Integrating the Healthcare Enterprise

IHE IT Infrastructure
Technical Framework Supplement

Mobile Health Document Sharing
MHDS

HL7® FHIR® agnostic

Revision 1.0 – Draft for Public Comment

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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.

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework V16.0. 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 January 21, 2020 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 February 14, 2020.

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.

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This profile does not specify any FHIR encoding as it leverages the grouped profiles. Thus this profile is not FHIR version specific.

Introduction to this Supplement

This profile will show how to build a Document Sharing Exchange using IHE profiled FHIR®[1] standard, rather than the legacy IHE profiles that is dominated by XDS and HL7®[2] v2. This profile will assemble profiles and define a Document Registry.

The central HIE infrastructure defined in this Profile might be a single FHIR Server implementing all the defined profile actors, or may be virtual cloud of the systems implementing the defined profile actors. These deployment models allow for modularity where each service function could be provided by different vendors, leveraging as much as possible from a reference implementations of a FHIR Server, and also leverage as much as possible of modularity enabled by defined Profiles.

Core business functions provided by MHDS Profile:

- Publication of Document based information
  - Content agnostic but CDA®[3] and FHIR preferred
- Persistence and lifecycle management of Documents, DocumentManifest, DocumentReference, and List resources
  - Enabling centralized document storage, or distributed document storage at a service identified at the source
- Patient Identity Management –
  - specifically a golden patient identity for use within the domain, cross-reference to other identities, and lifecycle of updates
  - Appropriate comprehensive handling of patient identity updates including merge

[1] FHIR is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.

[2] HL7 is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.

[3] CDA is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.

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- Participant Organizations management
  - Enabling use of CSDm directory for author identity management
- Authorization management
  - Consent
  - User Role-Based-Access-Control (RBAC) or Attribute-Based-Access-Control (ABAC)
  - Application
  - PurposeOfUse
- Encryption and Integrity requirements
- Audit Log Management
- Consumption side can be further refined using mXDE and QEDm

Open Issues and Questions

1. Given that this profile audience is likely to include those new to IHE Document Sharing exchange, there is more detail included in this supplement in order to be more self-contained and not rely on the reader referencing other whitepapers and handbooks. Is the level of detail within this supplement appropriate? Is there some text that could be removed? Is there some concept that is not well enough defined?
2. Is there a need to show interaction with XDS exchanges? Current presumption is that this is not minimally needed, but likely would be a future need. Those exchanges that want to be XDS based already have a solution in MHD. The goal of this profile is to provide a FHIR stack without XDS or HL7 v2 backend. Thus, the only interaction one might see in the future is an XCA interface to this MHDS.
3. Can Document Author be recorded as a link to data in the mCSD managed Directory, or must it continue to be mandated to be 'contained'? Clearly it can be included as contained but is this still a mandate when the Organization and Practitioner are known to be managed.
   a. This profile includes an option that allows the Document Registry to authorize the use of References where MHD forces contained. The necessary change to MHD has not been done yet in order to get feedback from Public Comment.
4. Can sourcePatientInfo be a version specific link to the centrally managed (PMIR) identity? Clearly it can continue to be contained but is this still a mandate when the Patient is known to be managed.
   a. There seems to be feedback that the need identified in XDS for sourcePatientInfo has not been important. Many exchanges recommend this element be left empty as one

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either has good control of patient identity. If one doesn't have good control, the sourcePatientInfo element is only going to add to the confusion.

5. In this profile, there is no formal Document Repository, although the functionality is provided virtually when a Document Source chooses to not include the document as a Binary resource, but rather include a URL to a repository that is recognized as part of the trust domain. This distinction is available in MHD today, although it is not pointed out as such and thus not well known. The only value to creating a Document Repository is to define input transaction as different from output transaction. By specifically defining a Document Repository we enable third-party Repository systems. A Document Repository could be supported as is today but is not defined by IHE MHDS Profile. Please comment for and against the need to create a formal Document Repository Actor.
6. The Figure X.1-1 is a high-level picture of the overall solution. It is not typical picture for an IHE profile. This high-level picture is used in the appendix in more detail. Is there comments or recommendations on how to improve this diagram?

Closed Issues

1. This profile was renamed from MHD-HIE to Mobile Health Document Sharing (MHDS). This name leverages the concept of "Document Sharing" as defined in the HIE whitepaper and includes the original MHD acronym while removing the word "access" which is important in MHD to define it as an API and inserting the word "Sharing" which indicates persistence.
2. There is no action defined for the Document Registry when the PMIR feed transaction indicated a Delete action on a Patient that the Document Registry has records for. The concern is that this action is not clear outside of a policy. It is reasonable that policy may choose to ignore Delete, may choose to mark the affected Resources inactive, or may choose to delete the affected Resources. Thus, we have left this action undefined. It is expected that a Delete action is unusual, and that administrative user interface may be the better solution.

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General Introduction and Shared Appendices

The IHE Technical Framework General Introduction and Shared Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

*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 Appendix A:

Actor Name	Definition
No new actors	

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction Appendix B:

Transaction Name and Number	Definition
No new transactions	

Appendix D – Glossary

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

Glossary Term	Definition
No new terms	

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Volume 1 – Profiles

Copyright Licenses

NA

Domain-specific additions

NA

Add new Section X#

X Document Sharing Exchange on FHIR (MHDS) Profile

MHDS Profile specifies how a collection of IHE profiles can be used by communities for exchanging health information. These IHE profiles include support for patient identification, health document location and retrieval, provider directories, and the protection of privacy and security. MHDS shows how several IHE profiles work together to provide a standards-based, interoperable approach to community health information sharing.

The IHE IT Infrastructure Domain has published several resources to support document sharing:

- ITI Technical Framework: Vol. 3 - Section 4.0 Metadata used in Document Sharing
- Health Information Exchange: Enabling Document Sharing Using IHE Profiles
- Document Sharing Metadata Handbook
- Template for XDS Affinity Domain Deployment Planning

This MHDS Profile defines a Document Sharing Exchange that is based around the HL7 FHIR standard, following the principles described in the whitepaper on Document Sharing. This Document Sharing exchange requires the same management of metadata as described in the metadata handbook:

Further elaboration of the use-cases and solutions can be found in Section X.4 below.

X.1 MHDS Actors, Transactions, and Content Modules

This profile orchestrates actors in many existing profile and creates one new actor. The actor that is specific to this profile is a Document Registry. Figure X.1-1 is a high-level diagram showing a set of actors that would be deployed in a virtual central infrastructure. They do not need to be deployed in the same physical location, but they will act as one central service.

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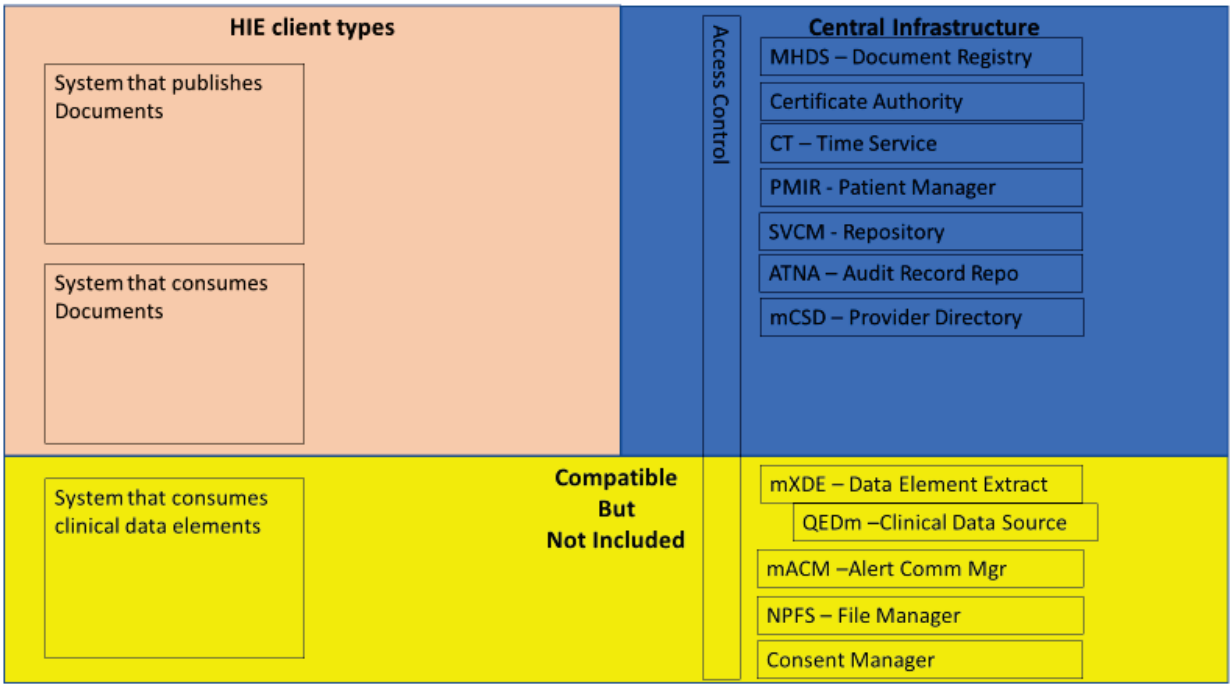

Figure X.1-1: MHDS Actor Diagram

The Document Sharing Health Information Exchange will also host a set of Service endpoints as shown in Figure X.1.1-1. These provide services to the Document Sharing Community (aka Community):

- **CT: Time Server** – to provide consistent time to all participant systems
- **ATNA – Audit Record Repository** – to capture audit events and provide appropriate audit log access for security and privacy use-cases
- **IUA – Authorization Service** – to enable centralized authorization decisions
- **PMIR – Patient Manager** – to provide patient identity lookup by demographics or identity, and to receive create and update of patient identity from participants
  - **PIXm – Patient Manager** – Patient Identity cross-reference lookup
  - **PDQm – Patient Manger** – Patient Identity lookup by demographics
- **SVCM – Vocabulary Registry** – Provide vocabulary and value set management within the Community
- **mCSD – Provider Directory** – Provide endpoint lookup and optionally provider identity management

There are other useful actors that are compatible with MHDS, but are not required by the MHDS Profile:

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- **NPFS – File Manager** – Provide files that are needed in the community but are not patient specific such as policy documents
- **mXDE – Data Element Extractor** – to enable QEDm access to data elements derived from published documents
    - **QEDm – Clinical Data Source** – to enable access to data elements (aka FHIR clinical Resources)
- **mACM – Alert Communication Manager** – to enable community supported alert communications

In addition to these IHE defined actors, the Community will also select how they will manage Digital Certificates through a Certificate Authority, and other functionalities and non-functional requirements such as response-time, service-level-agreements, remediation-planning, remediation-access, etc.

The Document Registry is grouped with a set of actors from other profiles. The MHD Document Responder and Document Recipient are grouped to provide the MHD service side capabilities to the Participating clients. The PMIR Patient Identity Consumer is provided to enable patient identity synchronization and specifically the merge function to be applied to any data managed in the Document Registry. The SVCM Consumer enables the Document Registry to gain access to ValueSets that the Registry is enforcing Metadata consistency. The mCSD Consumer enables the Registry to have access to Organization and Practitioner resources. IUA and ATNA are grouped to enable the Document Registry to be secure and support secure transactions. The CT Time Client assures that all records of time done by the Document Registry are aligned with the Time Source. This Document Registry does not have any exposed transactions, rather all the exposed transactions are by the grouped actors.

