Integrating the Healthcare Enterprise

IHE ITI
Technical Framework Supplement

Patient-centric Data-element Location Service (PDLS)
Access to Document-extracted Data-elements

Rev. 1.0 – Draft for Public Comment

Date: May 26, 2017
Author: IHE ITI Technical Committee
Email: iti@ihe.net

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework V13.0. 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 May 26, 2017 for public comment. Comments are invited and can be submitted at http://www.ihe.net/ITI_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by June 25, 2017.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

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

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

Information about the IHE IT Infrastructure 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.

The current version of the IHE IT Infrastructure Technical Framework can be found at http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

The Patient-centric Data-element Location Service (PDLS) Profile introduces the means to access data elements extracted from shared structured documents. The profile enables the deployment of health data exchange infrastructures where fine grained access to health data coexists and complements the sharing of coarse grained documents and the fined grained data elements they contain.

This profile is based on the reality that health information sharing relies on different granularities of exchange:

- **Document-Level 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 steps. This granularity is optimum to ensure that contained data has clarity of context in care delivery and reflects source attestation (responsibility) of clinical data shared.
- **Data Element-Level Granularity**: Access a specific type of data elements (e.g., diagnostics, medications, etc.). This mode is optimum when a list of data elements relevant to a "time span" or a set of encounters are of interest. Examples of situations where this level of granularity may be optimum include access to a list of allergies at the time of medication dispensation, or information reconciliation at the time of hospital admission.

Each granularity level delivers unique benefits and this profile provides efficient access to both levels.

The sharing of documents across community/regional/national health information exchange platforms is one of the fundamental paradigms of exchange of health records. Currently, these kinds of records are often shared using IHE profiles such as: Cross-Enterprise Document Sharing (XDS), Cross-Community Document Sharing (XCA), and Mobile access to Health Documents (MHD with XDS on FHIR®[1]).

However, many health information exchange platforms that support document sharing are considering extending their services by offering cross-document data aggregation. This can be addressed, in part, with the access to documents created on-demand with the On-Demand Document Source in the XDS Profile, and, in part, with profiles such as PCC's Query for Existing Data for Mobile (QEDm) Profile that supports the granular access to specific data elements (e.g., list of medications, list of allergies).

The PDLS Profile allows an integrated approach to health records by using existing services from these the IHE profiles mentioned above. It is based on an array of already defined actors and transactions that are considered as foundational elements for this IHE profile and combined to smoothly achieve an interoperable solution.

[1] FHIR is the registered trademark of Health Level Seven International.

The mapping of the document content to data-elements is outside scope of profile. It needs to be specified based the specific document content and data element managed for each implementation deployments.

The PDLS Profile doesn't address reconciliation of the fine-grained data elements gathered by the Clinical Data Source and/or Clinical Data Consumer Actors. Grouping those actors with the PCC RECON Reconciliation Agent would not be successful, as the current version of the RECON Profile needs be updated to make this actor properly work together with QEDm and PDLS Actors.

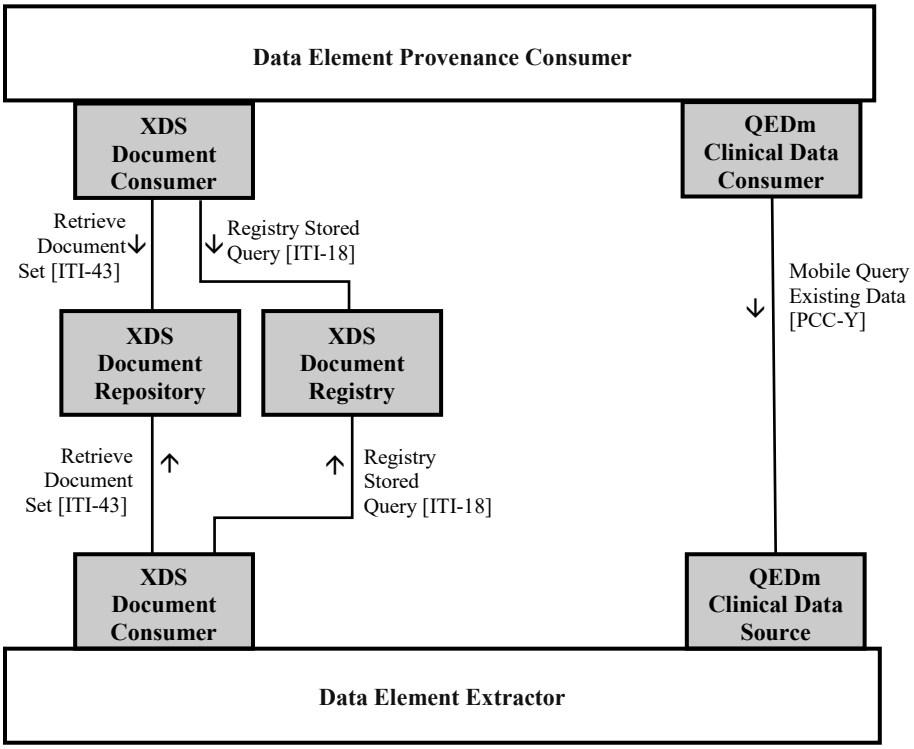
Open Issues and Questions

PDLS_101: The actor diagram is shown as three alternative groupings of actors. Should we simplify the presentation by showing a single diagram and include some text explaining the choices that are introduced later as options?

PDLS_102: What other Deployment Models should be considered besides the two described in Section E.7, if any?

PDLS_103: Should we consider the integration of a document sharing environment where an XDS Document Consumer is grouped with a Data Element Extractor?

Guidance is sought from reviewers around the need to introduce an option where an XDS Document Consumer is grouped with the Data Element Extractor to gain access to documents content and extract data elements along with creation of provenance resources. See diagram.



On the one hand, this option would allow a Data Element Extractor to be an independent product from the XDS Document Registry, and to be able to work in both XDS and XCA environments. On the other hand, this approach would likely be less efficient than the already document option integrating with a Document Registry. It might be possible to mitigate some of those inefficiencies through document subscriptions and content prefetching.

Input is requested on whether there is need for such an option.

Closed Issues

PDLS_201: how to manage fine grained data 'Location' and Reconciliation in an Affinity Domain with N Repositories?

We are defining a data locator service that allows to collect all the fine-grained information of interest by querying in a 'central point'.

Case #1: 1 XDS Registry + 1 XDS Repository (& Fine-Grained Data Repository)

- the Clinical Data Source can be providing data-elements resources as the central point for querying & retrieving ALL fine-grained data
- Reconciliation may be placed at this central point.

⇨ OK (for centralized reconciliation & access)

Case #2: 1 XDS Registry (with a central Clinical Data Source or Fine-Grained Data Repository)+ N XDS Repositories

- The unique XDS Registry still works well as master top-level index for coarse grained XDS Documents,
- The Clinical Data Source & Reconciliation grouped with the Registry/Responder still works well as a central point to query/access fine-grained information.
- The Clinical Data Source is grouped with a Document Consumer to access and extract data-elements out of documents content from the N Document Repositories, each providing a subset of the data (this may happen with caching when new documents are registered or on demand when the Clinical Data Source is queried for Data Elements.

Case #3: 1 XDS Registry + N XDS Repository (Each with a Clinical Data Source or Fine-Grained Data Repository)

- The unique XDS Registry still works well as master top-level index for coarse grained XDS Documents, but there is no longer have a central point to query/access fine-grained information.
- When the Clinical Data Source Actors placed at the level of each Doc Repository, each provides a subset of the data
- This case raises two issues:
  - The Clinical Data Sources are no longer unique. Is that an issue? It may imply that some deduplication/reconciliation may be necessary by the Clinical Data Consumers
  - This deployment requires specific behavior from the Clinical Data Consumers to locate the various Clinical Data Sources.

