



1. The overall “assembly” of the new profile with integration of existing transactions from existing profiles (such as MHD and XDS, except for the “QED on FHIR” – See component 3 below). This is a very classical profile, which will be simple to write, as the actors and transactions are all known and well defined (including QED on FHIR that is functionally equivalent to QED).
2. The specification of the “Points of consistency” between transactions of this proposed profile is to ensure that the health data exchanged at different level of granularity can be linked (See Section 5.3). This is the key value added element of this profile enabling the “linking” between documents and data elements.
3. The specification of a “*thin QED on FHIR*”. Having a “stub” for such a new profile is important for the usefulness and adoptability of this new profile proposal (See component in point 1 above). Such a Thin QED on FHIR” is realistic given:
   1. the work done in HL7 with DSTU3 in that area,
   2. the implementation experience of the US Argonaut that supports the DSTU3 emergence.
   3. The scoping and TF Volume 1 framework that exists for existing QED (only 7 pages long).

The missing work is only the Volume 2 transaction development that will be a direct reference to FHIR (via Argonaut Profiles, digested by HL7) using the query list code identified in QED (work done).

IHE-ITI has coordinated with IHE-PCC and reached the following agreement:

* 1. **PCC will decide:**
     1. the profile “packaging” (distinct profile or integrated into QED, possibly retire QED), update existing supplement.
     2. the core set of “resources” that align with QED, FHIR stability and Argonaut work, plus PCC member input)
     3. the query parameters in Volume 2.
  2. **PCC work needed:**
     1. 2 hours face to face time in Feb, April and 4 hours in July, plus one 2 hour t-con in March, May, June (between face to face meetings).
  3. **ITI editor work needed:** 
     1. develop a TI version for the PCC framework (7 pages Vol.1-same as current QED and 10 pages Vol.2-down from 35 pages for current QED).
     2. account for the above decision points” (See 1 above).
     3. Reference “QED on FHIR profile” as PCC supplement in ITI profile.
  4. **Approval and Ownership - The QED on FHIR TI profile:**
     1. once developed by ITI editor, to be reviewed by ITI for technical “touch points” between resources and documents
     2. to be submitted to PCC for overall approval in July.
     3. to be handed over to PCC in August 2017 as PCC supplement