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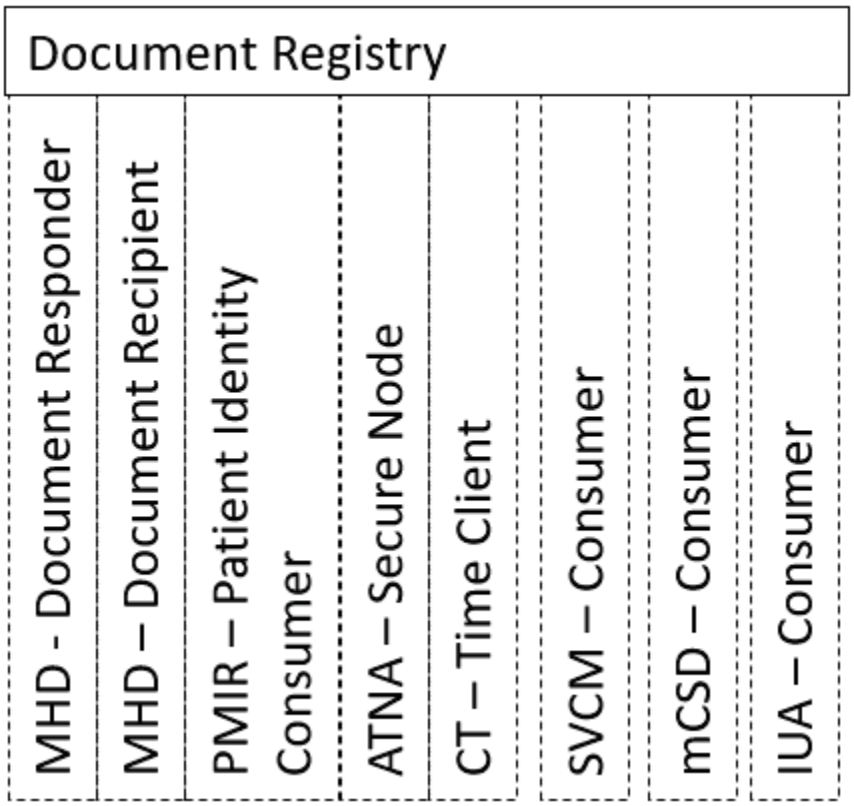

Figure X.1-2: MHDS Registry Actor Diagram

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

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

Actors	Transactions	Initiator or Responder	Optionality	Reference
Document Registry	(none)		R	ITI TF-2: 3.Y1

X.1.1 Actor Descriptions and Actor Profile Requirements

The following are additional functional requirements of this profile.

This profile assumes that some Health Information Exchange (HIE) authority manages the configuration of the Community. This includes specification of an appropriate Certificate Authority, Time Source, Domain Name Service, SVCM Service, mCSD Directory, ATNA Audit Record Repository, PMIR Patient Identity Manager, and IUA OAuth authority.

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Optional use of mXDE, QEDm, and mACM will also demand management by the HIE authority.

The HIE authority is responsible for setting Patient Identity quality criteria including the minimally acceptable Patient identity constraints. This would set the data elements that describe the Patient within the Community and the quality of the identity proofing and identity confirmation necessary by all participants in the Community.

The HIE authority is responsible for setting Document Sharing Metadata rules, following the metadata rules and using the Metadata Handbook to set specific metadata element requirements including the specification of mandatory ValueSets. See Document Sharing Metadata Handbook.

X.1.1.1 Document Registry

The Document Registry SHALL include a configuration management function to enable configuration of the grouped actors, including Metadata rules, policy, and security. This configuration management MAY be enabled by use of the NPFS Profile; however, the details of this mechanism is not further defined.

The Document Registry SHALL utilize the CT – Time Client to keep internal clocks synchronized to the identified Time Source so that records of time are correlated.

The Document Registry SHALL obtain a Digital Certificate from an HIE-defined Certificate Authority.

The Document Registry SHALL be grouped with an ATNA Secure Node or Secure Application. The Document Registry SHALL support at least the ATNA "STX: TLS 1.2 Floor using BCP195" Option. The Document Registry SHALL allow only authorized access to the protected resources managed by the Document Registry. The Document Registry SHALL record all security relevant events to ATNA Audit Record Repository. This SHALL include all IHE-defined audit events that are in the control of the Document Registry, including its grouped actors.

When the grouped MHD – Document Recipient – is triggered

Triggered by a: Provide Document Bundle [ITI-65] transaction:

1. The Document Registry SHALL confirm its identity to the requesting system by use of the ATNA Secure Node or Secure Application TLS protocol using a Certificate assigned to the Document Registry.
2. When the Authorization Option is implemented and enabled, the Document Registry SHALL confirm the client identity using the IUA Profile.
3. Additional policy driven requirements, not specified here, may also apply.
4. The Document Registry SHALL validate that the subject of the DocumentReference, DocumentManifest, and List resources is the same Patient, and that Patient is a recognized Patient within the Community. The Patient identity must be recognized by the

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approved PMIR Patient Identity Manager system. This may be accomplished by a query of the PMIR manager, by way of a cached internal patient database, or other means.

5. The Document Registry SHALL validate the data received according to the appropriate validation rules, and configured ValueSets to assure that the document submission request is valid. If any of the data are found to be not valid then the transaction shall be rejected.
6. When the SVCM Validation Option is implemented and enabled, the Document Registry SHALL use the grouped SVCM – Consumer to validate data metadata elements as appropriate to configured policy. For example the DocumentReference.type often must be a value within a Community agreed to ValueSet.
7. Provided the request is valid, the Document Registry SHALL persist all DocumentManifest, DocumentReference, List, and Binary that are received by way of the grouped MHD - Document Recipient – Provide Document Bundle [ITI-65] Transaction.
8. The Document Registry SHALL record success and failure events into the ATNA Audit Record Repository.

When the grouped MHD – Document Responder – is triggered

Triggered by any: Find Document Manifests [ITI-66], Find Document References [ITI-67], and Retrieve Document [ITI-68] Transactions.

1. The Document Registry SHALL confirm its identity to the requesting system by use of the ATNA Secure Node or Secure Application TLS protocol using a Certificate assigned to the Document Registry.
2. When the Authorization Option is implemented and enabled, the Document Registry SHALL confirm the client identity using the IUA Profile.
3. Additional policy driven requirements, not specified here, may also apply. Such as enforcement at the Document Registry of Patient-specific Consent Directives.
4. The Document Registry SHALL validate that the subject of the find or retrieve request is a Patient that is a recognized Patient within the Community. The Patient identity must be recognized by the approved PMIR Patient Identity Manager system. This may be accomplished by a query of the PMIR manager, by way of a cached internal patient database, or other means.
5. The Document Registry SHALL provide the persisted resources to the grouped MHD Document Responder in support of the Document Responder duties to return results.
6. The Document Registry, if the Authorization Option is used, SHALL confirm that only authorized results are returned.
7. The Document Registry SHALL record a success or failure event into the ATNA audit record repository.

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When the grouped PMIR – Patient Identity Consumer – is triggered

Triggered by a: Mobile Patient Identity Feed [ITI-93] transaction with a Merge:

The Document Registry SHALL search for any resources with the deprecated _id value in the DocumentManifest.subject, DocumentReference.subject, and List.subject; and replace subject value of with the surviving id. The Document Registry SHALL record a single audit event indicating the Merge action, with a .entity element for each of the updated Document Registry Resources updated. The Document Registry SHOULD record a single Provenance record indicating the Merge action, with the .target element pointing at all updated Document Registry resources modified.

No behavior is expected of the Document Registry on receipt of a feed containing create, delete, or update, although the Document Registry is free to consume and persist these for reasons outside the scope of this profile.

X.2 MHDS 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: MHDS – Actors and Options

Actor	Option Name	Reference
Document Registry	Authorization Option	X.2.1
	Consent Manager Option	X.2.2
	PMIR Query Option	X.2.3
	SVCM Validation Option	X.2.4
	Author Reference Option	X.2.5

Note that Consent Manager Option requires the Authorization Option

X.2.1 Authorization Option

Document Registry includes an OAuth Authorization endpoint to request OAuth tokens for access to the Document Registry. Thus all accesses to the Document Registry must have a token issued by this endpoint.

This option requires the Document Reference include a grouping with an IUA Authorization Server.

X.2.2 Consent Manager Option

Document Registry includes a functionality to track and enforce patient specific consents. All accesses to the Document Registry SHALL be checked against the internal functionality status of the patient consents. Uses BPPC Profile to enable Implicit Consent OPT-IN, Implicit Consent OPT-OUT, Explicit Consent OPT-IN, and Explicit Consent OPT-OUT. With support for

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PurposeOfUse to support consent by purpose, and support with time range to enable expiration of consent.

The IUA Authorization Server shall be used for consent decisions as well.

X.2.3 PMIR Client Option

Document Registry is grouped with PMIR Patient Identity Consumer.

To enable external PMIR Patient Identity Manager that is queried as needed. The Document Registry receives all the Patient Identity Feed data, but may choose not to persist, thus would use the PMIR Client Option to query an external PMIR Patient Identity Manager.

X.2.4 SVCM Validation Option

The Document Registry is grouped with a SVCM Client and uses this interface to do validation of submitted metadata codes as being contained in the community assigned valueSet

X.2.5 Author Reference Option

The Document Registry allows DocumentReference.author to be a Reference to a Resource published in the associated centrally managed mCSD Selective Supplier. This is an architectural difference from XDS and MHD given that the centrally managed mCSD Selective Supplier is managing the referenced Resource and thus forcing it to be contained is unnecessary.

When the Author Reference Option is used, then the mCSD Selective Supplier must be persisting long term the data within the mCSD directory so that the Resources within the Document Registry are available for the life of the Document Registry entry.

X.3 MHDS Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions in this profile ***in addition to all*** of the requirements for the grouped actor (Column 3).

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.

MHDS Actor	Grouping Condition	Actor(s) to be grouped with	Reference
Document Registry	Required	CT – Time Client	
	Required	ATNA – Secure Node or Secure Application	
	Required	MHD – Document Responder	
	Required	MHD – Document Recipient	
	Required	PMIR – Patient Consumer	
	if the Authorization Option	IUA – Consumer	
	if the Author References Option	mCSD – Care Services Selective Consumer	

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MHDS Actor	Grouping Condition	Actor(s) to be grouped with	Reference
	if the SVCM Validation Option	SVCM – Consumer	

X.4 MHDS Overview

This section is adapted from the IHE Whitepaper Health Information Exchange: Enabling Document Sharing Using IHE Profiles. The adaption is to the specifics of the MHDS Profile.

The Integrating the Healthcare Enterprise (IHE) standards profiling organization has developed a collection of profiles which can be leveraged for use by healthcare communities for the purposes of document sharing. One of the most significant applications of healthcare information technology is the exchange of health information among disparate clinical information systems and otherwise unaffiliated care providers. Across the world, various communities have developed or are developing methods for exchanging health information among healthcare providers, patients, and other authorized parties.

MHDS Profile specifies how a collection of IHE profiles can be used by communities for exchanging health information. These IHE profiles include support for patient identification, health document location and retrieval, provider directories, and the protection of privacy and security. MHDS shows how various profiles work together to provide a standards-based, interoperable approach to community health information sharing.

Effective health information exchange involves a diverse set of activities and a broad set of challenges, whether that exchange takes place among affiliated or unaffiliated care providers. The IT Infrastructure (ITI) domain of IHE has addressed many of these challenges by defining a series of integration profiles to address specific aspects of exchanging healthcare information. Each integration profiles addresses part of the broad set of challenges involved in health information exchange. The profiles, however, do not attempt to address governance and policy choices that significantly affect how the profile is adapted in any particular community. IHE cannot address all such governance and policy issues but will provide some guidance on where governance and policy issues are applicable and offer some common approaches.

It is very important to note that IHE focuses only on interoperability and does not attempt to solve every issue involved in exchanging health information. These solutions are meant to be plugged into an architecture that is designed and executed by the exchange communities themselves. Thus, while each community will generate an architecture that meets its individual needs, the use of IHE profiles will lead to the creation of standards-based communities.

The MHDS Profile focuses on explaining how IHE profiles are used to address interoperability aspects of document sharing and how they work together to solve common document sharing problems. The IHE White Paper, "Template for XDS Affinity Domain Deployment Planning", provides support for policy and deployment planning. The IHE "Document Sharing Metadata Handbook", provides guidance on developing policy and vocabulary valuesets for use within the community. For application of Document Sharing for particular clinical use cases, consider the

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work of the clinical IHE domains: Anatomic Pathology, Cardiology, Eye Care, Laboratory, Patient Care Coordination, Patient Care Device, Pharmacy, Quality, Research and Public Health; Radiation Oncology, and Radiology.

X.4.1 Overview

A health document sharing community (community) exists for the purpose of increasing the accessibility of patient health information across multiple organizations so that clinicians can make more informed decisions about the care that they provide. Today, there are many communities already in production and many more are being planned. The size, nature and scope of communities vary widely but can be characterized by a number of different aspects.