Resolution:

⇨ ***When multiple Doc Repositories in an affinity domain deployment, Case 2 should be supported, but case #3 appears to be a very particular case that need not be covered by PDLS. Case #1 and # 2 will be the two deployment models to be***

discussed in an informative section (See Section 7 on Deployment Models).

PDLS_202: Is fine-grained content always derived/derivable from Documents?

PDLS assumes that the shared Repository/Registry is being fed by document sources with documents that are shared.

The data elements contained in these documents is offered for data-element level query and extracted as a Clinical Data Source and delivered as query responses to clinical data consumers.

Is this the only input that is used?

Couldn't we consider fined grand data elements that have not be created/shared through the provide and register of documents?

This was already considered in the on-demand documents option of XDS.

Another way to ask the same question, is whether the PDLS Profile should be limited to consider fine-grained content derived/derivable from Documents that are persisted in a certain XDS Repository?

Resolution:

- ⇨ ***It is allowed in PDLS to have data-elements not coming from documents. Impacts of such flexibility will be analyzed (e.g., impact on privacy).***

PDLS_203: Privacy and BPPC consent policies

Any specification about privacy?

It is necessary to provide some "guidance", but no need for a solution as this would be the topic of the grouping of PDLS with existing or future privacy IHE profiles.

The grouping with existing profiles may be of interest.

Resolutions:

- ⇨ ***To apply the existing BPPC/APPC consent from the source document to each "fine-grained" element (privacy properties inheritance). This may be a simple and effective way to ensure consistent policies for both document-level and fined-grained data-element level access.***
- ⇨ ***For fine-grained data elements not coming from documents it's suggested to consider a new BPPC/APPC consent for specifying if someone can query or not for a certain category of information (e.g., consent to access the Vital Signs)***

PDLS_204: Integrity and credibility of information accessed

The profile provides a controlled approach to access the same health information either in a document level coarse grain level granularity or in a fine-grained data-element granularity.

The relationship between these two levels results in a number of situations that could result in "defects in information integrity and/or credibility in the information being accessed. The following points should be discussed in the profile:

1. Different forms of mappings may have to be performed. Although it is beyond the scope of the PDLS Profile to specify such mapping between data elements in documents and fined-grained data elements accessed directly, it is important that implementers note that:
    a. Such mappings may not be perfect (typical limitations in semantic mappings).
    b. Some information contained in the documents may not be "expressed" as data-elements (e.g., textual elements) and be "lost" in the data-element queries vs the documents
2. Some sources that have "signed" a document may object that it is "taking apart in data-elements" having the data elements taken out of the context offered by the document. These data-elements may not be made visible in the data-element granularity queries. Include examples: non-coded information is critical to interpret the coded information, constraint on use (e.g., document for display only), a treatment with stress induced that results non-generic vital signs. In all of those context is key to correct clinical interpretation.
3. PDLS is designed to "limit" these above issues, by offering the means to avoid these weaknesses of the "data-element granularity", by allowing the user that gets from a query lists of data elements, to easily request the document(s) that are sources of any of those fined-grained data-element of interest.

Resolution:

⇨ ***It is necessary to provide a good discussion on the above issues and "guidance" on the profile to help implementers of the profile.***

PDLS_205: Check/add the key requirements to ensure that health data is consistently exchanged at different level of granularity

The following points of consistency seem to be most important:

- *When a Data Element is accessed by a Clinical Data Consumer and found relevant, one need to offer a simple way to extract:*
    - *Identifiers from the Data Element in order to access one or more Documents in which this item was initially shared.*
    - *Use the above identifiers to access these documents content and "related" items that may have been shared.*
- *Some of those 'identifiers" may also be needed for clinical decision traceability.*

Resolution:

285 ⇨ ***PDLS shall precisely define the identifiers that grant consistency between Documents and/or Fine-Grained Data Elements (e.g., from Data Element → discover the Document from which the resource is extracted). The concept of a Provenance Resource is profiled by PDLS to address these requirements.***

General Introduction

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

Appendix A – Actor Summary Definitions

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

Data Element Extractor – The Data Element Extractor extracts data elements from documents along with the associated provenance information that traces back to the source document.

Data Element Provenance Consumer – The Data Element Provenance Consumer uses the provenance information associated with data elements to access the source information.

Appendix B – Transaction Summary Definitions

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

Not applicable

Glossary

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

No new terms added.

Volume 1 – Profiles

Add Section X

X Patient-centric Data-element Location Service (PDLS) Profile

The Patient-centric Data-element Location Service (PDLS) Profile introduces the means to access data elements extracted from shared structured documents. The profile enables the deployment of health data exchange infrastructures where fine grained access to health data coexists and complements the sharing of coarse grained documents and the fined grained data elements they contain.

This profile is based on the reality that health information sharing relies on different granularities of exchange:

- **Document-Level 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 in care delivery and reflects source attestation (responsibility) of clinical data shared.
- **Data Element-Level Granularity:** access a specific type of data element (e.g., vital signs, medications, etc.). This mode is optimum when the list of data elements relevant to a "time span" or a set of encounters are of interest. Examples of situations where this level of granularity may be optimum include access to a list of allergies at the time of medication dispensation, or information reconciliation at the time of hospital admission.

Each granularity level delivers unique benefits and this profile provides efficient access to both levels.

This profile defines rules to ensure consistency and traceability of information used for clinical decisions: when a data element is accessed by a Clinical Data Consumer, identifiers from that Data Element can be used to access one or more Documents in which this data element was originally recorded, providing a valuable broader clinical context.

Profile Introduction and concepts

The sharing of documents across community, regional, or national health information exchange platforms is one of the fundamental paradigm of exchange of health records. Currently, these kinds of records are often shared using IHE profiles such as Cross-Enterprise Document Sharing (XDS), Cross-Community Document Sharing (XCA), and Mobile access to Health Documents (MHD with XDS on FHIR).

However, many health information exchange platforms that support document sharing are considering extending their services by offering cross-document data aggregation. This can be addressed, in part, with the access to documents created on-demand with the On-Demand Document Source in the XDS Profile, and, in part, with profiles such as PCC's Query for

Existing Data for Mobile (QEDm) that supports the granular access to specific data elements (e.g., list of medications, list of allergies).

The PDLS Profile takes it one step further. It allows an integrated approach to health records by using existing services from the IHE profiles mentioned above. It is based on an array of already defined actors and transactions that are considered as foundational elements for this IHE profile and combined to smoothly achieve an interoperable solution.

The mapping of the document to data-elements is outside scope of profile. It needs to be specified based the specific document content and data element managed for each implementation deployments.

In the figure below, the sharing of health information supported by PDLS is depicted conceptually; highlighting that health information could be shared at different levels of granularity: document-level of granularity (shown with the green documents) and the data-element level of granularity (shown with orange hexagons). The health data exchange infrastructure depicted as a “hub” in the middle is providing a location service to access both documents-level or data-element-level health data in a patient centric manner.

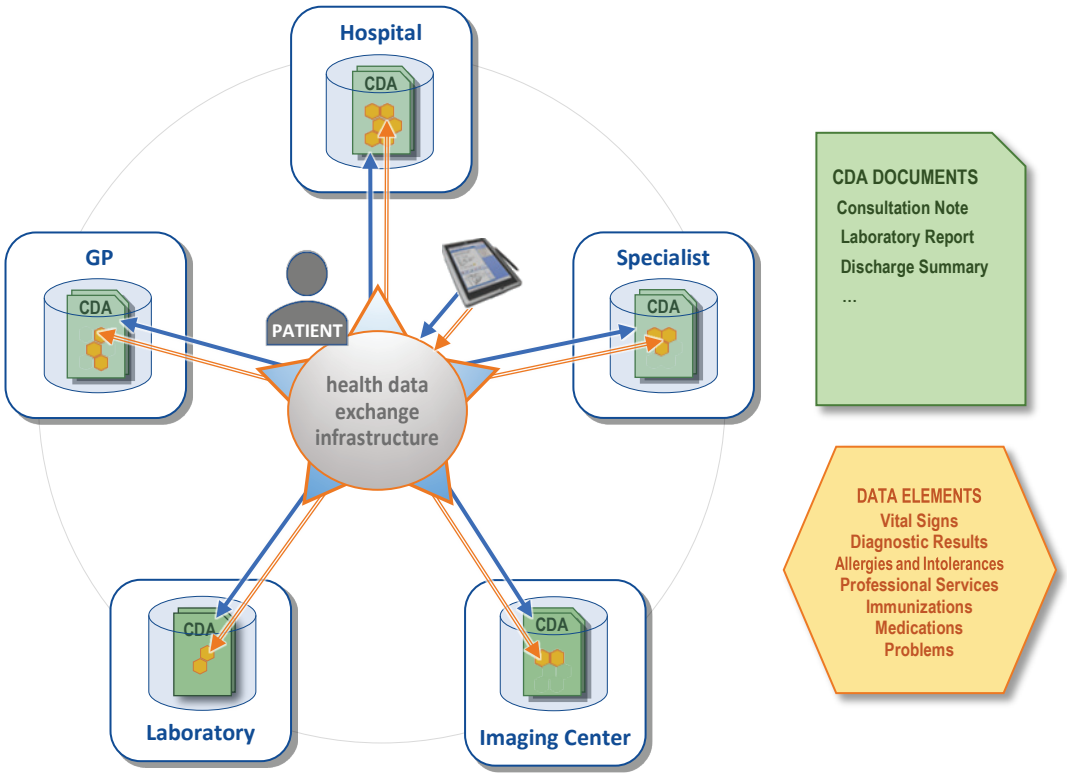


Figure X-1: PDLS environment and multilevel granularity access to health information

The actors of the PDLS Profile together with actors and transactions of other profiles which operate the exchange of information (MHD, XDS and QEDm) may also be used in conjunction with other transactions from these profiles that complement PDLS as depicted in Figure X-2 below.

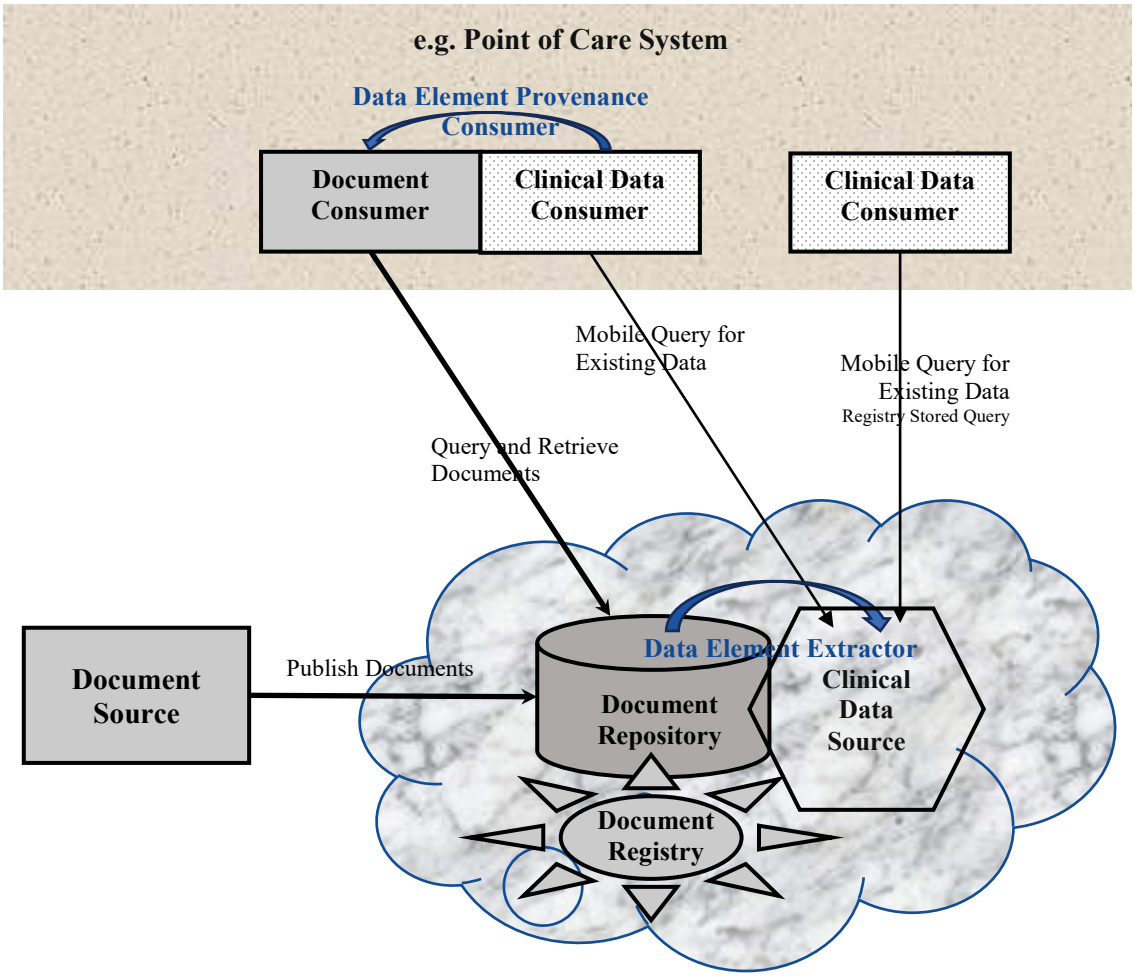


Figure X-2: PDLS Profile combining actors and transactions of other IHE Profiles

- Document-granularity "publication" is performed using the XDS Provide and Register transaction or the MHD (with XDS on FHIR) Provide Document transaction.
- Data Element-granularity access that is central to PDLS as discussed below in Section X.1. Leveraging the Provenance information returned with each fine-grained data element in the Query responses, the document from which the fine-grained Data Element was extracted, is identified.
- Document-granularity "consumption" that is central to PDLS as discussed below in Section X.1. Using the identification of the document from which the data element was extracted, it is possible to access the clinical context in which the fine-grained data element of interest was observed.

This profile supports a variety of deployment models. Some of those are discussed in Section 7.X

X.1 PDLS Actors, Transactions and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks, General Introduction, Appendix A at http://ihe.net/TF_Intro_Appendices.aspx.

Three alternatives groupings of actors are supported by PDLS. Each one is depicted by a separate figure that shows the actors directly involved in the PDLS Profile and the relevant transactions between them.

Each alternative groupings of actors supported is shown in conjoined boxes. The actors shown with dotted line boxes are not specified by the PDLS Profile.