First, some communities are geographically focused while others are not. What often comes to mind when speaking of a community is a regional organization that facilitates information exchange across multiple organizations that are relatively close in proximity. Major metropolitan areas tend to be the focus of these communities, but often a regional community encompasses several rural locales. On the opposite extreme of the geographic aspect of communities is the network of United States Veterans Hospitals. The VA (Veterans Administration) hospitals are spread across the entire map of the US and beyond, yet significant efforts have been spent on being able to exchange data among these geographically separated care centers.

A second characteristic by which to categorize communities is the organizational structure of the community. In some cases, the community consists of a single hospital and several out-patient clinics that have a referral relationship with the hospital. In other cases, a network of competing hospitals, laboratories and private clinics may collaborate to form a community.

A third means by which to describe communities is the scope of the content shared. Some communities have very limited exchange functionality. For instance, a community may focus entirely on electronic lab result delivery or e-prescribing. Most communities define a moderate scope to their exchange activities that might include results delivery, electronic referrals, and perhaps some sharing of encounter-based information (e.g., dictations). More advanced communities leverage their network to include even larger scopes (perhaps including the sharing of documents with the patient's Personal Health Record, exchange of clinical summaries, regional patient centric workflows, etc.). No two communities are alike in terms of the set of exchange activities that they facilitate.

Finally, a fourth aspect of a community is the size, scope and political jurisdiction(s) that regulate it. The simplest community uses only an adhoc arrangement to push documents from one organization to another. National and sub-national jurisdictions have significant effects on the organization and operations of a community.

Despite all the variance among communities, each has the same ultimate goal: to increase the authorized exchange of patient health information across organizations so that clinicians can make more informed decisions about the care that they provide. This ultimate goal provides the reason why the community exists, it is their affinity.

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Once communities are formed there is a need to exchange health documents across the communities as well as within them. IHE uses the concept of cross-community to describe a federation of communities which use mostly peer-to-peer interactions for the purposes of health document sharing. A community may be a single organization, like the USA Veterans Administration, a complex community of many organizations, or a more simple organization like a single small hospital or facility. Cross-community describes an environment where multiple communities, be they simple, small, complex or large, interact without any understanding of or access to the internal structure of any of the other participants.

The MHDS Profile designs a single community document sharing exchange.

X.4.2 Principles of IHE for Health Document Sharing

This section describes several principles which are foundational to IHE's approach to health document sharing.

X.4.2.1 General IHE principles

The following general IHE principles are applicable to the set of IHE profiles used for Document Sharing, including MHDS:

- IHE profiles describe the interactions between systems and not the implementation within systems. Interactions between systems are typically described by transactions which are technically specific and detailed enough to ensure interoperability among implementing systems. The internal implementation of the systems is not prescribed by IHE. For example, for patient demographic matching IHE specified the format of the query and response but not the algorithm or method used for the demographic matching. This allows freedom for implementations to address scalability, creative functionality, reliability, and other value-add.
- IHE profiles are designed to support a wide variety of governance and policies. Because IHE supports adoption of its profiles around the world it is rarely possible to define policies that are applicable in all countries. For this reason, IHE profiles are designed with a variety of governance and policies in mind and are therefore applicable to a wide variety of environments. IHE profiles are designed to be policy neutral and support a broad set of governance; before they can be deployed there are many governance and policy issues that the communities must agree on. Examples of governance and policy issues are things like: roles and responsibilities, privacy, signature requirements, authorization, when to publish, what to publish, administrative roles, configuration, service level agreements, clinical pathways, long-term availability, etc.
- IHE assumes there is a general understanding of widely implemented Information Technology Standards. IHE profiles typically leverage underlying technology like XML, TCP/IP, DNS, Digital Certificates (PKI), etc. without detailed explanations.

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X.4.2.2 Document Sharing Governance

IHE enables interoperable sharing of documents but assumes this sharing occurs under a document sharing governance structure agreed to by all parties involved. The governance structure addresses all policy issues necessary to enable document sharing; content format and coding; and other operational characteristics. The IHE profiles are designed to be agnostic to governance and policy, while also being designed to support and enforce those governance and policy choices. The governance may apply only within a small group, such as a hospital and small physician's office, or may apply at a large level, like an entire nation. In fact, sometimes temporary or informal governance (e.g., via phone call) based on understanding of existing laws or customs is used for exchange among participants. Typically, in order to allow for effective and efficient interactions, the governance structure is formalized through some legal mechanism. Overlapping governance is common, where one set of agreements exist in the region and a different set of agreements exist across the nation, yet most organizations will eventually want to exchange documents regionally, nationally and internationally.

In addition to general governance agreements, a document sharing community should address the following issues:

- **Format of document content**: To enable interoperable transfer of documents the receiving side must understand the format and structure generated by the sending side. Typically, there is an agreement on a set of document formats which must or may be supported. This could include unstructured content like PDF or text documents. Or a more structured format like CDA or a specific implementation guide applied to CDA for a particular purpose. The key is to ensure that whatever type of content is shared, the receiving system is able to interpret the content in an appropriate way, either through human review or machine processing.
- **Coding within documents**: Structured documents often include coded data derived from a given coding system. Agreeing on which coding systems to use for which data is often covered by an implementation guide for the structured document. Agreeing to an implementation guide, or a general guideline for coding systems to use, is necessary to enable semantic understanding of the document received.
- **Coding of metadata**: Metadata are data that provide information about one or more aspects of the document. In the case of IHE-defined document exchange, specific metadata are coded within the structure of the content being exchanged. See Section X.4.2.6 where the metadata defined by IHE are introduced. Some of that metadata have values chosen from a coding system defined by the governance of the sharing community. Because IHE profiles can be applied in many parts of the world where coding systems are different, IHE has not specified which code sets to use and this decision must be made among the systems exchanging documents.

The purpose of this aspect of governance is to enable semantic interoperability among participating partners.

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X.4.2.3 Distinction between Documents and Messages

The HL7 standard for Structured Documents Section 1.2 describes the document vs. message distinction as follows "A document is designed to be persistent for long periods of time, whereas messages are more often expected to be transient. There is a place for both of these constructs in healthcare." HL7 characterizes a document by the following properties:

- *Persistence* – Documents are persistent over time. The content of the document does not change from one moment to another. A document represents information stored at a single instance in time.
- *Wholeness* - A document is a whole unit of information. Parts of the document may be created or edited separately, or may also be authenticated or legally authenticated, but the entire document is still to be treated as a whole unit.
- *Stewardship* –A document is maintained over its lifetime by a custodian, either an organization or a person entrusted with its care.
- *Context* - A clinical document establishes the default context for its contents
- *Potential for authentication* - A clinical document is an assemblage of information that is intended to be legally authenticated.

Health messages, on the other hand, are not expected to be persistent, but represent a unit of information at a moment in time where the context is often implied by the transaction partners. The content is not always whole, where context may exist in the messaging environment rather than inside the message itself. The distinction between message and documents can get blurry at times, as messages sometimes can be persisted and can contain all necessary context. In fact, messages can be converted to documents and can carry documents within their content. But documents are expected to be persistent, relevant over time and having the same meaning regardless of environment. And messages need not be any of those things.

The scope of 'document' in the MHDS Profile and other IHE Document Sharing Profiles would prefer that documents have the above "Document" properties, but does not require that documents have these properties. The only property required is that there is a mime-type for the document.

X.4.2.4 Longitudinal Patient Record

Building on the document concepts described above in Section X.4.2.3 of persistence, wholeness, stewardship and context, we can identify the principle of the longitudinal patient record which is foundational and central to health document sharing. Document Sharing Communities are patient centric, and the patient identity is associated with every document shared

Care providers, which may support a broad variety of healthcare facilities: private practice, nursing home, ambulatory clinic, acute care in-patient facility, etc., are typically the sources or creators of health documents. Typically, a patient will go through a sequence of encounters in

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different care settings over the course of his/her lifetime. With each encounter there is the potential that a provider will produce a health document that can be shared with the community. Documents shared by the provider and tracked by a centralized registry (see Section X.4.3.2) or federation of communities (see Section X.4.3.3) form a longitudinal record for the patients that received care among those providers within the community. Longitudinal records, therefore, are expected to last over the span of many decades, just as the documents that comprise them are expected to have persistence, wholeness, stewardship, context, and potential for authentication. As a health information exchange is adopted it is a common practice to use an historical bulk data load, or comprehensive patient summary to initialize the electronic patient record with data for historical purposes.

Within a care setting Clinical Data Repositories (CDR) or Clinical Information Model Infrastructure databases might be used to enhance Clinical Decision Support as a complement to document discovery. These databases would not be nationwide, but rather be local to the patient's care facility, like EHRs themselves,. Document Sharing supports interoperability amongst local systems and supports a longitudinal patient record that spans across many local systems potentially using multiple different database systems.

X.4.2.5 Use of Documents

IHE Document Sharing profiles are content neutral, meaning that any type of information without regard to content and representation is supported. A document is any collection of bytes, including proprietary and textual formats. It is expected that a deployment of Document Sharing will restrict the format and content of documents exchanged to those agreed to by the partners in the exchange, as stated in Section X.4.2.2. While the format and content of a document is not restrictively defined, it is expected to be a coherent set of healthcare data that includes enough context to be useful to a practitioner. A document should have the characteristics as described in Section X.4.2.3 namely, persistence, wholeness, stewardship, context and potential for authentication.

IHE Document Sharing profiles assume that a patient identity is associated with every document shared (see Section X.4.2.4).

The most common document content standards that are profiled by IHE are HL7 Clinical Document Architecture (CDA), and an emerging HL7 FHIR Document. These standard formats support the coding of the clinical content which allows for use of the content both for display purposes as well as machine processing. Although IHE encourages the use of CDA or FHIR as the document content type of choice, it does not restrict the content of a document in any way. Many times, a document will be encoded in PDF or simple text (e.g., U.S. Department of Veterans Affairs "Blue Button" program). Images and manifest documents may also be exchanged using the same infrastructure. By defining a document so liberally, IHE enables a common health record sharing infrastructure that is flexible enough to handle the content types agreed to by the partners in the exchange.

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IHE and other organizations have profiles which define document content for specific, commonly occurring cases. For example, the IHE Laboratory domain has defined an XD-LAB content profile to support sharing laboratory reports. Likewise, the IHE Patient Care Coordination (PCC) domain has defined various content profiles including a Medical Summary (XDS-MS) content profile and an Emergency Department Referral (EDR) content profile. XDS-MS supports a patient's transfer of care from one care setting to another, and EDR supports the situation where a physician determines that a patient should proceed directly to an emergency department for care. In each of these cases, it is useful for IHE to profile (define) both the transport and the content of the documents so that true interoperability can more easily be achieved throughout the healthcare continuum.

The IHE Content Profiles utilize two abstract actors "Content Creator" and "Content Consumer", utilizing an abstraction of "Share Content"; where "Share Content" can be any of the Document Sharing infrastructures including MHDS, XDS, XDR, XCA, etc.:

Figure X.4.2.5-1: MHDS Actor Diagram

IHE Content Profiles can be found:

- CDA https://wiki.ihe.net/index.php/Category:CDA
- FHIR-Document https://wiki.ihe.net/index.php/Category:FHIR-Doc

X.4.2.6 Value of Metadata

Another key principle leveraged by IHE Document Sharing is the use of metadata. As defined in Section X.4.2.2, metadata are data that provides information about one or more aspects of the document. While a document may be any collection of bytes, IHE defines a collection of metadata about the document that aid its identity, discovery, routing, security, provenance, privacy, authenticity and electronic pre-processing. The set of metadata is defined to facilitate interoperability, so that receiving systems can manage, route and administer documents even if they are unable to interpret the contents of the document. IHE metadata are defined in such a way that additional metadata, defined outside of IHE, can be sent. Of course, systems not enabled to understand the additional metadata will ignore them, but this capability allows the set of metadata defined by IHE, which is already extensive and robust, to be extended when local needs arise.

Metadata serve multiple purposes. They allow systems to perform:

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- automated management of the documents – like assigning priorities or work tasks
- automated patient identification – adding the new information to the correct patient's local record
- support for provenance management – making decisions based on authority of creator of content
- support for episodic searches – by type, date of service
- support relationships between documents
- support privacy/authorization controls – enabling access to content only where appropriate
- support security and integrity controls

Any metadata element may support overlapping purposes, but the combination of metadata elements provides a robust understanding of the document and enables automated and manual management of the document without the requirement access to the detailed clinical information contained within the document.