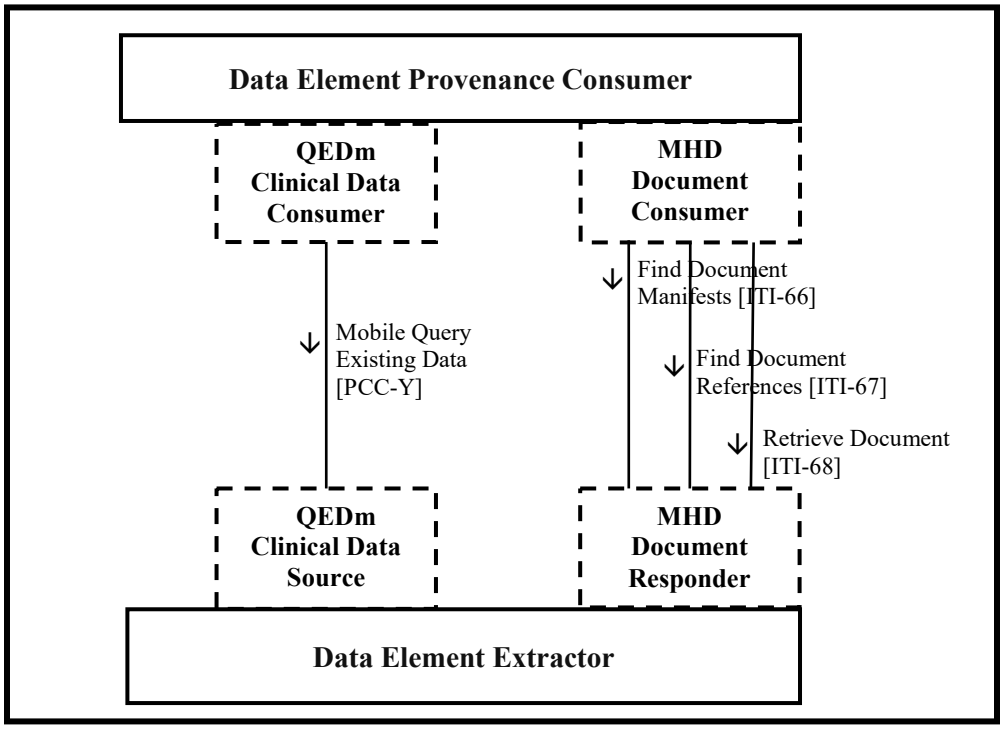


Figure X.1-1: QEDm and MHD based PDLS Actor Diagram

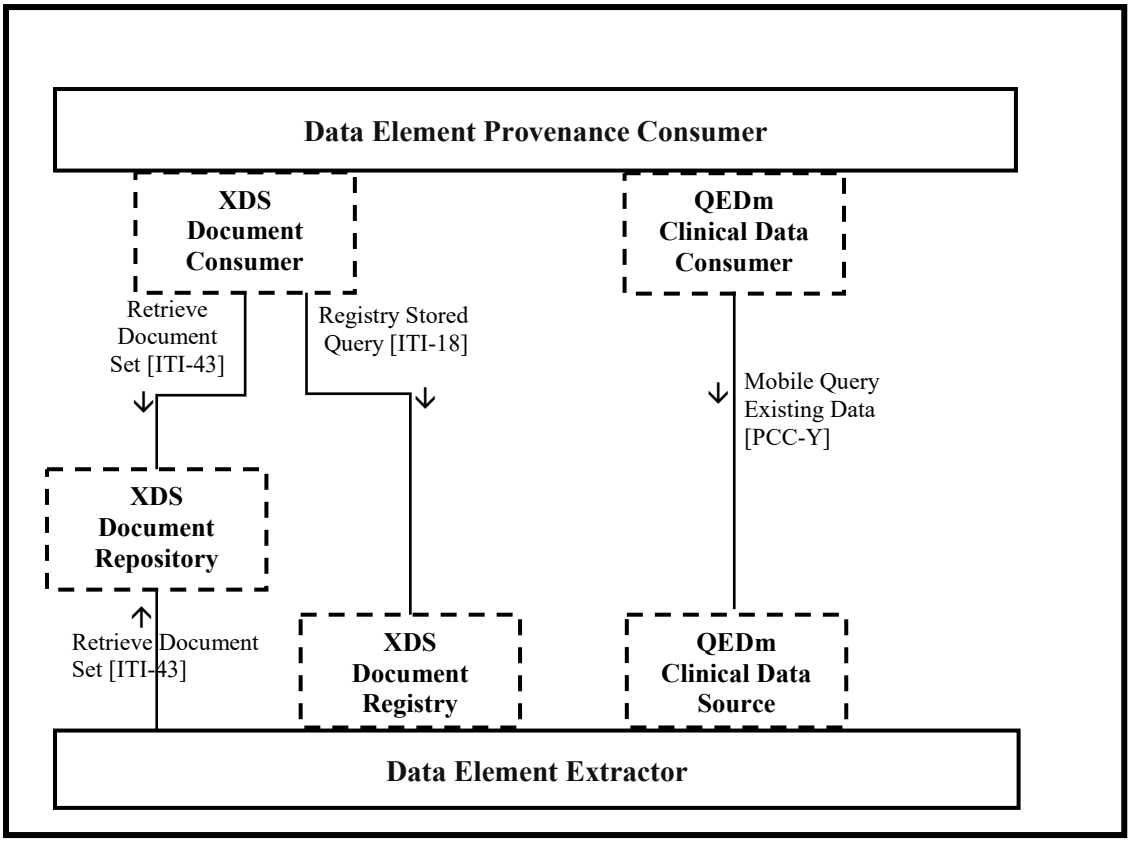


Figure X.1-2: QEDm and XDS based PDLS Actor Diagram

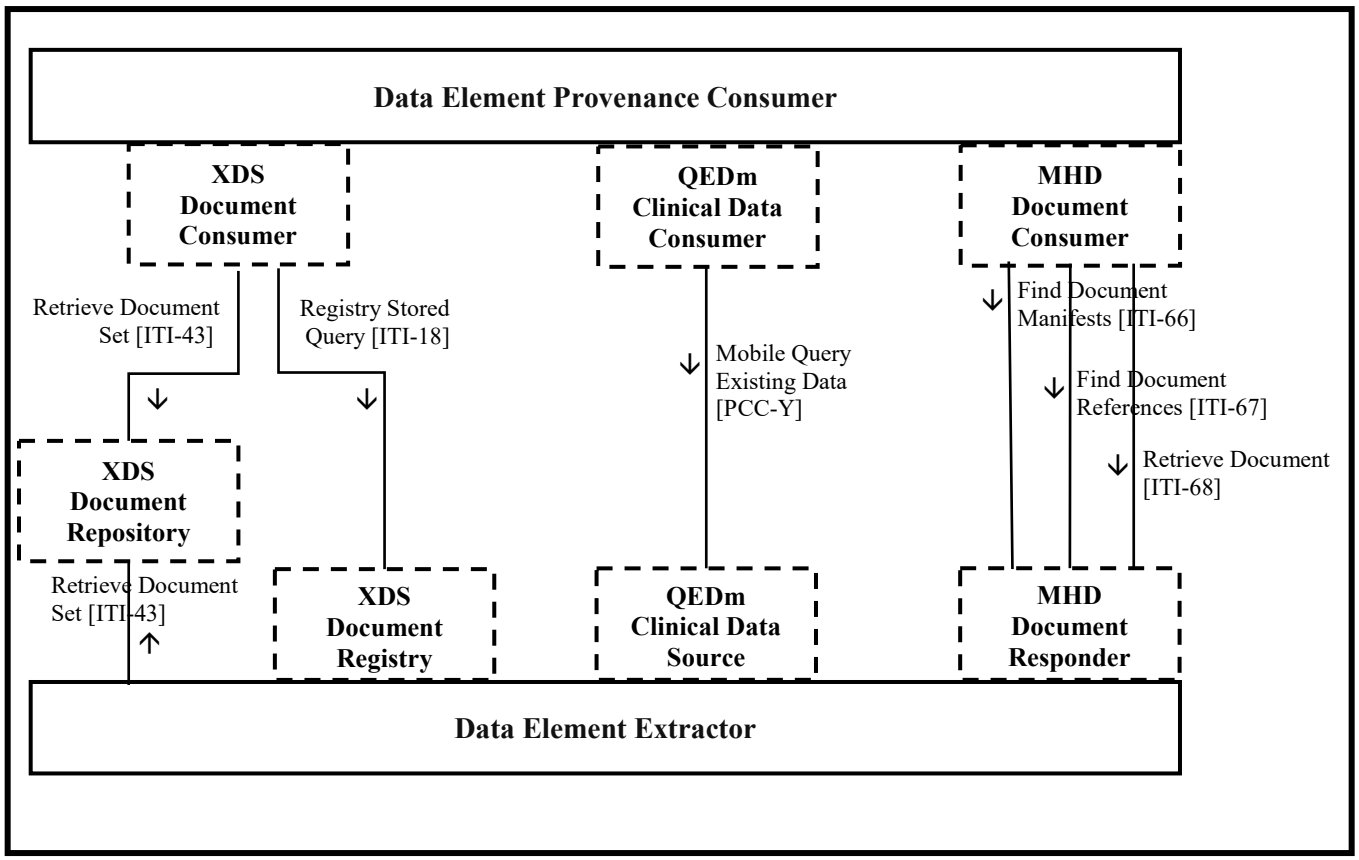


Figure X.1-3: QEDm, XDS and MHD based PDLS Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the PDLS Profile.

Table X.1-1: PDLS Profile - Actors and Transactions

Actors List	Transactions	Optionality	Reference
Data Element Extractor	Retrieve Document Set [ITI-43]	O (See note 1)	See ITI TF-2b: 3.43
Data Element Provenance Consumer	None	-	-

Note 1: This transaction required if the XDS Support-Document Registry Option is supported.

X.1.1 Actor Descriptions and Actor Profile Requirements

X.1.1.1 Data Element Extractor

The Data Element Extractor:

- Shall access Documents, through:

- A grouped XDS Document Registry and the Retrieve Document Set [ITI-43] transaction, or
- A grouped MHD Document Responder.

- Shall extract the Data Element information from the retrieved Documents
- Shall obtain and create the provenance information associated with each extracted Data Element so that it can be referenced and the Document from which it has been extracted may be accessed.
- Shall make this information available to the grouped PCC QEDm Clinical Data Source so that this provenance information can be returned in its query responses along with the extracted Data Elements.

X.1.1.2 Data Element Provenance Consumer

The Data Element Provenance Consumer:

- Shall be grouped with the QED Data Consumer to retrieve Data Elements through Data Element Queries.
- May extract the provenance information returned in responses to Data Element Queries. The provenance information identifies the source Document from which the Data Element was extracted.
- May use the provenance information to access a source Document through:
  - a grouped XDS Document Consumer, or
  - A grouped MHD Document Consumer.

X.2 PDLS Actor Options

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

Table X.2-1: Patient-centric Data-element Location Service – Actors and Options

Actor	Option Name	Reference
Data Element Extractor	XDS Support-Document Registry (note 1)	Section X.2.1.1
	MHD Support-Document Responder (note 1)	Section X.2.1.2
Data Element Provenance Consumer	XDS Support-Document Consumer (note 2)	Section X.2.2.1
	MHD Support-Document Consumer (note 2)	SectionX.2.2.2

Note 1: The actor shall implement at least one of the options XDS Support Document Registry or MHD Support-Document Responder

Note 2: The actor shall implement at least one of the options XDS Support Document Consumer or MHD Support-Document Consumer

X.2.1 Data Element Extractor Actor Options

X.2.1.1 XDS Support-Document Registry

The support of this option by a Data Element Extractor enables:

- the extraction of data elements contained in documents stored in an XDS Document Repository.
- the tracking of document provenance for the extracted data elements through references to source documents managed by the XDS Document Registry.

The Data Element Extractor that supports this option:

- shall be grouped with an XDS Document Registry
- shall create a Provenance resource for each of the Documents registered in the grouped XDS Document Registry. These Documents shall be retrieved using an XDS Retrieve Document Set [ITI-43] transaction.
- shall create a Provenance resource that meets the requirements of the PCC QEDm Profile Provenance Option (see PCC QEDm Trial Implementation Supplement, Volume 2, Section 3.Y.4.2.2.1 “Resource Specific Contents”).
- shall make the Provenance resource available to a QEDm Clinical Data Source so that it can be returned with references to Data Elements in query responses.

X.2.1.2 MHD Support-Document Responder

The support of this option by a Data Element Extractor enables:

- the extraction of Data Elements contained in Documents provided by the MHD Document Responder.
- the tracking of document provenance references for the extracted Data Elements through references to source documents provided by the MHD Document Responder

The Data Element Extractor that supports this option:

- shall be grouped with an MHD Document Responder
- shall create a Provenance resource for each one of the Documents provided to the MHD Document Responder
- shall create a Provenance resource as specified by the QEDm Profile Provenance Option (See PCC QEDm Trial Implementation Supplement, Volume 2, Section 3.Y.4.2.2.1 “Resource Specific Contents”).
- shall make this information available to a QEDm Clinical Data Source so that it can be returned with Data Elements in query responses.

X.2.2 Data Element Provenance Consumer Actor Options

X.2.2.1 XDS Support-Document Consumer

The support of this option by a Data Element Provenance Consumer enables:

- obtaining data elements through PCC QEDm Data Element Query (PCC-Y) issued by the grouped QEDm Clinical Data Consumer.
- the extraction of document provenance referencing each one of the data elements returned by QEDm Data Element Queries (PCC-Y).
- the ability to access the referenced source documents managed by the XDS.b Document Registry and Repositories.

The Data Element Provenance Consumer that supports this option:

- shall be grouped with a QEDm Clinical Data Consumer to perform QEDm data element query [PCC-Y] using the QEDm Profile Provenance Option
- shall obtain provenance resources associated with returned data elements so that it may identify the Documents from which a data element was extracted
- shall be grouped with an XDS Document Consumer and be capable of accessing the documents referenced by any provenance resource.

X.2.2.2 MHD Support-Document Consumer

The support of this option by a Data Element Provenance Consumer enables:

- the extraction of document provenance referencing each of the data elements returned by QEDm Data Element Query [PCC-Y]
- the ability to access the referenced source documents managed by the MHD Document Responder.

The Data Element Provenance Consume that supports this option:

- shall be grouped with a QEDm Clinical Data Consumer to perform QEDm data element query [PCC-Y] using the QEDm Profile Provenance Option
- shall obtain provenance resources associated with returned data elements so that it may identify the Documents from which a data element was extracted.
- shall be grouped with an MHD Document Consumer and be capable of accessing the documents referenced by any provenance resource.

X.3 PDLS Required Actor Groupings

Each one of the three alternatives of actor diagrams specified for the PDLS Profile in Section X.1 have different required actor groupings. An actor from this profile (Column 1) shall

implement all required transactions for the grouped actor (Column 2) in one of the three Required Actor Groupings Tables as shown below.