X.4.2.6 Document Relationships

The metadata defined in the IHE Document Sharing model encompasses more than just characteristics of documents. In fact, the metadata model is very rich, encompassing the relationships between documents through use of folders, submission sets, and associations.

Documents: Each document shared using IHE-defined constructs comes with a collection of metadata which describes the document. The metadata describing the document includes things like: document identifier, patient identifier and demographics, document author, class of document, confidentiality of document, creation time, and events causing creation of document, document format and several more. For a complete list of document metadata refer to ITI TF-3: Section 4.1.

Folders: Metadata shared using IHE-defined constructs can also describe folders and document's membership in folders. A folder may be used to collect documents for many purposes, like ease of access or describing a functional purpose.

Submission Set: When documents are published or pushed using IHE transactions they are collected into submission sets to reflect the collection of documents sent at a given moment. Since a submission set reflects a collection of documents it shares some of the same metadata as a document, like patient identifier and author, and adds metadata reflecting the collection like identifier of the source, intended recipient and submission time.

Document Associations: The document sharing metadata supports the description of associations between documents. The associations supported are: append, replace, transform, transform with replace, and signs (i.e., digital signature). The append, replace, and transform

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associations support representation of document lifecycle events, where a document is associated with documents which are created as part of lifecycle events related to the original document.

X.4.2.8 Document Sharing Models

IHE has enabled three distinct Document Sharing Models that share the principles in this section. Because the principles are the same it is relatively simple to implement more than one model to accomplish multiple objectives. The three models are:

- **Direct Push** – in this model, clinical content in the form of documents and metadata is sent directly to a known recipient, or published on media for delivery
- **Centralized Discovery and Retrieve** – in this model, a centralized locator is used to discover the location of documents which enables a retrieval of the document from a custodian who has registered existence of the document with the centralized locator
- **Federated Discovery and Retrieve** – in this model, a collection of peer entities are enabled to query each other to locate documents of interest, followed by retrieval of specific documents.

These models share the common definition of a document and metadata describing documents, folders, submission sets and document associations. Each requires some level of governance structure in order to operate, although there is some difference in the governance needs. For instance, the centralized model requires knowledge only of the centralized locator which can then provide connections with distributed document repositories. For Direct Push and Federated approaches a detailed directory of participating entitles is typically used to ensure that the push or query transactions are sent to the proper place. All include strong support for authenticity and encryption on transport. Privacy requirements vary especially between the Direct Push, where privacy policy is generally determined prior to initiation of the action, and Discovery mechanisms where privacy policy is most often determined prior to responding to the request. So, while the issues that need to be resolved through governance are largely the same, the resolutions will sometimes vary depending on the model chosen.

It is expected that most communities of exchange will start with one of the three forms of document exchange and, if needed, adopt the others later. The addition of a new model to an existing deployment is relatively simple because the IHE profiles are based on common principles.

X.4.2.9 Patient Identity Management

The Document Sharing mechanisms enabled through IHE assume that a patient is associated with every document shared. That patient is described within the metadata describing the document.

In the Discovery models the document query requires the specification of a patient identifier as known by the query recipient. So, in these models it is necessary to resolve the patient prior to

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searching for documents. In fact, the query does not carry any patient demographic data beyond the patient identifier.

Resolving the patient is a complex subject made more complex through historic norms, regulations, and business factors. Some regions have a universal identifier, but most regions don't. IHE provides several profiles that aid the resolution of the patient identifier. The profiles are described in Section X.4.2.4.

X.4.2.10 Locating sharing partners

One of the challenges of Document Sharing that is not directly addressed by IHE is the identification of Document Sharing partners. Each Document Sharing model has a different type of need: where a centralized discovery approach requires the identification of the central locater, the peer based push and discovery mode requires identification of each of the peers. This ability to discover sharing partners can be accomplished in many different ways and a clear preference is not yet apparent. The approaches can be broadly characterized as a) locating electronic services which can provide information and b) locating patient specific source of information.

For locating electronic services which can provide information, some approaches currently used in various parts of the world are:

- Local configuration files – many organizations keep a local configuration file or address book which is managed manually whenever a new sharing partner is identified or updated.
- Service Registry – a services registry is sometimes used as a centralized service available to all participants.
- Healthcare Provider Directory – enables a directory of individual and organizational entities along with electronic services provided by those entities.

X.4.2.11 Security/Privacy

IHE addresses Privacy and Security through the use of Risk Assessment and Management. Each profile is assessed for various types of risks and the profile includes mitigations identified through that assessment in the privacy and security considerations.

IHE includes profiles specific to interoperability of security and privacy. Interoperability profiles are not enough to fully address privacy or security. Privacy and security are enabled and enforced at many levels of depth including policy, physical environment, procedures, organizational, departmental, functional, and information technology.

IHE provides profiles that support privacy and security audit logging, user and system identification and authentication, access control, encryption, data integrity, digital signatures, and privacy consent management. Security and Privacy and the profiles IHE offers are discussed in Section X.5.

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X.4.3 Document sharing profiles

The key actors in health information exchange are the document source actors – those applications or modules that create the document to be shared, and the document consumer actors – those applications or modules that retrieve the document to act on it (i.e., present it to the user, import it into the receiving system, etc.). The strength of the Document Sharing profiles is that they enable effective sharing of data among multiple, disparate systems in a way that minimizes the burden that data sharing imposes on those systems. These profiles may be categorized according to three different data sharing models:

- Direct Push – supports point-to-point push of documents where content is sent directly to the intended recipient found through manual means or infrastructure enabled directory
- Centralized Discovery and Retrieve – a community of sharing partners agrees to use a common infrastructure to enable Health Document Sharing. A document source will publish the existence of documents to a location that is accessible to other systems. Then, document consumers can discover document locations that have been previously published and pull a copy of the document.
- Federated Discovery and Retrieve – content is pulled directly from the content holder who is found through manual means or a directory

The three models are designed to support different use cases. The Direct Push model can be relatively simple but it cannot satisfy all use cases because it relies on the source of documents to know where those documents will be needed. The Discovery models can also handle use cases like:

- Treatment of a new condition where prior conditions may be relevant
- Open Referral, where the patient is allowed to choose the specialist
- Highly mobile patient
- Emergency
- Patient with many medical conditions
- Patient with complex condition

The IHE profiles addressing these models are:

- Direct Push – Mobile access to Health Documents (MHD), Cross-Enterprise Document Reliable Interchange (XDR), and Cross-Enterprise Document Media Interchange (XDM)
- Centralized Discovery and Retrieve (XDS Affinity Domain) – MHDS, and Cross-Enterprise Document Sharing (XDS)
- Federated Discovery and Retrieve – Cross-Community Access (XCA)

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The Mobile access to Health Documents (MHD) Profile is also an access (API) method to XDS or XCA environments. These models and other alternatives are further discussed in the White Paper on Enabling Document Sharing through IHE Profiles

X.4.3.1 Direct Push

This exchange model is not the focus of the MHDS Profile. This function can be achieved using MHD Profile with Document Source pushing to Document Recipient.

X.4.3.2 MHDS based Centralized Discovery and Retrieve

The MHDS Profile enables centralized discovery of health documents and retrieval of those documents from distributed document repositories.

The following scenario describes a typical exchange of clinical information using MHDS. Dr. Suwati works for New Hope Medical Partners which provides her with an EMR system. Her patient, Mary Gomez, just explained to the doctor that she was recently hospitalized at Norwalk General Hospital. Dr. Suwati would like to review the medical records that documented Mary's hospital stay. Using her EMR, Dr. Suwati searches for recent documents for Mary Gomez created by Norwalk General Hospital's EHR. Having found several documents (lab results, radiology reports, a discharge summary, etc.), Dr. Suwati chooses first to view Mary's radiology reports. Having read the reports, she discards them. However, Dr. Suwati reads the discharge summary and then saves it to Mary's record in the local EMR.

In this scenario of health information exchange, the primary player (Dr. Suwati) has three principal objectives: find patient records available from external systems, view a selection of those records, and incorporate a select number of those records to her local system. This sequence of actions is repeated continually in the healthcare setting. To address this very common scenario, IHE has created the MHDS Profile, a method to coordinate the authorized discovery and sharing of medical documents among disparate information systems.

MHDS minimizes the burden imposed on the document sources and consumers when sharing documents by establishing the use of two infrastructure components (the document registry and document repositories), which handle most of the effort involved in exchanging clinical data. This separation allows for minimal yet rich metadata to be centrally managed in a document registry while the full clinical details stay protected within distributed document repositories. The IHE profiles enable the automation of discovery and retrieve by more advanced health information systems.

X.4.3.2.1 Document Publishing

The MHD system acts like a Library for books. The document may be made available within the document registry or at the source organization, an organized resting place for books (i.e., medical documents) that are available to library patrons. The document registry is the library's card-catalog, a tool for locating specific books that lie on those rows and rows of shelves. Unlike a library, the bookshelves are potentially deployed within each participating organization; thus

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the books are controlled by the original organization until the moment that another organization requests a copy.

It is the responsibility of the publisher to put the books (documents) on the shelf and provide the information for the card-catalog (metadata). The library will step in to update the card-catalog with the data needed to find the new book. In IHE jargon the publisher is called the document source, whereas the act of putting the book on the shelf and then cataloging it.

The actual location of the document repository will depend on the local deployment. IHE provides flexibility to enable many different deployment approaches.

- The document repository may be combined with the document registry, allowing for an integrated environment where no external "update registry" transaction is needed.
  - In this case the Document Source includes the document in a FHIR Binary Resource within the "Provide Document Resources" [ITI-65] transaction
- The document repository could be combined with a document source allowing a large hospital system to enable its local EMR system to also act as a document repository. In this case there is no externally recognized "provide and register" transaction, but simply the "update registry" transaction from the hospital system to the central document registry.
  - In this case the Document Source stores the document in an accessible server and includes the URL to that location in the "Provide Document Resources" [ITI-65] transaction
- There is no restriction on how many document repositories can be associated with a single document registry. However any document repository must be made available for authorized retrieval of the documents contained and referenced within the Document Registry.
- There are no constraints on where a document repository is hosted, the decision is based on many implementation considerations. For instance, a hospital may want to keep its clinical content local in which case it supplies a repository hosted locally. Or a small physician office may have no ability to support a repository and will prefer to use a repository provided by an external organization, like a hospital system of an infrastructure only partner.

X.4.3.2.2 Document Discovery

To complete our analogy, we must consider the library patron (Dr. Suwati in our case), whose goal is to find specific books. The patron interacts with the catalog; sometimes searching for specific books, other times browsing what is available. Once the locations of interesting books are discovered, the patron fetches them from the shelves. In our MHDS drama, the document consumer (our library patron) interacts with the Document Registry through the Document Responder to find medical records of interest. This process is known as the "Find Document

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Manifest" [ITI-66], and "Find Document References" [ITI-67] transactions. The act of fetching the medical record from a Document Responder (repository) is known as the "Retrieve Document" [ITI-68] transaction. Of course, with the structured and coded metadata, this step of discovery can be highly automated.

X.4.3.2.3 Governance

As described in Section X.4.2: *Principles of IHE for Health Document Sharing* section, the MHDS Profile is document content neutral; uses document metadata that are represented in a structured, standard format; and supports longevity of document storage.

MHDS requires a governance structure as described in Section X.4.2.2 and defines the MHDS Community as the agent for that governance. An MHDS Community is a group of healthcare enterprises that have agreed to work together using a common set of policies and MHDS infrastructures for sharing patient clinical documents. Some examples are:

- Regional community of care
- Nationwide EHR
- Specialist (cardiology, oncology) or disease-oriented (diabetes) care networks
- Government-sponsored or federation of enterprises
- Insurance provider supported communities

The MHDS Profile is patient centric thus requires that a patient identity is managed centrally as well. The PIMR Profile enables this patient identity management domain to use a single Patient Identification Domain called a PMIR Golden Domain Patient. This ensures that, for example, when submitting documents for Mary Gomez the same unique patient identifier is associated with each document for Mary Gomez, and thus a search can reliably find all of Mary's documents by using this single unique identifier. MHDS species that PIXm or PDQm shall be used by document source and document consumer systems find the unique patient identifier assigned, see Section 4.