Table X.3-1: PDLS Profile - Required Actor Groupings for QEDm and MHD based PDLS

PDLS Actor	Actor to be grouped with	Reference
Data Element Extractor	PCC QEDm Clinical Data Source with the Provenance Option	<QEDm Reference here>
Data Element Extractor	MHD Document Responder	<MHD reference>
Data Element Provenance Consumer	PCC QEDm Clinical Data Consumer with the Provenance Option	<QEDm reference>
Data Element Provenance Consumer	MHD Document Consumer	<MHD reference>

Table X.3-2: PDLS Profile - Required Actor Groupings for QEDm and XDS based PDLS

PDLS Actor	Actor to be grouped with	Reference
Data Element Extractor	PCC QEDm Clinical Data Source with the Provenance Option	<QEDm Reference here>
Data Element Extractor	XDS Document Registry	XDS reference
Data Element Provenance Consumer	PCC QEDm Clinical Data Consumer with the Provenance Option	<QEDm reference>
Data Element Provenance Consumer		<XDS reference>

Table X.3-3: PDLS Profile - Required Actor Groupings for QEDm, MHD and XDS based PDLS

PDLS Actor	Actor to be grouped with	Reference
Data Element Extractor	PCC QEDm Clinical Data Source with the Provenance Option	<QEDm Reference here>
Data Element Extractor	XDS Document Registry	XDS reference
Data Element Extractor	MHD Document Responder	<MHD reference>
Data Element Provenance Consumer	PCC QEDm Clinical Data Consumer with the Provenance Option	<QEDm reference>
Data Element Provenance Consumer	XDS Document Consumer	<XDS reference>
Data Element Provenance Consumer	MHD Document Consumer	<MHD reference>

Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

X.4 PDLS Overview

X.4.1 Concepts.

See Section X, subsection: Profile Introduction and concepts.

X.4.2 Use Cases

The use case below assumes that every consumer device (mobile or not) knows or discovers the patient identity. The patient identity might be obtained through a transaction in an IHE profile such as PDQ, PDQV3, PDQm, PIX, PIXV3 or PIXm, or it might simply be entered via some device interface (RFID, Bar-Code, etc.) or a user interface, or be specified in a configuration setting (e.g., mobile PHR application).

X.4.2.1 General Use Case

A human using a consumer device needs to discover the available information of a certain patient and to retrieve the parts of interest in order to get coarse and fine-grained data based on the patient identity and on certain search criteria.

X.4.2.1.1 General Use Case Description

A patient encounters his family physician who advises him to make an appointment for a surgical procedure. Consequently, the family physician produces and shares (in an XDS Affinity Domain) a Transfer of Care document. He also shares a Pharmacy Prescription document.

Following the encounter, the patient makes an appointment with the local hospital for the intended surgery. He also picks up his prescribed medication at the local pharmacy which results in the pharmacy sharing a Pharmacy Dispensation document.

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 information is accessed by the patient portal app on his smartphone.

However, the patient's condition worsens, resulting in an emergency hospitalization.

At the emergency department, the emergency physician:

1. Urgently needs to stabilize the patient and seeks to obtain his current medication list (the medications prescribed and dispensed need to be extracted from at least two documents).
2. Decides to complete the patient admission and to schedule the intended surgery. For this, he retrieves the Transfer of Care document.

At the surgery department, the anesthesiologist:

1. While preparing the surgery, obtains the history of prescribed and dispensed medication and the list of known allergies (the allergies need to be extracted for the past 10 years from all shared documents for the patient)

At the conclusion of the hospital stay, the attending physician and other health professionals create and share the Discharge Summary document.

Back at home, the patient wants to review the Discharge Summary associated with his surgery. He opens the patient portal app on his smart phone, through which he:

1. Queries the Document Registry to list the recent documents shared for him and retrieves the selected Discharge Summary. The patient can read the recommendations on discharge and the new pharmacy prescription plus related dosage and decides to consult the family physician again for clarification.

In order to better evaluate the results, the family physician needs to check the improvements of patient health in time. The family physician uses his tablet to:

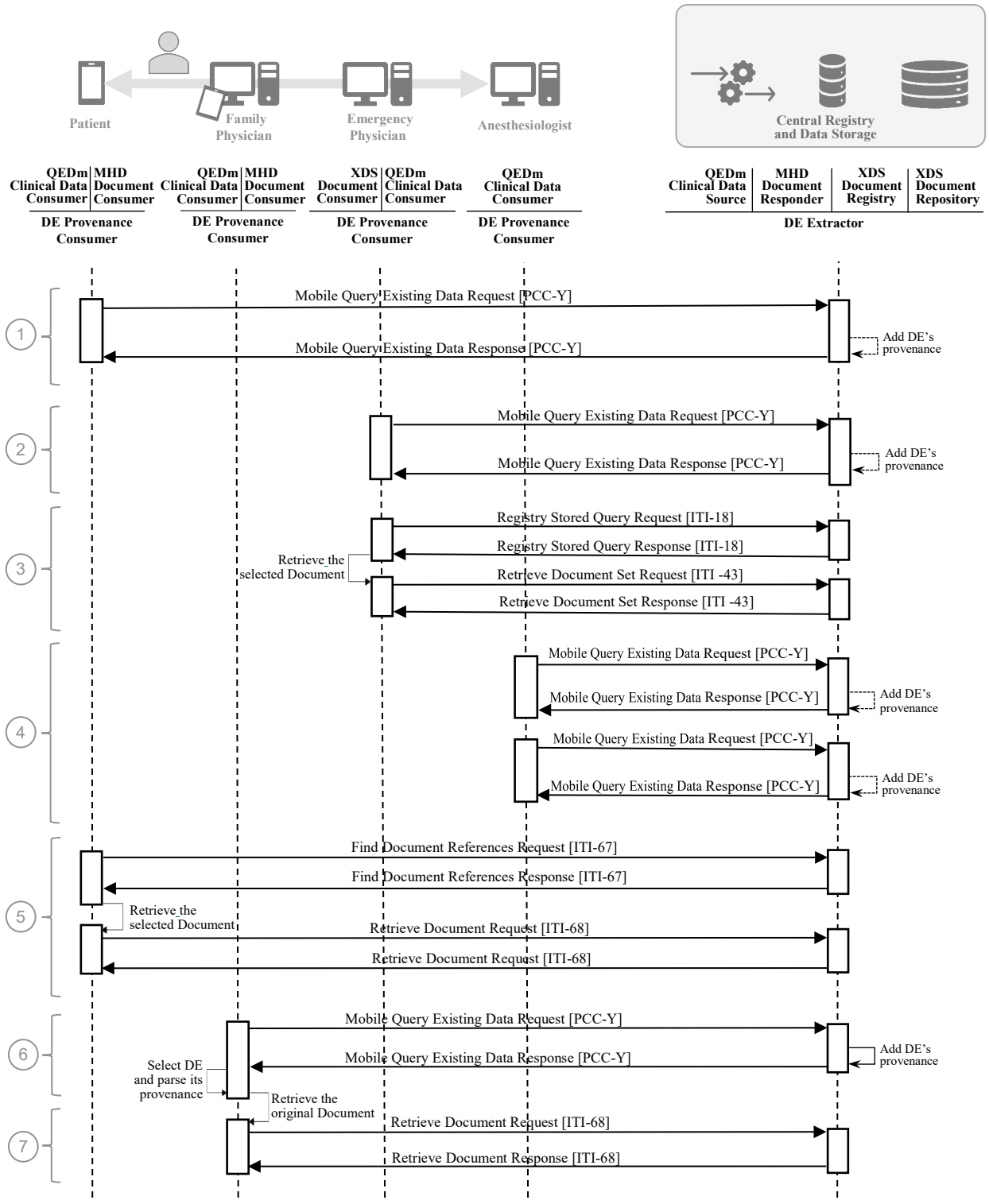
1. Query and access all the patient's vital signs and medications (directly as fine grained data elements) with related provenance information in order to reconstruct the patient's history about the cured pathology.
2. Then, each time he finds relevant changes in the patient's history, he uses the provenance information to identify any original document and eventually retrieves it. The document in which the original data was initially shared makes him understand the context at that time (other findings, observations, etc.) to better evaluate the meaning of fine grained information.

   This analysis helps the family physician to improve the care plan for the patient.