Further detail regarding deployment of an MHDS Community may be found in the "Template for XDS Affinity Domain Deployment Planning" IHE ITI White Paper.

X.4.3.2.4 Notifications

The MHDS environment does not yet have a Notification mechanism like found in XDS in the DSUB Profile.

X.4.3.3 Federated Discovery and Retrieve

MHDS has not yet addressed multiple communities federating. Where federation is critical the use of XDS and XCA are recommended.

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X.4.4 Patient identity management

The Document Sharing defined in this profile is patient centric, meaning that a patient is associated with each document shared. When data related to an individual patient is exchanged among healthcare information systems it is critical to ensure that the participating systems are referring to the same patient. This requirement can be accomplished in several different ways.

One possible way would have each transaction carry enough demographic data to ensure that the partner is able to match the patient through demographic matching with locally held characteristics. The challenges of "enough" demographic data is a difficult problem. It includes issues around demographics changing over time (name changes) and other aspects of demographics matching rules. There is also concern around privacy when unnecessarily transporting patient demographics.

Thus IHE recommends that the identification of the patient be done through patient identifiers in a common or accepted patient identification domain. Thus, prior to the exchange of healthcare information the partners agreed on a commonly known patient identifier to refer to the patient. Essentially any identifier that a patient provides can be used to correlate identities, with a Voluntary Health Identifier (VHID) being a specific example of an identifier assigned outside of treatment. This requirement, however, is often non-trivial and the patient identity management profiles serve the purpose of enabling this aspect of Document Sharing. Some regions and nations have enabled the use of a unique patient identifier that is widely available, but many places still need profiles which aid in patient identifier discovery.

Systems participating in Document Sharing frequently use locally assigned patient identifier domains. A patient identifier domain is defined as a single system or a set of interconnected systems that all share a common patient identification scheme (an identifier and an assignment process to a patient) and issuing authority for patient identifiers.

The Patient Resource Identity Management (PMIR) Profile supports the linking of patient identifiers from multiple patient identifier domains. The Patient Identity Cross-Reference for Mobile (PIXm) Profile supports a query given one identifier known to the client to request cross-referenced identifiers known to the Patient Identity Manager. The Patient Demographics Query for Mobile (PDQm) Profile supports the ability to query by a set of demographics and get in response a complete set of demographics, usually including patient identifiers in domains of interest.

X.4.4.1 Patient Identity Cross-Reference for Mobile (PIXm)

Most health information systems assign to each patient an identifier (usually a string of letters and/or numbers) that is unique to the patient within only that information system. Thus, Gary Collins may be identified as 3562A at the office of his primary Care Physician (PCP) and 0320 at his specialist's clinic.

IHE utilizes the concept of Patient Identifier Domains which defines a domain of patient identifiers, like identifiers assigned within a PCP office, assigned by a single authority and an

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identifier for each assigning authority. For example, the PCP office identifier is unique within the assigning authority for the PCP. If the PCP's system wants to communicate with the specialist's system about Gary Collins, both systems must be able to know that 3562A assigned by the PCP offices is equivalent to 0320 assigned by the specialist's office, and that neither of those identifiers is equivalent to Garry Collin with an ID of 333 at a local Hospital. This is known as a cross-reference that links the two patient identifiers for Gary Collins.

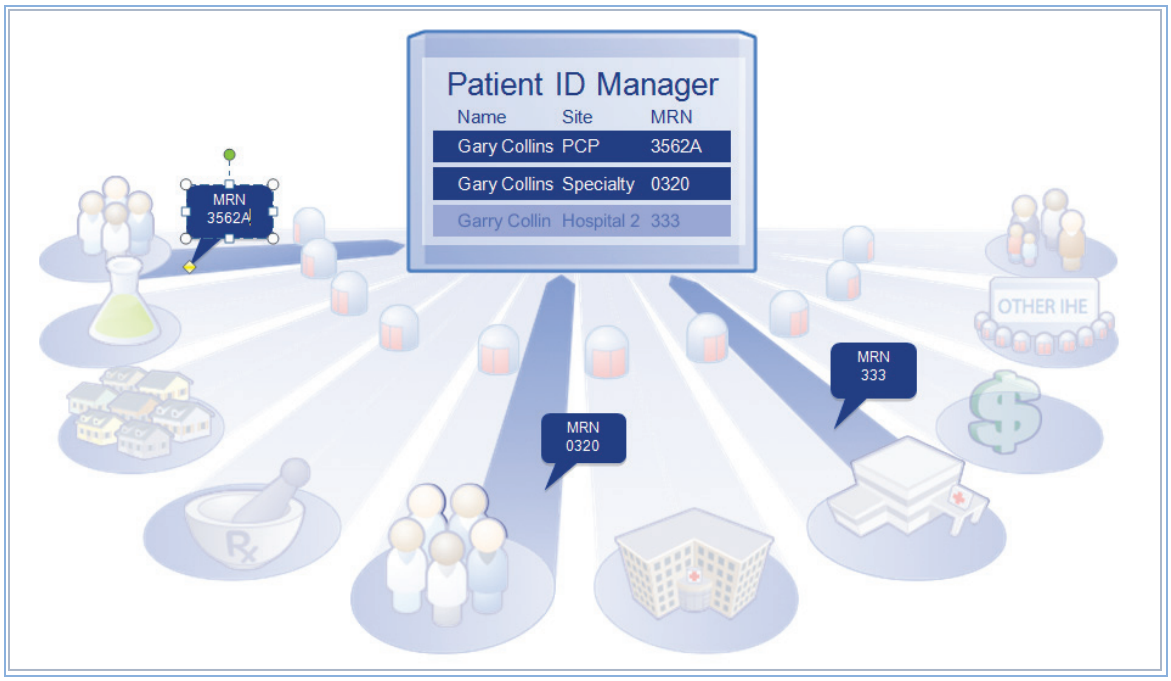

Figure X.4.4.1-1: Patient identifier cross-referencing

The PMIR Profile is IHE's answer to the difficulty of managing an individual patient's multiple Identifiers. A PMIR Patient Identity Manager system receives feeds from multiple patient identity domains, such as the PCP and specialist offices, and uses the demographics in those feeds to create a cross-referencing table which associates identities with matching demographics and does not associate identities found not to match. It should be noted that the PMIR Profile does not specify how patient matching occurs. Each region is welcome to use their own matching algorithms to determine which IDs should be cross-referenced. The IHE profile focuses only on the interfacing characteristics that would be consistent regardless of how the PMIR Patient Identity Manager matches the identifiers.

A consumer system may query the PMIR Patient Identity Manager to receive a list of identifiers which are cross-referenced with the identifier specified in the query sing the PIXm Profile. In this way the PCP office can discover the identifier used by the specialist's system and thus can communicate with that system using a known patient identifier.

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A primary use of the PIXm Profile is to enable document consumers and document sources using the MHDS Profile to find the patient's identifier in that Community Patient Identifier Domain. See Section X.4.3.2.

X.4.4.2 Patient Demographics Query for Mobile (PDQm)

Demographics (information describing the patient in general) are used to help identify the patient. With information on dates of birth and sex, information about Leslie Ramsi, a male born on May-2-1968, can be distinguished from that of Leslie Ramsi, a female born on July-23-1987. To help information systems improve their management of patient demographic information, IHE defines a profile called patient demographics query (PDQm). The premise of this profile is that some information systems will have more comprehensive and more accurate demographic information about a patient than other systems. The following paragraph describes a typical use of the PDQm Profile.

A typical use of PDQm is to discover the patient's Community Domain Patient ID. Imagine that Justin McCarthy heads to the local public health department for a vaccination. The public health department's clinical system does not assign local patient identifiers and thus cannot use the PIXm Profile to discover Justin's Community Domain Patient ID (a required element for the MHD transactions described above). The public health department can use PDQm to find matches for Justin and will receive Justin's Community Domain Patient ID as part of the demographics returned. With the knowledge of Justin's Community Domain Patient ID, the public health department can now publish his vaccination record to the community via the MHDS Profile.

X.4.5 Common Provider Directory

As with patient identity management, the management of data related to healthcare providers (both individual providers and provider organizations) is a fundamental challenge for communities. IHE has defined the Mobile Care Services Discovery (mCSD) Profile to addresses this challenge. There are two principal benefits of using the mCSD Profile. First, mCSD provides a means to disambiguate the identity of providers (i.e., allow one to distinguish between the 58 year-old male pediatric nurse named Lindsay Smith and the 32 year-old female orthopedic surgeon Lindsay Smith). Second, mCSD offers a method to discover a provider's contact information (e.g., phone numbers, street address, etc., as well as an electronic endpoint and digital certificate that may be used for trusted communication).

The referral process (one provider referring a patient to the care of another provider) is one of the most common uses of the mCSD Profile. When Dr. Palov wishes to send his patient Mary Blythe to a female endocrinologist who speaks Spanish, he may query the Directory to find contact information for providers that match those criteria. Similarly, Dr. Palov may wish to refer another patient, Thomas Reed, to the local Mercy Hospital. Dr. Palov could query the Directory to discover the hospital's electronic endpoint (e.g., a secure email address or a Document Registry endpoint) so that he may forward some of Mr. Reed's medical records to the hospital in advance of his visit.

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The mCSD Profile describes both how to store data regarding healthcare providers and also how to subsequently access that information. Within the directory, one may also store relationships between providers. For example, Nurse Joe may be an individual provider who belongs to the organizational provider General Hospital.

mCSD does not support attributes intended directly for Access Control.

Where mCSD is used to manage a set of identities, these managed identities can be used for the author in the metadata, whereas when these identities are not managed they must be included within the metadata as contained resources.

X.5 MHDS Security Considerations

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

This section will discuss how a community that leverages the MHDS Profiles for document sharing can protect patient privacy and information security.

A very important aspect that is beyond the scope of IHE is the definition of the overall Policies of the community. There is guidance in the IHE Technical Framework, but there is no single policy that must be put in place by an IHE based community to ensure privacy and security. In this section we will discuss potential policy decisions and positions with regard to the profiles. It is very important for the reader to understand that the scope of an IHE profile is only the technical details necessary to ensure interoperability. It is up to any organization building a community to understand and carefully implement the policies of that community and to perform the appropriate risk analysis. Although this section is not going to define the policies that a community should have, it will explore some of the policy building activities to demonstrate how such policies can be supported.

The Policy Environment is made up of many layers of policies. These policies work together in an interlocking hierarchy. We will introduce some of these layers in this section and show how they influence the technology. At the highest layer are international policies, like the International Data Protection Principles. Countries or regions will have specific policies. Some examples are USA HIPAA Security and Privacy Rules, with further refinement by the states. There are horizontal policies that are common among a specific industry, such as those from medical professional societies. Then within the enterprise will be specific information technology policies. As shown in this section, the IHE Profiles offer not only the means to exchange information, but to do so in a way that is supportive of many of the policies mentioned.

The policy landscape that the community is built on needs to be defined well before the community is built.

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X.5.1 Policies and Risk Management

IHE solves Interoperability problems via the implementation of technology standards. It does not ***define*** Privacy or Security Policies, Risk Management, Healthcare Application Functionality, Operating System Functionality, Physical Controls, or even general Network Controls.

While community Policies and Risk Management are outside its scope, IHE does recognize that these elements are a necessary piece of a system implementation. IHE IT Infrastructure technical white paper, "Template for XDS Affinity Domain Deployment Planning" outlines some of the issues that should be evaluated for inclusion in the local Policy creation and Risk Management decisions. It is therefore the duty of system implementers to take this guidance into account as part of their Risk Management practices.