X.4.2.1.2 Process Flow

The following diagram assumes some plausible grouping between actors based on the scenario described for the Use Case. In particular, it assumes that a consumer application running on a mobile device (e.g., the patient's smartphone and the family physician's tablet) should support IHE profiles designed for mobile use, e.g., the MHD Document Consumer and the QEDm Clinical Data Consumer actors.

But different actor groupings could be conceived. The only mandatory groupings in the PDLS Profile are those specified in Section X.3.



595 **Figure X.4.2.1.2-1: Basic Process Flow in PDLS Profile**

X.5 PDLS Security Considerations

All interactions must be appropriately protected according to the various Security Considerations. That is QEDm, MHD, and XDS access controls apply and thus technology specific security profiles (e.g., XUA, and IUA). These access controls would continue to need to enforce any Privacy as well as Security rules (e.g., BPPC, APPC, etc.).

The Data Element extraction will access Documents using a user identity that indicates the automaton that is the exaction service. This identity will need appropriate access rights to access the document metadata and documents. This identity will thus likely have access to more documents than the user that uses QEDm to access the data elements.

QEDm is informed of the source of each elements by way of the Provenance. QEDm access control decision can thus be informed by this linkage, and that linkage can inform decisions to blind elements that come from a document that is blocked by a Privacy Consent.

Use of ATNA to record all transactions, automated or human initiated, is encouraged/required.

X.5.1 PDLS integrity and credibility of information accessed

The PDLS Profile provides a controlled approach to access the same health information either in a document-level (coarse grain) granularity or in a data-element level granularity (fine-grain). The relationship between these two levels results in a number of situations that could result in defects in information integrity and/or credibility in the information being accessed.

The implementer of this profile should consider the following specific issues:

1. Different forms of mappings may have to be performed when actor groupings have been implemented (it is beyond the scope of the PDLS Profile to specify such mapping between data elements in documents and data elements accessed directly), but the consequences need to be accounted for:
    a) Such mappings may not be perfect (typical limitations in semantic mappings).
    b) Some information contained in the documents may not be “expressed” as data-elements (e.g., textual elements) and will be unavailable in the data-element queries
2. Some sources that have approved or signed a document, may object to it being taken apart in data-elements out of the overall document context. The data elements from such documents would not be visible at the data-element level of access. Examples when such a situation arises are:
    a) non-coded information is critical to interpret the coded information,
    b) constraints that require that specific information be only for display but excluded from being copied or imported,
    c) a treatment summary with a stress induced test that results in “unusual” vital signs-in this context.

3. PDLS is designed to limit the above issues; it offers the means to avoid these weaknesses of the data-element granularity by allowing the user that retrieves a query list to easily request the document(s) that are sources of the data-element(s) of interest.

X.6 PDLS Cross Profile Considerations

ITI PIX - Patient Identity Cross Referencing and ITI PDQ - Patient Demographics Query

A PDLS Data Element Provenance Consumer may be grouped with a Patient Identifier Cross-reference Consumer in the PIX, PIXV3, or PIXm Profiles or with a Patient Demographics Consumer in the PDQ, PDQV3, or PDQm Profiles to resolve patient identifiers prior to submitting QEDm, XDS or MHD queries.

X.7 Deployment Models

For the implementation of the PDLS Profile, a number of actors that generally are considered as part of a health information sharing infrastructure may be organized in various architectural structures. Two deployment models are identified for information in this section. These may not be exhaustive and other variants may be supported.

In each one of these two deployment models, the "interoperability" defined by the PDLS transactions is the same.

Here are the main data flows described for each model:

1. Providing documents
2. Accessing data-element content and if desired one or more of the documents from which the data element was extracted. This access uses the document references conveyed in a provenance resource associated with the data element.

The systems involved in each deployment model are represented by grey boxes. Below are listed the actors implemented.

For simplicity, the flow diagrams use generic names for transactions that can be easily associated with the IHE transactions supported by the implemented actor.

This informative section also discusses the pros and cons of each deployment model.

X.7.1 PDLS Deployment Model A - Central Document Registry/Repository and Central Fine-Grained Data Source

In this deployment model, the health information infrastructure is designed as a centralized system, and groups an XDS Document Registry and Document Repository, and a QEDm Clinical Data Source to which fine-grained queries are directed. The operation of this deployment model is described through the transaction flows below.

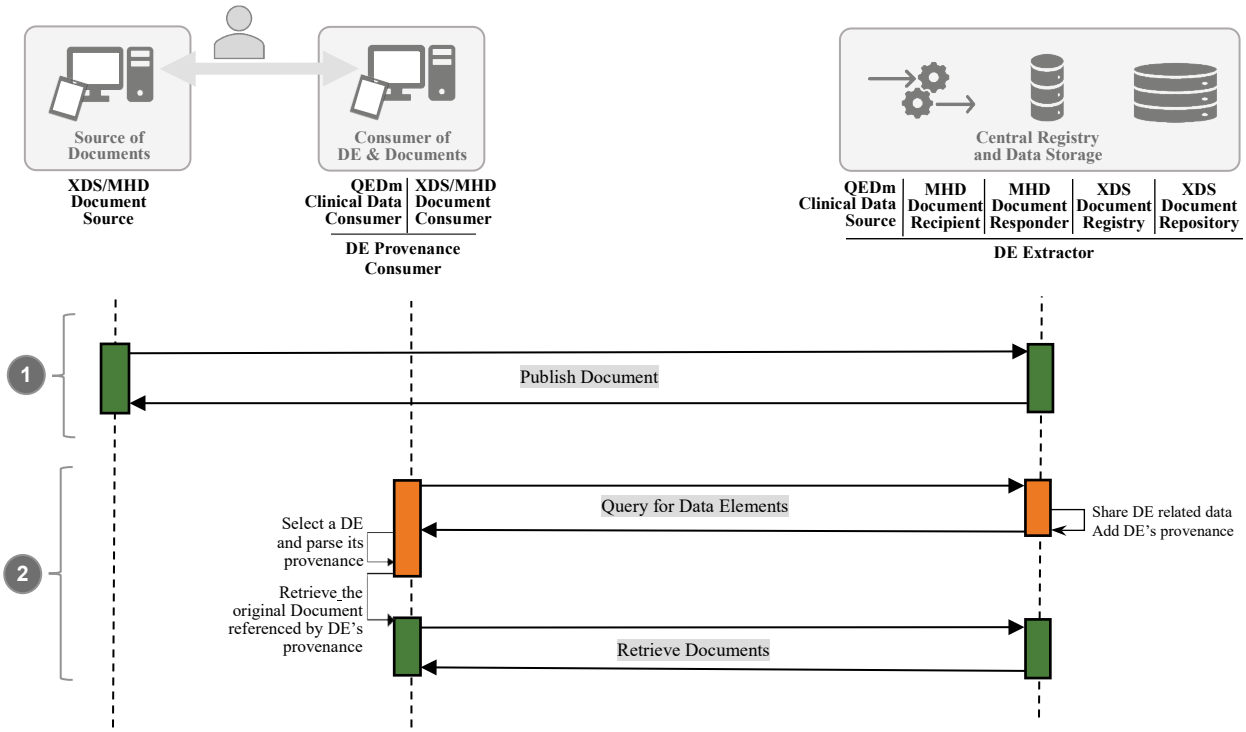


Figure X.7.1-1: PDLS Deployment Model A

Because of the centralized nature of the Document Registry/Repository that is tethered with the Clinical Data Source responding to QEDm queries, obtaining the Provenance information and its sharing with the Clinical Data Consumer and the Document Consumers is quite simple.