Implementers need to be aware of different kinds of policies that need to be harmonized with those policies of the local health enterprises connected to the community. The following is a list of sample policy fragments to stimulate discussion:

- Policies for who has access to what type of documents in the community
- Policies for who is allowed to publish documents into the community
- Policies on the acceptable types of documents that can be published into the community
- Policies that indicate acceptable levels of risk within community
- Policies that indicate what sanctions will be imposed on individuals that violate the community policies
- Policies on training and awareness
- Policies on user provisioning and de-provisioning within the community and local operation
- Policies on emergency mode operations
- Policies on acceptable network use (browser, decency, external-email access, etc.)
- Policies on user authentication methods that are acceptable
- Policies on backup and recovery planning
- Policies on acceptable third party access
- Policies on secondary use of the information in the community
- Policies on the availability of the community systems (are the community systems considered life critical, normal, or low priority)
- Policies for maintenance downtime
- Policies for length of time that information will be maintained in the community

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These policies are not a flat set, but often interlock and at other times cascade. An important set of policies are those around emergency modes. There are wide definitions of cases that are referred to as emergency mode. These emergency modes need to be recognized for the risks they present. When these use cases are factored in up-front, the mitigations are reasonable.

- Natural or manmade catastrophic disaster (e.g., Hurricane, Earth Quake) – often times additional workforce migrates into the area from other places to help out. These individuals need to quickly be screened and provisioned with appropriate access.
- Utility failure (e.g., electric failure) – this situation is common and easily handled through uninterruptible power supplies and backup generation
- IT infrastructure failure (e.g., hard drive crash) – this situation is also common and handled through common infrastructural redundancy
- Need to elevate privileges due to a patient emergency, often called break-glass (e.g., nurse needs to prescribe)
- Need to override a patient specified privacy block due to eminent danger to that patient – this override is not a breaking of the policy but would need to be an explicit condition within the policy.

Often times being in the emergency department is considered as an emergency mode, but the emergency department is really a normal mode for those scheduled to work there. When looked at as normal mode, the proper privileges and workflow flexibility can be specified.

Policy development often is frustrated by apparent conflicts in policies. These conflicts are often only on the surface and can be addressed upfront once the details of the policy are understood. This superficial conflict might be addressed by recording genetic markers instead of race. Another good example of a policy conflict is in records retention requirements at the national level vs. at the Medical Records level. Medical Records regulatory retention is typically fixed at a short period after death, yet if the patient has black lung then the records must be preserved well beyond.

X.5.2 Technical Security and Privacy controls

In 1980, the Organization for Economic Cooperation and Development ("OECD") developed Guidelines on the Protection of Privacy and Transborder Flows of Personal Data. These guidelines were intended to harmonize national privacy laws, uphold human rights, and promote the free flow of information among its 30 member countries. The OECD guidelines have served as a basis for data protection laws in the United States, Europe, Canada, Japan, Australia, and elsewhere. Together, these principles and laws provide a useful framework for developing general data protection requirements for health information systems. For more information see http://oecdprivacy.org.

Based on the experience of the IHE participants in implementing community environments there is a common set of Security and Privacy controls that have been identified. These controls are

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informed by a combination of the OECD data protection principles, experience with explicit policies at community implementations, and Security Risk Management.

These security and privacy controls are:

1. Audit Log Controls – The controls that can prove the system is protecting the resources in accordance to the policies. This set of controls includes security audit logging, reporting, alerting and alarming.
2. Identification and Authentication Controls – The controls that prove that a system or person is who they say that they are. For example: personal interactions, Oauth, OpenID-Connect
3. Data Access Controls – The controls that limit access by an authenticated entity to the information and functions that they are authorized to have access to. These controls are often implemented using Role Based Access Controls (RBAC), or Attribute Based Access Controls (ABAC).
4. Secrecy Controls– As sensitive information is created, stored, communicated, and modified; this control protects the information from being exposed. For example: encryption or access controls.
5. Data Integrity Controls – The controls that prove that the data has not changed in an unauthorized way. For example: digital signatures, secure hash algorithms, CRC, and checksum.
6. Non-Repudiation Controls – The controls that ensure that an entity cannot later refute that they participated in an act. For example, author of a document, order of a test, prescribe of medications.
7. Patient Privacy Controls – The controls that enforce patient specific handling instructions.
8. Availability Controls – The controls that ensure that information is available when needed. For example: backup, replication, fault tolerance, RAID, trusted recovery, uninterruptible power supplies, etc. (not an area where Interoperability applies)

X.5.3 Applying Security and Privacy to Document Sharing

IHE does not set policies but is policy sensitive. Therefore, we now discuss the policy enabling technologies and not the policies themselves.

This section shows how the existing security controls in the local health IT system are leveraged and extended when they become interconnected through document sharing.

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X.5.3.1 Basic Security

IHE recognizes that in healthcare, with patient lives at stake, audit control is the primary method of accountability enforcement. The profile that provides this basic security principle is Audit Trail and Node Authentication (ATNA). This profile requires three things of each system:

1. User authentication and Access Controls are enforced accordingly,
2. Security Audit Logs are recorded, and
3. Strong network authentication and encryption for all communications of sensitive patient data

The Security Audit Logging includes a set of security relevant events that must be audited. When one of these events happens the record of the event must be described a specific way. The systems are expected to support the recording of all of the security relevant events that might happen in the system. The ATNA Profile offloads the recording, filtering, alerting, and reporting to an audit service. The more centralized this audit log analysis can be, the easier it is to prove accountability across the whole Document Sharing exchange.

Once it is known that the system will enforce Access Controls and Audit Controls then it can be connected to other systems that have also been assessed positively. In this way these systems only talk to other systems that also agree to enforce the common policies. This creates a basis for a chain of trust through accountability among all of the systems participating in the Document Sharing exchange. The communications between these trusted systems is also encrypted.

X.5.3.2 Protecting different types of documents

The IHE Document Sharing profiles, like MHDS, allow for many different types of documents to be shared. These documents are likely to have different levels of confidential information in them. For instance, one document might contain the very basic health information that the patient considers widely distributable. Another document might be made up totally of information necessary for proper billing such as insurance carrier and billing address. Yet another document might carry the results of a very private procedure that the patient wishes to be available only to direct care providers. This differentiation of the types of data can be represented using a diagram like found in Table X.5.3.2-1: Sample Access Control Policies

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Table X.5.3.2-1: Sample Access Control Policies

Sensitivity Functional Role	Research Information	Billing Information	Administrative Information	General Clinical Information	Sensitive Clinical Information	Mediated by Direct Care Provider
HL7 confidentialityCode (2.16.840.1.113883.5.25)	**U**	**L**	**M**	**N**	**R**	**V**
Administrative Staff		X	X			
Dietary Staff			X			
General Care Provider			X	X		
Direct Care Provider			X	X	X	X
Emergency Care Provider (e.g., EMT)				X		
Researcher	X					
Patient or Legal Representative		X	X	X	X	

Then documents can be labeled with one or more of the codes on the columns, and results in the specified Functional Roles to be given access to that type of document. In this way, the document sharing metadata informs the Role-Based Access Control (RBAC) decisions through self-describing sensitivity, known as confidentialityCode.

In the same way that the Document Sharing metadata 'doctype' defines what the document is in terms of the clinical/administrative content, the confidentialityCode defines what the document is in terms of privacy/security content, sometimes referred to as sensitivity. The confidentialityCodes should be looked at as a relatively static assessment of the document content privacy/security characteristics. Some documents are so sensitive in nature that they simply should not be shared or published.

The rows are showing a set of functional roles. These roles would be conveyed from the requesting organization through the use of the Internet User Assertion (IUA) Profile. This profile defines how a user and the security/privacy context of the request is defined. Additional information can be carried such as the purposeOfUse, what the user intends to use the data for. Note that Privacy Policies and Access Control rules can leverage any of the user context, patient identity, or document metadata discussed above.

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X.5.3.3 Patient Privacy Consent to participate in Document Sharing

The topic of Patient Privacy Consent (Authorization) to collect, use, and disclose is a complex topic. This complexity does not always need to be exposed in full detail across a Document Sharing exchange. That is, a request for information does need to consider the current status of any Patient Privacy Consent that the patient has given, but most of the time explaining the detail of this Privacy Consent to the requesting system/individual adds no value. Most often the requesting system/individual is either fully empowered to receive and use the content, or not authorized at all. In these cases the use of user identity context, as discussed above around the IUA Profile, is sufficient to make the Access Control decision. The trust relationship of the Document Sharing exchange includes background governance on appropriate use, as discussed above around the ATNA Profile.

Privacy Consents may need to be expressed in a way that all parties in a Document Exchange can understand. IHE has published the Basic Patient Privacy Consents (BPPC) Profile that can be used to enable basic privacy consent controls, and Advanced Patient Privacy Consents (APPC) that can encode more complex rules specific to a patient consent. The encoding of Consent and advanced rules in FHIR "Consent" resource is possible but has not yet been profiled by IHE.

Some examples of the type of policy that can be necessary for Patient Privacy Consents are:

- Explicit Opt-In (patient elects to have some information shared) is required which enables document sharing
- Explicit Opt-Out (patient elects to not have information shared) stops all document sharing
- Implicit Opt-In allows for document sharing
- Explicit Opt-Out of any document sharing
- Explicit Opt-Out of sharing outside of use in local care events, but does allow emergency override
- Explicit Opt-Out of sharing outside of use in local care events, but without emergency override
- Explicit authorization captured that allows specific research project
- Change the consent policy (change from opt-in to opt-out)

The BPPC Profile can be used as a gate-keeper to the document sharing community. BPPC does not define the policies, but does allow for a community that has defined its set of policies to capture that a patient has chosen one or more of those policies.

For example: Let's say that the above set of sample policy fragments was available to a patient sharing in a community. The patient could agree to Opt-In, and also agree to a specific research project. This set of acknowledgments would be captured as one or more BPPC documents. These

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documents would indicate the policy that is being acknowledged, the date it is being acknowledged, an expiration date if applicable, etc. Then the systems involved in the document sharing can know that the patient has acknowledged these policies and thus the patient's choices can be enforced. A system that is doing research can see that this patient has acknowledged participation in the research project, while other patients have not.

Let's further examine what happens when the patient changes their decision. For example, the patient is moving to a totally different region that is not served by this community. The patient can acknowledge the Opt-Out policy. This policy would then be registered as a replacement for the previous Opt-In policies including the research policy. Thus now if that research application tries to access the patient's data, it will be blocked as the patient does not have a current acknowledgement of the research policy.

X.5.3.4 Security and Privacy in a Patient Safety Environment

The IHE security and privacy model supports both centralized and distributed control. The entities that are allowed to participate in community based document sharing need to be evaluated to assure that they have the capability to enforce the policies they are expected to enforce. This may mean that access control is enforced at the edge systems, at the center, or more likely in both places.

In healthcare, beyond the basic security principles, we must additionally be sensitive to patient care and safety. The applications closest to the patient are best informed for determining the context of the current situation. It is primarily at this level that emergency mode can be handled in a robust way (often called break-glass).

The IHE security and privacy model is very careful to include security while allowing for flexible and safe provision of healthcare by individual participants.

X.5.4 IHE Security and Privacy Controls

The following is a breakdown of the security and privacy controls and in what way the IHE profiles can help. The following table shows the set of identified Controls (identified in above) as columns and the supportive IHE Profiles as rows. In this table a '√' indicates a direct relationship. A direct relationship means that the Profile addresses the security and/or privacy principle. An '." indicates an indirect relationship, meaning that the Profile assists with the principle. Further details on the '√' direct and '.' Indirect relationships can be found in the profile text or through other webinars.

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Table X.5.4-1: Profiles relationship to Controls

Security & Privacy Controls / IHE Profile	Audit Log	Identification and Authentication	Data Access Control (Authorization)	Secrecy	Data Integrity	Non-Repudiation	Patient Privacy
Audit Trails and Node Authentication	√	√	√	√	√	√	√
Consistent Time	√	·				√	
Internet User Authorization		√	√			·	·
Cross-Enterprise User Assertion		√	·			·	·
Basic Patient Privacy Consents			·				√
mobile Care Services Directory		√	·			·	
Document Digital Signature		√			√	√	
Document Encryption			√	√	·		

X.6 MHDS Cross Profile Considerations

X.6.1 Interaction Diagram for the MHDS environment.

The following diagram shows a simplified view of a

1) Patient Identity Feed representing new knowledge about the Patient at the source. Deeper details on this interaction can be found in the PMIR Profile
    a. This diagram does not show the PMIR feed out to all the community participants, but this is enabled by PMIR, where all the community participants can subscribe to the PMIR manager for feed.
2) Publication of new Documents to represent a case where new data need to be published.
    a. In this diagramed case the PIXm is used to get the golden patient identifier for use in the Document Registry. The PDQm transaction could also be used when a more broad lookup is needed. Additionally the Source may know the golden patient identifier because it is subscribed to the PMIR feed.
    b. In this diagram the Provide transaction does not include the Binary resource containing the document, but rather the DocumentReference.content.attachment.url is populated with a full URL to where the document can be retrieved.
    c. If the Provide transaction contains the Binary, the Registry will persist the Binary and update the DocumentReference.content.attachment.url to the location.

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3) Query and Retrieve of a document

a. This portion starts with the patient visiting the Recipient. Thus there is a potential for a PMIR feed updating the PMIR manager. Not all visits will result in a feed.

b. Given that the Recipient wants to discover documents, it will first use PIXm to get the proper identity for the community. As indicated above other methods are available other than PIXm.

c. The Recipient queries the Registry to find appropriate entries, and selects the one of interest

d. The Recipient will GET the document given the DocumentReference.content.attachment.url

e. The diagram shows that this GET is to the Source defined location. At that service the it is diagramed that a local inspection of consent could be used to determine if the document should be returned. This consent check is not profiled in MHDS, but is allowed to enable rich policies.

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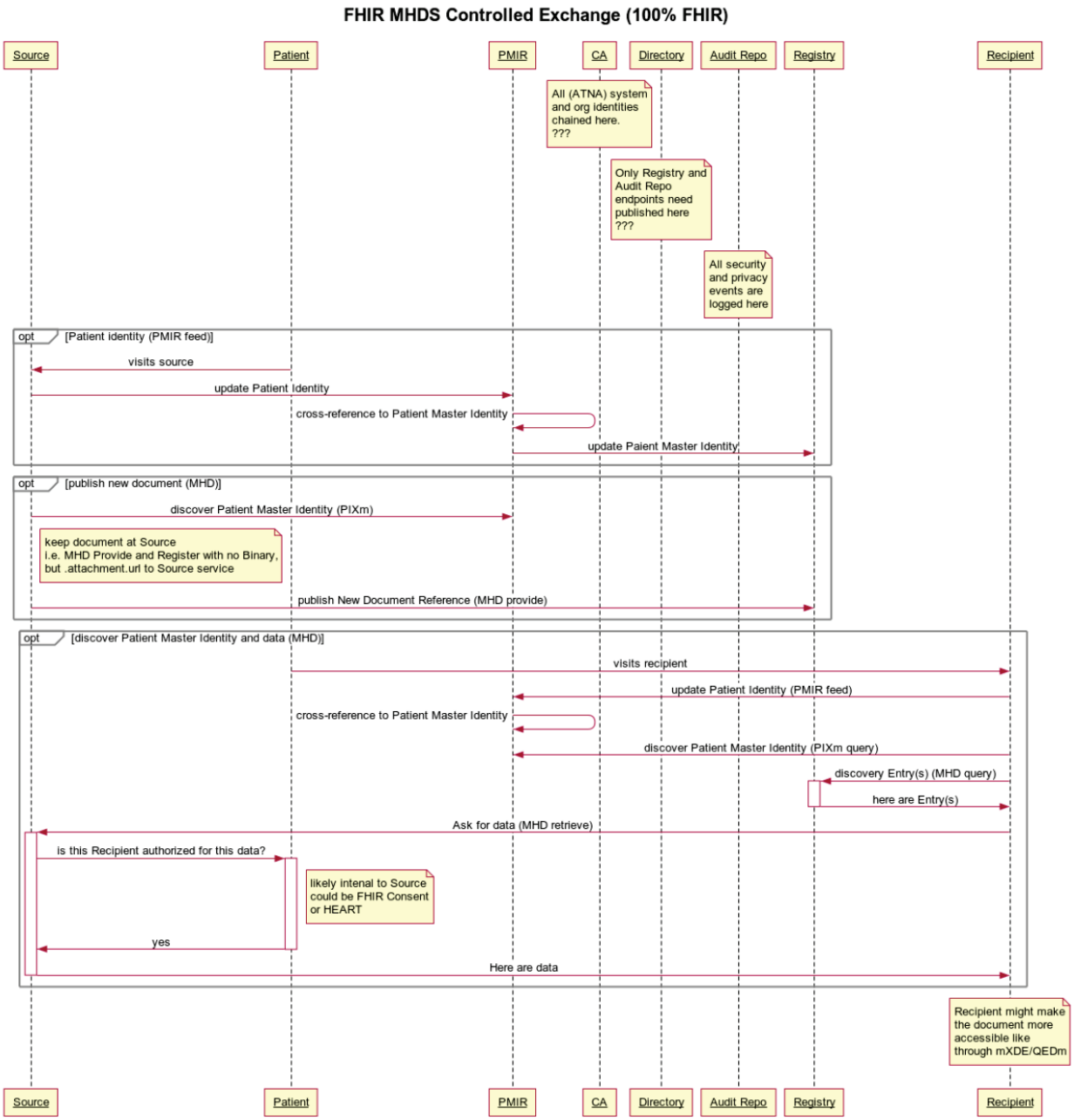

1335 *Source for WebSequence diagram above*

```
title FHIR MHDS Controlled Exchange (100% FHIR)

participant Source
participant Patient
```

```
participant PMIR
participant CA
participant Directory
participant Audit Repo
participant Registry
participant Recipient

note over CA
All (ATNA) system
and org identities
chained here.
???
end note

note over Directory
Only Registry and
Audit Repo
endpoints need
published here
???
end note

note over Audit Repo
All security
and privacy
events are
logged here
end note

opt Patient identity (PMIR feed)
Patient->Source: visits source
Source->PMIR: update Patient Identity
PMIR->PMIR: cross-reference to Patient Master Identity
PMIR->Registry: update Patient Master Identity
```

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```
end

opt publish new document (MHD)
Source->PMIR: discover Patient Master Identity (PIXm)
note right of Source
keep document at Source
i.e. MHD Provide and Register with no Binary,
but .attachment.url to Source service
end note
Source->Registry: publish New Document Reference (MHD provide)
end

opt discover Patient Master Identity and data (MHD)
Patient->Recipient: visits recipient
Recipient->PMIR: update Patient Identity (PMIR feed)
PMIR->PMIR: cross-reference to Patient Master Identity
Recipient->PMIR: discover Patient Master Identity (PIXm query)
Recipient->+Registry: discovery Entry(s) (MHD query)
Registry->-Recipient: here are Entry(s)
Recipient->+Source: Ask for data (MHD retrieve)
Source->+Patient: is this Recipient authorized for this data?
note right of Patient
likely internal to Source
could be FHIR Consent
or HEART
end note
Patient->-Source: yes
Source->-Recipient: Here are data
end

note over Recipient
Recipient might make
the document more
accessible like
```

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```
through mXDE/QEDm
end note
```

X.6.2 Typical Client System Designs

This section shows a typical client system design. This is informative to help explain how these various actors interact. The lines are shown to shown as follows:

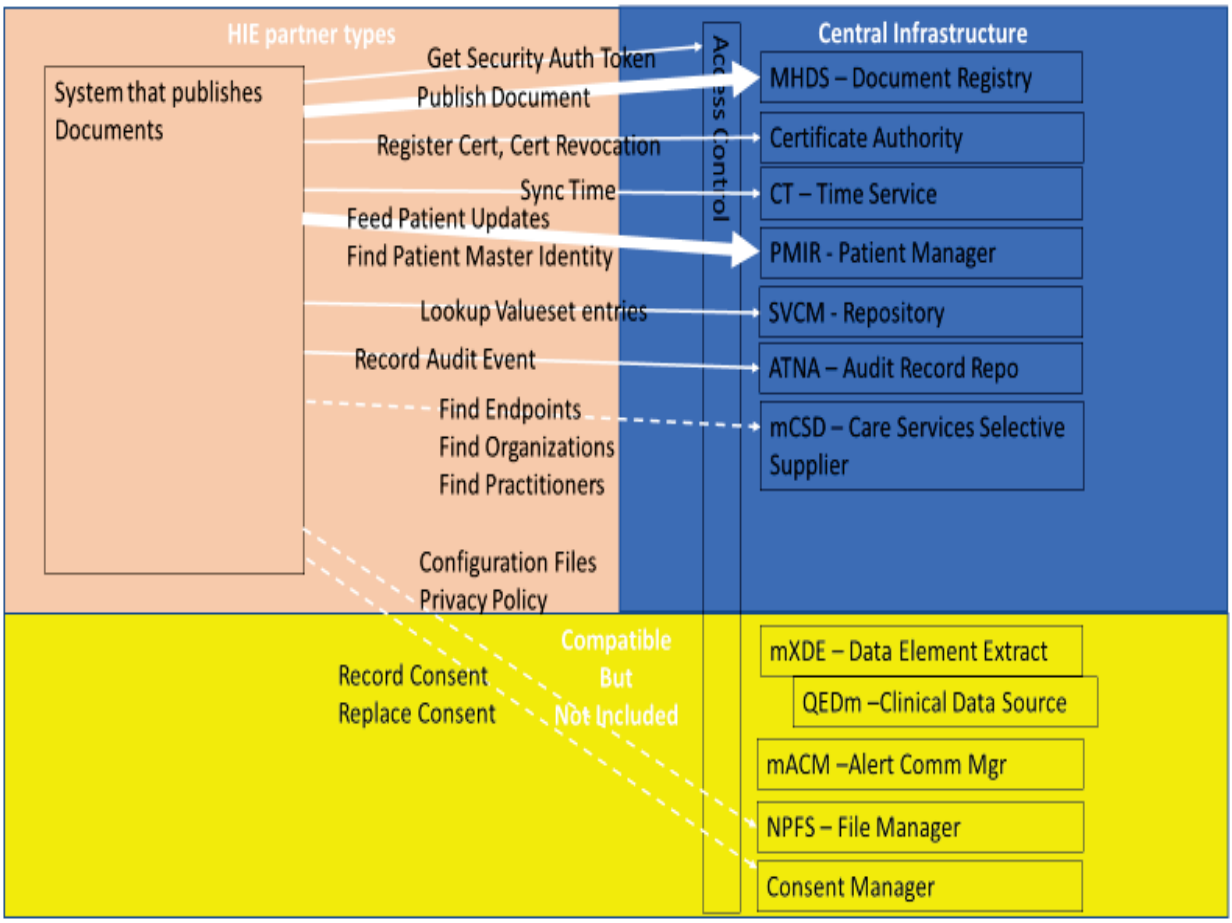
a) Very bold white line – Most used interaction

b) Light bold white line – Used interactions for specific functions

c) Dashed white line – Optional functionality for specific functions

The actors and transactions are not fully explained here, please see the formal profiles referenced for details on the actual actor and transaction functionality, responsibility, and interoperability.