X.7.2 PDLS Deployment Model B - Distributed Document Repository and Central Fine-Grained Data Source

In this deployment model, the health information infrastructure is designed around an XDS Document Registry and a QEDm Clinical Data Source that are centralized but with multiple Document Repositories. The fine-grained queries are directed towards this centralized Clinical Data Source, but because the Document Repositories have been distributed, the centralized

Clinical Data Source has to access the Document content to extract Data Elements, and aggregate them across the various Document Repositories. The operation of this deployment model is described through the transaction flows below.

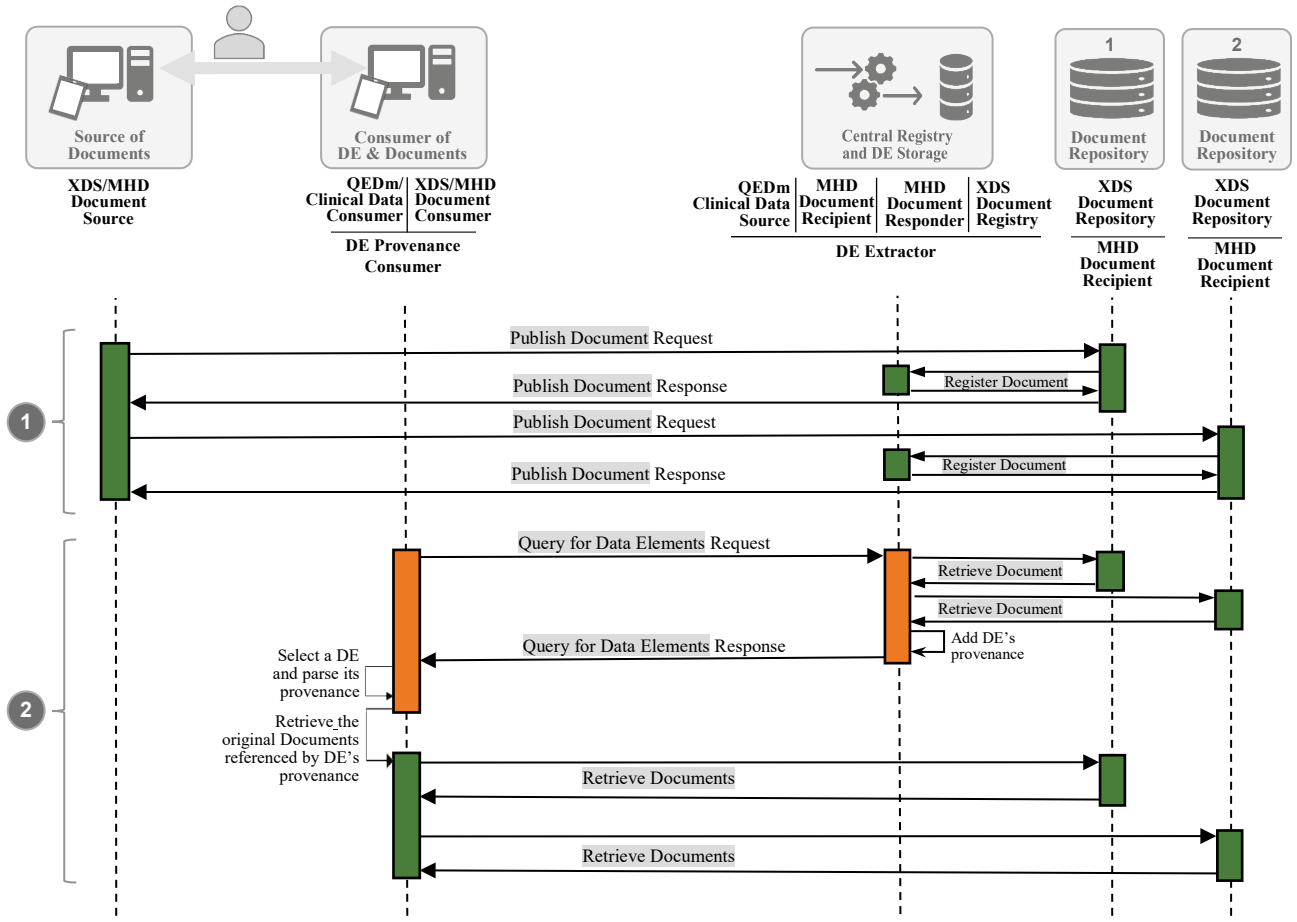


Figure X.7.2-1: PDLS Deployment Model B

Because of the decentralized nature of the Document Repositories, the central Clinical Data Source responding to QEDm queries has to assemble the provenance information from Documents coming from various Document Repositories and consolidate this information for the Clinical Data Consumer. This deployment model is a little more complex than the previous one due to the distributed repositories. It is no more complex for the Document Consumers.

Volume 2 – Transactions

Update Volume 2b, Sections 3.43, 3.43.1 and 3.43.2 as follows.

3.43 Retrieve Document Set

This section corresponds to transaction [ITI-43] of the IHE Technical Framework. The Document Consumer, Document Repository and Initiating Gateway actors use transaction [ITI-43].

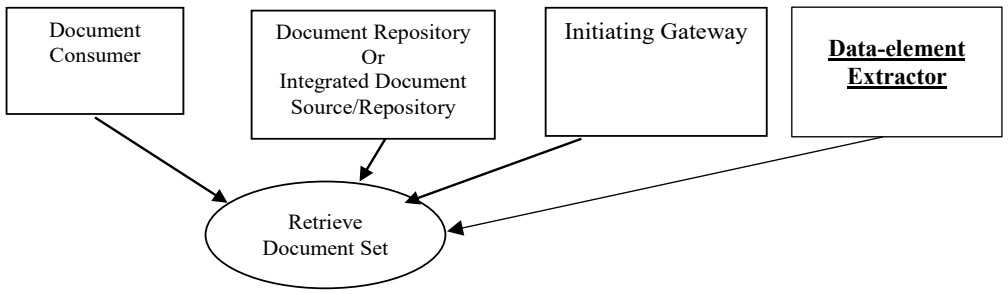
Integration Profiles using this Transaction
Cross-Enterprise Document Sharing-b (XDS.b)
Cross-Community Access (XCA)
Patient-centric Data-element Location Service (PDLS)

Actors that support the Asynchronous Web Services Exchange Option shall support Asynchronous Web Services Exchange on all XDS.b transactions they implement. Refer to ITI TF-2x: V.5 Synchronous and Asynchronous Web Services Exchange for an explanation of Asynchronous Web Services Exchange.

3.43.1 Scope

This transaction is used by the Document Consumer to retrieve a set of documents from the Document Repository or Initiating Gateway. The Document Consumer has already obtained the XDSDocumentEntry uniqueId and the Document Repository repositoryUniqueId from the Document Registry/Initiating Gateway by means of the Registry Stored Query transaction.

3.43.2 Use Case Roles



XDS Actors:

Actor: Document Consumer

Role: Obtains document.

Actor: Document Repository or Integrated Document Source/Repository

Role: Provides documents.

XCA Actors:

Actor: Initiating Gateway

Role: An Initiating Gateway which implements the XDS Affinity Domain Option retrieves a set of documents by using the Cross Gateway Retrieve transaction and/or a Retrieve Document Set transaction.

Note: Within this transaction, the Document Repository and Integrated Document Source/Repository actors can be used interchangeably.

PDLS Actors:

Actor: Data-element Extractor

Role: The Data Element Extractor extracts data elements from documents along with the associated provenance information that traces back to the source document.

The Data-element Extractor obtains documents in the very same manner as the Document Consumer does. Implementation of the PDLS Data-elements Extractor is identical to the implementation of the Document Consumer.

Volume 3 – Content Modules

Not applicable.