X.6.2.1 System that publishes documents System Design



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System that publishes documents - Integration Statement

Profiles Implemented	Actors Implemented	Options Implemented
MHD	Document Source	
CT	Time Client	
PMIR	Patient Identity Source	
PIXm	Patient Identity Consumer	
PDQm	Patient Demographics Consumer	
SVCM	Consumer	
ATNA	Secure Node	
IUA	Authorization Client	
mCSD	Care Service Selective Consumer	
NPFS	File Consumer	
BPPC	Content Creator	
	Content Consumer	

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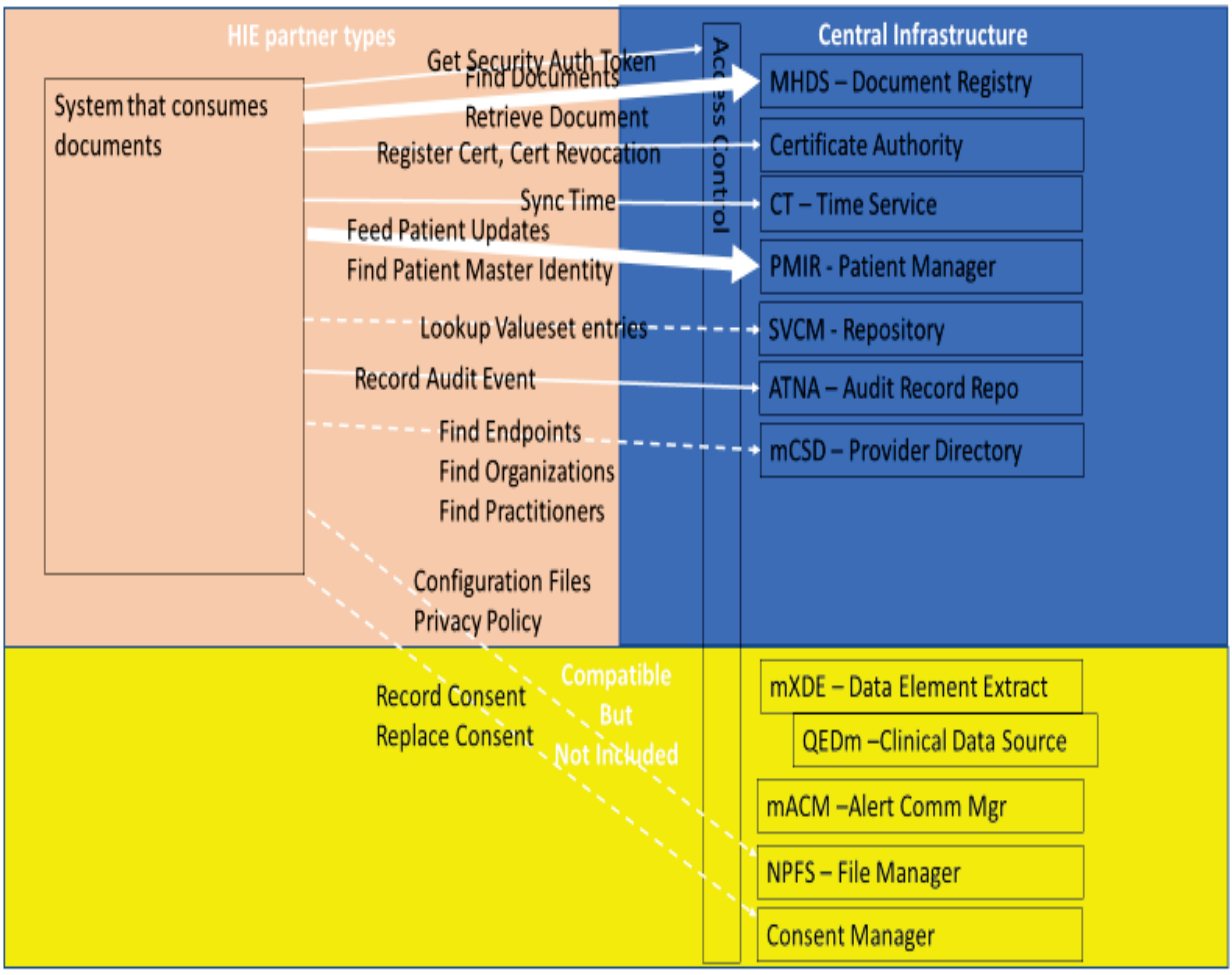
X.6.2.2 System that consumes documents System Design



1425 **System that consumes documents - Integration Statement**

Profiles Implemented	Actors Implemented	Options Implemented
MHD	Document Consumer	
CT	Time Client	
PMIR	Patient Identity Source	
PIXm	Patient Identity Consumer	
PDQm	Patient Demographics Consumer	
SVCM	Consumer	

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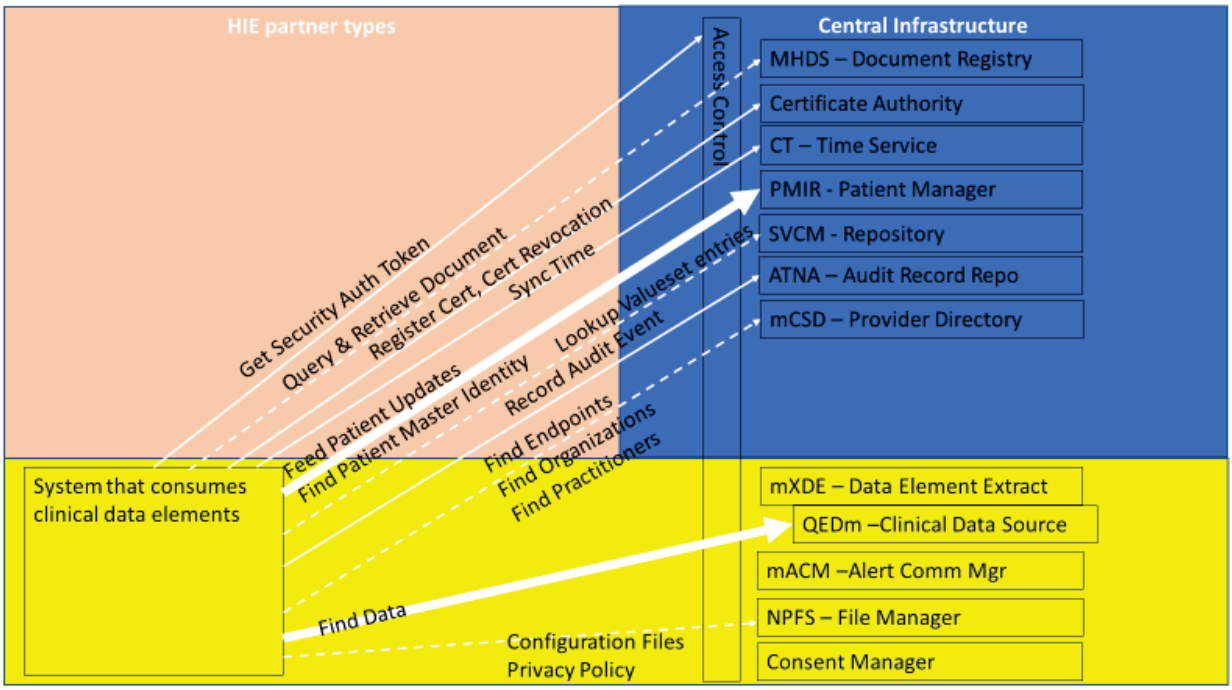
Profiles Implemented	Actors Implemented	Options Implemented
ATNA	Secure Node	
IUA	Authorization Client	
mCSD	Care Service Selective Consumer	
NPFS	File Consumer	
BPPC	Content Creator	
	Content Consumer	

X.6.2.3 System that consumes clinical data elements Systems Design



System that consumes clinical data elements - Integration Statement

Profiles Implemented	Actors Implemented	Options Implemented
QEDm	Clinical Data Consumer	
MHD	Document Consumer	
CT	Time Client	

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Profiles Implemented	Actors Implemented	Options Implemented
PMIR	Patient Identity Source	
PIXm	Patient Identity Consumer	
PDQm	Patient Demographics Consumer	
SVCM	Consumer	
ATNA	Secure Node	
IUA	Authorization Client	
mCSD	Care Service Selective Consumer	
NPFS	File Consumer	
BPPC	Content Creator	
	Content Consumer	

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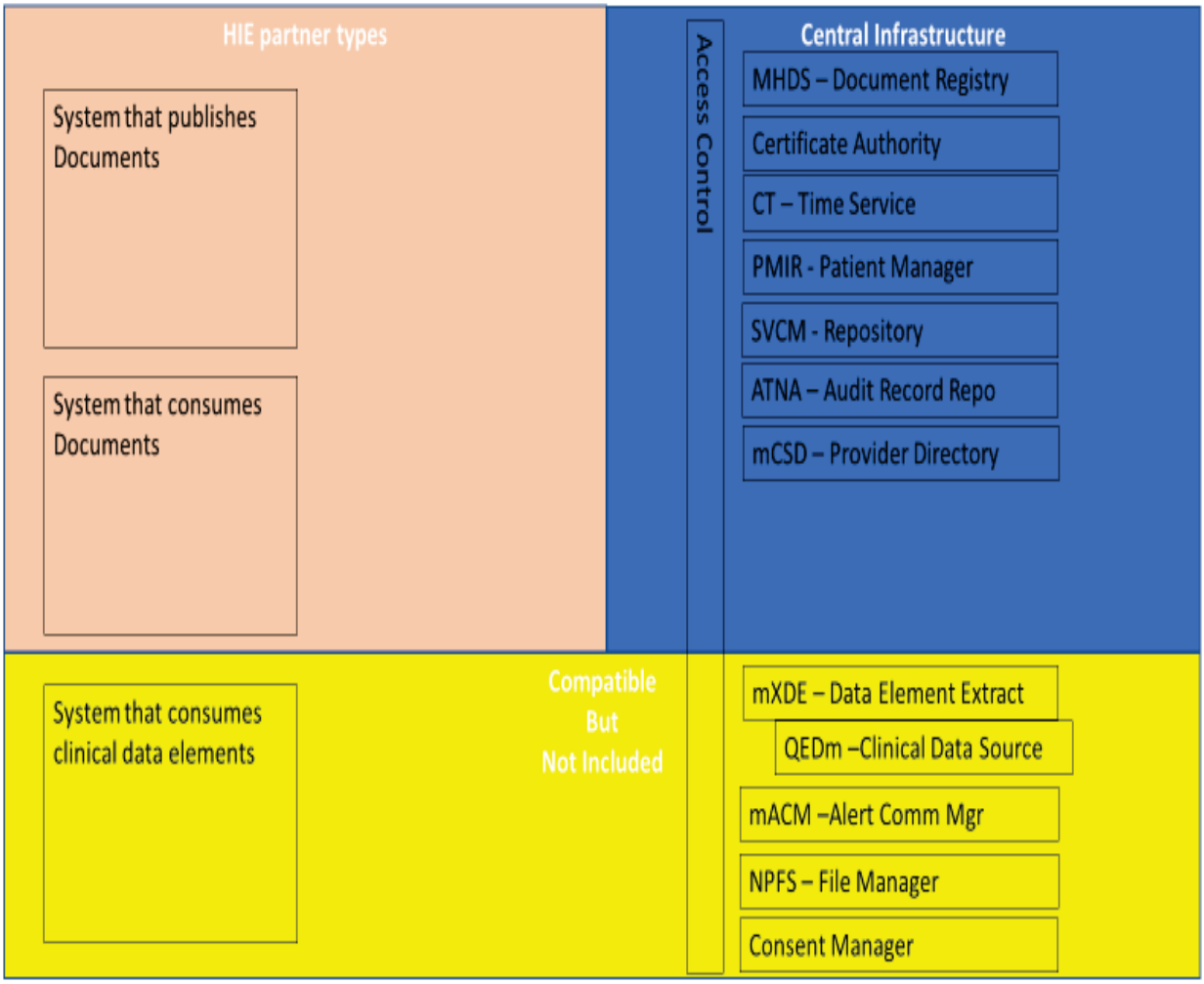
X.6.2.4 Central Infrastructure as a single system



Following the Diagram is a sample IHE Integration Statement for that client system. For more details on the full use and format of an IHE Integration Statement (see Appendix F).

Central Infrastructure Integration Statement

Profiles Implemented	Actors Implemented	Options Implemented
MHDS	Document Registry	Authorization Option
		Consent Manager Option
		PMIR Query Option

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Profiles Implemented	Actors Implemented	Options Implemented
		mCSD Query Option
		SVCM Validation Option
MHD	Document Responder	
MHD	Document Recipient	
PMIR	Patient Identity Consumer	
CT	Time Client	
SVSM	Consumer	
IUA	Resource Server	
ATNA	Secure Node	STX: TLS 1.0 Floor with AES Option
		STX: TLS 1.0 Floor using BCP195 Option
		STX: TLS 1.2 Floor using BCP195 Option
		ATX: FHIR Feed Option
BPPC	Content Consumer	
CT	Time Server	
PMIR	Patient Identity Manager	
PIXm	Patient Identity Source	
PDQm	Patient Demographics Source	
SVCM	Consumer	
ATNA	Audit Record Repository	STX: TLS 1.0 Floor with AES Option
		STX: TLS 1.0 Floor using BCP195 Option
		STX: TLS 1.2 Floor using BCP195 Option
		ATX: FHIR Feed Option
IUA	Authorization Server	
	Resource Server	
mCSD	Care Service Selective Supplier	
NPFS	File Server	
mXDE	Data Element Extractor	

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Profiles Implemented	Actors Implemented	Options Implemented
QEDm	Clinical Data Source	
BPPC	Content Creator	
	Content Consumer	

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